NANOGEN INC
Form 10-K
March 30, 2004
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2003

OR

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

For the transition period from _____ to _____

Commission File Number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

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

Registrant s telephone number, including area code: (858) 410-4600

Securities registered pursuant to Section 12(b) of the Act:

NONE

Securities registered pursuant to Section 12(g) of the Act:

Common Stock $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 __X__ NO _____

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

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

YES _____ NO __X__

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 30, 2003 (the last day of the registrant s most recently completed second fiscal quarter), as reported on the Nasdaq National Market was approximately $52,592,000. 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 31,182,060 as of March 19, 2004.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its annual meeting of stockholders to be held in 2004 are incorporated by reference in Part III of this Form 10-K.

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NANOGEN, INC.

FORM 10-K

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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, mergers, acquisitions 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, our 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 genetics 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 in a report from SG Cowen to be approximately $1.2 billion in 2002 and is predicted to grow to over $3.0 billion in 2005. Of the $1.2 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), Hepatitis C

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Virus (HCV), *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) and the remaining twenty- five percent (25%) was spent on 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 (SNPs), 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 to help physicians diagnose and treat patients. 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 Pre Market Approval (PMA) application. Clinical diagnostic laboratories normally run clinical assays to help physicians diagnose and treat patients with various diseases and typically such assays require a 510(k) or PMA application prior to being offered for sale or distribution.

We believe that molecular diagnostics customers seek 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 the basic customer requirements. These platforms lack the versatility to perform both simple and complex assays. 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, and are seeking a cost-effective technology platform that will assist in optimizing capital and labor costs.

The healthcare industry is also evolving as a result of advances in molecular diagnostics. The Company believes that genetic testing will lead to a greater emphasis on predictive diagnoses rather than just symptomatic diagnoses and that healthcare and medicine will become more individualized and patient-focused. The Company believes that this will lead to a greater emphasis on the development of new drugs related to genetic characteristics and to prescribing practices based on a patient s own genetics. The development of predictive, patient-centered diagnosis is also leading to the development of new molecular diagnostic business models that reflect opportunities for companies to market and direct certain of their diagnostic products and services directly to consumers and to broaden the molecular diagnostics market to include a wider range of predictive healthcare products and services.

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 was founded on the vision of integrating multiple sciences to develop diagnostic products. Through advances in genomic and pharmaceutical research, we believed that diagnostics and therapeutics would become closely linked. Further, we believed that by using electronics, we could develop a highly accurate and flexible set

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of products that would facilitate the analysis of complex genetic relationships and the correlation to disease and therapies. This vision in turn led to the definition of the Company s mission: to become a leading provider of high quality innovative advanced diagnostic products and services to patients, providers and pharmaceutical companies.

Nanogen currently 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. In furtherance of its mission to become a leading supplier of advanced diagnostics testing products, Nanogen is developing a broad menu of ASRs and other commercial applications for the NanoChip® System. The Company continually conducts research and development by itself and with third parties, to improve the NanoChip® System and to extend its technology to other applications such as biodefense, forensics, drug discovery and pharmacogenomics.

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 microlocations 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.

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 (4) Nanogen s general purpose reagents and accessories used to facilitate assay and protocol development and validation on the NanoChip® Platform. 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.

In February 2004, we announced that we had entered into a definitive agreement for the acquisition of SynX Pharma Inc., a point-of-care diagnostics company based in Ontario, Canada. SynX currently markets point-of-care diagnostic tests for myocardial infarction in Europe and Canada, and infectious diseases and drugs of abuse in Canada. SynX is preparing to commercialize a diagnostic product for congestive heart failure (CHF). We expect the acquisition will provide us with a pipeline of complementary products in order to expand our market share in the in vitro diagnostics market and augments our technology platform for developing advanced diagnostic products. Additional information regarding the SynX acquisition can be found in Part II, Item 7: Management s Discussion and Analysis of Financial Condition and Results of Operations.

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

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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 in meeting the need of molecular diagnostic customers, 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.

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.

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:

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Accuracy: Accuracy is critical in laboratory analysis. To date, the NanoChip® System has been shown to be exceptionally accurate when performing various genetic molecular analysis. 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 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. 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 2003 was dedicated to developing and marketing a menu of ASRs that many laboratories perform routinely. 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.

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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. 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 to support SDA applications on future instruments.

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. Ultimately, the laboratory migrated 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.

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Nanogen has focused on capturing the molecular diagnostics market by creating an open platform that we believe can automate laboratory testing. The process of consolidating various molecular tests onto one platform is what we have termed Platformation. 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. The NanoChip® System could transform molecular diagnostics by, 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.

Nanogen s strategy to establish the NanoChip® System as the leading molecular diagnostics platform is five-fold.

Increase Installed Base of NanoChip® Systems

Our first strategy is to increase the installed base of the NanoChip® Molecular Biology Workstation 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 and strategic site agreements.

Nanogen typically sells its NanoChip® Systems directly to its customers through the Company s sales representatives in the U.S. or through distributors in Europe and other countries throughout the world. As of December 31, 2003, the Company had placed 100 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 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. While there may always be customers who wish to purchase the NanoChip® System outright, it is our belief that there will be many high complexity CLIA-certified clinical laboratories 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 validation period that normally runs from 60 to 120 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.

The final type of agreement whereby a customer may use and eventually purchase a NanoChip® System, is a development or strategic site agreement. These agreements are normally with leading research organizations and laboratories or companies that could provide us with certain rights to commercialize the discoveries made using our system. 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. Nanogen installs a NanoChip® System at a customer site for a period ranging typically from six to twelve 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 typically assigns to Nanogen rights to improvements to the System and Nanogen and the customer agree on certain Nanogen rights to any assays

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developed or other intellectual property discovered thereon. Once the agreement 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.

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

The second strategy 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 Platformationstrategy, the Company seeks to increase the number of commercially available ASRs that it provides its customers to increase the attractiveness of the NanoChip® System as well as to increase revenue from the sale of associated consumables.

During 2003, Nanogen introduced seven products, including five ASRs, which may be utilized by customers for development of tests that detect gene mutations associated with diseases such as cystic fibrosis, hereditary hemochomotosis, Canavan disease, beta thalasemia (in Europe) and Alzheimer s disease.

In the future, we intend to file with the FDA for clearance to market both the next generation of 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. This may be a costly and time consuming process. FDA clearance will be essential to expanding our product offerings beyond CLIA certified laboratories.

Development and Introduction of Research Products

Our third strategy is to develop products that facilitate customers development and validation of their own home brew tests on the NanoChip® System. We provide research customers with most of the tools and reagents needed to develop and validate their own home brew tests on our system and take advantage of our open architecture. During 2003, Nanogen entered into a license agreement with Institut Pasteur and began development work on research reagents for the European market involving the detection of gene mutations associated with the diagnosis of hereditary deafness. We also intend to develop and commercialize other products for our research 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.

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

Our fourth strategy is to continually improve the NanoChip® System through our engineering and advanced technology groups along with Hitachi, the manufacturer of the NanoChip® System. Initial 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 onto a disposable cartridge. The availability of this lab-on-a-chip technology would fulfill a substantial unmet need in both commercial laboratory and academic research markets.

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 or collaborators. Such products include those under development in the forensics, defense and pharmacogenomics arenas.

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.

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Our fifth strategy is 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.

During the third quarter of 2003, Nanogen entered into a collaboration agreement with Prodesse, Inc., a biotechnology company focused on developing reagents that can be used by CLIA-certified laboratories to develop assays to detect infectious pathogens. The collaboration agreement involves the development of automated, highly sensitive microarray-based products to detect a number of infectious disease agents, including influenza, pneumonia, adenovirus, herpes, West Nile Virus, and SARS. The Companies will integrate Prodesse s proprietary multiplex amplification technology with the automated NanoChip® platform and jointly develop and market gene-based testing products to clinical reference labs and health care providers.

We will pursue additional collaborations in various forms, including research and development agreements, licensing agreements and joint ventures.

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 research and molecular diagnostics laboratories.

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 a consumable Cartridge 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) is designed and constructed using microlithography and semiconductor 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 employs 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 reaction site of the microchip. 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.

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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.

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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 currently offers a separately priced software package designed to streamline routine or frequent testing for the same genetic markers (which must be validated by the customer). AMS enables users to run protocols they have 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 the research orientation of most of the currently available software. We believe that this software provides a significant competitive advantage for the NanoChip® System.

Analyte Specific Reagent (ASRs)

ASRs are the specific reagents that enable 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 currently have five ASRs that are commercially available for (1) Factor II/Factor V multiplex launched in the first quarter 2003; (2) CFTR launched in the first quarter 2003; (3) HFE launched in the first quarter 2003; (4) ApoE launched in the second quarter 2003; and (5) ASPA launched in the second quarter of 2003. Below is a more detailed description of the ASRs:

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 believes that it 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

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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 enable the customer 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.

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 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 should include 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. 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). 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. Our 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.

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. Nanogen s ApoE ASRs consist of various reagents that may be used by laboratories to develop and validate a test for the detection of ApoE4, the main Apolipoprotein E allele associated with increased risk for Alzheimer s disease. The Alzheimer s Association estimates that approximately 14 million Americans will develop the disease by 2050.

ASPA ASRs

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

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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 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.

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.

Beta Thalassemia Research Reagents

Nanogen, working with a company in Europe, developed a product for the detection of certain genes associated with beta thalassemia, a disease that is most prevalent in the Mediterranean regions of Europe. These research reagents have been initially marketed through the European company as an alternative method for testing beta thalassemia. Nanogen s research use only product for beta thalassemia consists of various reagents that can be used to detect mutations of the HBB gene, which is most commonly associated with beta thalassemia. Mutations in the HBB gene affect the production of hemoglobin, a protein in red blood cells that carries oxygen to tissues of the body. People whose hemoglobin does not produce enough beta protein have beta thalassemia, which can cause life-threatening anemia in children, for which there is no cure. The frequency of this mutation in the general population is about one in 300. However, people with Mediterranean (including North African), Middle Eastern or southeast Asian ancestry have a risk of about one in 30 for carrying this mutation, most likely related to the selective pressure from malaria. Beta thalassemia is an autosomal genetic disorder: if both parents have the HBB disease causing gene, each offspring has a one in four risk of being affected.

Products and Applications in Research and Development

We plan to further develop the NanoChip® System, integrating new features and broadening the applications of the currently marketed System, including enhancing chip design and simplifying 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 applications 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 should be more compact and less costly in order to access smaller hospital laboratories and other customers for molecular-based testing.

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Additional Potential ASRs and other Products

Infectious disease related products

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 and identify disease causing microorganisms and to determine antibiotic sensitivity. 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.

In September 2003, we entered into a collaboration agreement with Prodesse, Inc. to develop automated, highly sensitive microarray products to detect a number of infectious disease agents, including influenza adenovirus, herpes, West Nile Virus, and SARS. The collaboration will integrate Prodesse s proprietary multiplex amplification technology with the automated NanoChip® and jointly develop and market gene-based testing products to health care and clinical reference labs.

Most infectious disease diagnostics are culture-based and labs often take a week or longer to produce results. Consequently, physicians frequently prescribe antibiotics or antivirals prior to determining the exact pathogen causing the infection. By combining Prodesse s pathogen detecting products with the NanoChip® Molecular Biology Workstation, the Company expects to be able to offer reagents for the development of an automated process for testing patient samples within hours, enabling physicians to obtain results and prescribe therapeutics in response to test results. The Company believes that this should help reduce inappropriate treatment with antibiotics, the overuse of which has resulted in an increase in antibiotic-resistant strains of bacteria and a decrease in the effectiveness of many commonly prescribed antibiotics.

Prodesse currently offers six different multiplex products that can be used to detect a total of 28 different pathogens, and it expects to release five more products with an additional 19 targets. The Company s technology amplifies the sequences for many different pathogens, simultaneously with virtually no lose of sensitivity and with no cross-reactivity, which is important for obtaining of precise test results.

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. This agreement was extended and modified in 2003. 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. If ASRs or FDA cleared products are brought to market, Bionomics will market such products in Australia and New Zealand and Nanogen will market products to the remainder of the world.

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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, Nanotechnology 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.

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.

Nanotechnology

As of December 31, 2003, Nanogen had been issued six key nanotechnology patents that relate to the electronic fabrication of micro and nanoscale devices. In May 2003, Nanogen received U.S. Patent No. 6,569,382 Method and Apparatus for the Electronic, Homogenous Assembly and Fabrication of Devices . The 382 patent relates to methods to integrate micro and nanoscale devices as light emitting diodes (LED) for displays, highly integrated biosensors and micromechanical devices, into higher order structures and devices. In November 2003, Nanogen received U.S. Patent No. 6,652,808 Methods for the Electronic Assembly and Fabrication of Devices . The 808 patent relates to a nanofabrication technology that combines an electric field assisted manufacturing platform and programmable self-assembling nanostructures (for example, DNA building blocks) for the fabrication of a wide range of unique higher-order nano and microscale devices, structures and materials.

Subsequently, in March 2004 the Company was issued another key nanotechnology patent, U.S. Patent No. 6,706,473, Systems and Devices for Photoelectrophoretic Transport and Hybridization of Oligonucleotides, by the U.S. Patent and Trademark Office. The 473 patent relates to new devices for nanofabrication that enable the photoelectric transport and positioning of self-assembling DNA nanostructures (and microstructures) on a semiconductor substrate material. These devices use directed light beams to create precise electric fields on the substrate material. Charged nanostructures (such as DNA derivatized nanoparticles) are transported to the electric field site where they become attached and can then lead to the further self-organization of higher-order nanoscale or microscale structures and devices.

Nanogen s proprietary nanotechnology may provide a technological foundation for the effective use of nanocomponents in many diverse applications. It is the current intention of Nanogen to realize value from our nanotechnology patents through use in biomedical applications or through licensing or partnering opportunities.

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.

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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.

Nanogen Recognomics

Nanogen Recognomics, a joint venture of Nanogen and Aventis Pharma Deutchland, GmbH (formerly Aventis Research and Technologies), combines the NanoChip® technology and Aventis 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 research efforts have included genetic-based in vitro human detection, diagnostics, screening and monitoring applications, including research into novel oligonucleotide chemistries. The shareholders of Nanogen Recognomics have recently decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sale transactions.

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.

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 several 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. In July 2003 we entered into another manufacturing agreement with Hitachi relating to the manufacture of our next generation system.

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During the third quarter of 2003, Nanogen entered into a collaboration agreement with Prodesse, Inc., a biotechnology company focused on developing ASRs that can be used by CLIA certified laboratories to detect infectious pathogens. The Company believes that the products developed with Prodesse will enable physicians to immediately select and initiate appropriate therapy for patients.

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 was formed to allow us to benefit from the development of new technological advances for our platform while we are 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 intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to develop new products and applications for the NanoChip® System. The shareholders of Nanogen Recognomics have recently decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sale transactions.

Hitachi

Manufacturing Agreements

In January 2000, the Company executed an agreement with Hitachi, Ltd., effective as of December 15, 1999, for the full-scale commercial manufacturing and distribution of the NanoChip® Molecular Biology Workstation in specified research markets. Hitachi, Ltd. s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip® Molecular Biology Workstation s components.

Pursuant to the agreement, Hitachi, Ltd. has the right to be the sole distributor of NanoChip® Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip® Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip® Molecular Biology Workstations sold by Hitachi, Ltd. in Japan. The Company retained the right to distribute, directly or through others, NanoChip® Molecular Biology Workstations outside of Japan. In addition, the Company manufactures NanoChip® Cartridges at its San Diego, California facility for distribution worldwide. The Company also retained the right to form other manufacturing and distribution agreements. Pursuant to our manufacturing agreement with Hitachi, the Company is required to provide annual purchase commitments to Hitachi for NanoChip® Workstations.

In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of a new clinical instrument being developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the new clinical instrument, when development is completed, exclusively for the Company for worldwide distribution. Once production instruments are received by the Company, the Company is required to meet certain annual purchase commitments for the new instrument.

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Research Collaboration Agreement

In July 2000, the Company executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute additional potential products based on the parties proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute, toward the research and development efforts of the Company, up to $28.5 million in cash over the ten-year period. At a minimum, the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. In addition, the Company is liable to repay to Hitachi fifty percent of all funding provided by Hitachi over an indefinite period of time. Repayment amounts are determined as a percentage of the Company s gross NanoChip® Cartridge sales until the liability is paid in full. Furthermore, Hitachi made an equity investment in the Company by purchasing 74,590 shares of the Company s common stock worth approximately $2.0 million pursuant to a private sale by the Company based on a per share price of $26.813 (the fair market value as of the signing date of the Hitachi agreement). 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.

In August 2003, the Company received written notice from Hitachi to exercise its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi s exercise of its right to terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Neither Nanogen nor Hitachi has terminated any of the other agreements between the companies. Based on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new clinical instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new clinical instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

Service Agreement

In November 2003, the Company entered into an amendment to an agreement with Hitachi signed in October 2000 for the service by Hitachi of the NanoChip® Molecular Biology Workstations in the United States after sale or placement by the Company with the Company s customers. The agreement modified the agreed-upon amount the Company pays to Hitachi for annual service for each Workstation covered under the agreement.

Government Grants

In 2003, 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.

Also, in 2003, we received Phase II and Phase III grants totaling approximately $858,000 from the National Institutes of Health to develop on-chip SDA amplification techniques.

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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 and for the NIH. As a result, we believe that our government and commercial programs complement one another.

Proprietary Technology and Patents

As of December 31, 2003, we have 58 issued U.S. patents and 42 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 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.

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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. In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of a new clinical instrument being developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the new clinical instrument, when development is completed, exclusively for the Company for worldwide distribution. Once production instruments are received by the Company, the Company is required to meet certain annual purchase commitments for the new instrument. 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 in 2002.

Our commercial organization includes direct sales representatives and sales management, customer support personnel, field support personnel and marketing. We began selling our product in 2000 to customers in the United States, Canada, Mexico and several European 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. Hitachi s distribution company, Hitachi High Technologies, began distributing our product in Japan during the latter part of 2000 as well. In January 2004, we entered into a distribution agreement with Transgenomic Inc. for distribution of our products in certain European countries. We expect to augment our commercial selling process by adding additional distributor partners in other countries. In San Diego, we support 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.

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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 marketed for the detection of known sequences in the U.S. and primarily 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 (which delineates the Class II and III ASRs, and otherwise exempts from the 510(k)/PMA requirements ASRs distributed to (1) *in vitro* diagnostic manufacturers or (2) organizations that use the reagents to make tests for purposes other than providing diagnostic information to patients and practitioners) and 21 C.F.R. § 809.30 (which places limitations on the distribution, labeling, advertising, and promotion of ASRs). Future short term plans include distribution of these reagents for research use in Europe with eventual CE marking of the next generation system under the European IVDMDD regulations.

For our initial commercial markets, the biomedical research market and the high complexity CLIA certified laboratory market, we may not need FDA or other regulatory clearances for our NanoChip® System and certain ASRs prior to marketing. The FDA has recently communicated, however, that certain microarray devices that qualify as ASRs by regulation, may nonetheless lose their Class I, 510(k)-exempt status by operation of other provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360(1)) and FDA regulations (21 C.F.R. § 864.9), i.e., if the microarray is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. It is unclear what the impact of these FDA communications and determinations will be on Nanogen and its current and future products. 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 seek to 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 require pre-market authorization 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, Warning Letters, 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 (510(k)) or premarket approval (PMA) 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 the safety and effectiveness of the product.

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Generally, Class I devices are subject to general controls (e.g., labeling, postmarket controls, Medical Device Reporting and adherence to Quality System Regulations, or QSR). Generally, Class II devices are subject to general and special controls (e.g., performance standards, premarket notification and postmarket surveillance). Generally, Class III devices are new technology or high-risk 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 may not require regulatory approvals or clearance. Some *in vitro* diagnostic products will require 510(k) clearances, 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 FDA may determine that we must adhere to the more costly, lengthy, and burdensome PMA approval process for our potential products.

The Premarket Approval (PMA) application process is more expensive, burdensome, and lengthy than the 510(k) clearance process. A PMA must establish 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 certain of our products and products under development, are exempt from the investigational device exemption (IDE) requirements, including the need to obtain the FDA s prior approval. We believe certain of 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. To fall within this exemption to the IDE requirement, 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.

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 pre-approval 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. Significant modifications to the design, labeling or manufacturing process of a PMA-approved device may require approval by the FDA of a PMA supplement. 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 marketed 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.

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Medical device labeling and promotional activities are subject to scrutiny by the FDA and, in many circumstances, by the Federal Trade Commission. FDA enforcement policy prohibits the marketing of unapproved devices or marketing 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 (and state equivalent requirements). The QSR requirements include design controls for which there is a relatively high cost of compliance. We may incur significant costs to comply with laws and regulations in the future and these laws and regulations may have a material adverse effect upon our business, financial condition and results of operation.

Any of our customers using our potential future diagnostic devices for clinical use in the U.S. may be regulated under the Clinical Laboratory Improvement Act of 1988 (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, 2003, we had 136 full-time employees and 1 part-time employee, of whom 21 hold Ph.D. degrees and 14 hold other advanced degrees. Approximately 47 are involved in research and development, 45 in operations, manufacturing and quality assurance, 23 in sales and marketing, and 22 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

If our products are not successfully developed or commercialized, we could be forced to curtail or cease operations.

We are at an early stage of development. As of December 31, 2003, we had only a limited product offering that includes our NanoChip® System (which consists of our NanoChip® Molecular Biology Workstation and NanoChip® Cartridge), NanoChip® Cartridge, five ASRs, Assay Toolbox and a product available only in Europe solely for research use for beta thalasemia. 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.

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As of December 31, 2003 we have placed a total of 100 NanoChip® Systems. This includes instruments we have placed at various customer sites under development or strategic 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. 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. Many of our reagent rentals and cost-per-test agreements entered into as of December 31, 2003 require customer acceptance of our CFTR ASRs as a pre-condition to the customer s commitment to purchase the instrument. Our CFTR ASRs may be utilized by customers to develop and validate tests for the detection of mutations in the CFTR gene associated with cystic fibrosis. 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.

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. In September 2003 we took an accounting charge of $829,000 to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required. 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 do not know whether our 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.

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In August 2003, Hitachi, Ltd. exercised its right to terminate the research collaboration agreement it has with us. The agreement is scheduled to terminate during the second quarter of 2004. Until the agreement terminates, we and Hitachi expect to continue to work on the development of a new clinical instrument. Our manufacturing and distribution agreements with Hitachi remain in place. In June 2001, we formed a new 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. In February 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sales transactions.

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

Since our inception, we have incurred cumulative net losses which, as of December 31, 2003, total approximately $176.3 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.

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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 approval from the U.S. Food and Drug Administration 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.

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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 Technologies. We have opposed one allowed European patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. Oxford Gene 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 of the European Patent Office 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 Oxford Gene and the original claims are reinstated, or if an application relating to arrays is 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 may continue to be involved in intellectual property litigation that may be costly, time-consuming and may impact our competitive position.

In December 2002, Oxford Gene Technologies filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with Oxford Gene Technologies pursuant to which the lawsuit was dismissed by Oxford Gene Technology without prejudice. If the litigation were to be reinitiated, significant attorneys costs and fees could result. Although it is our position that Oxford Gene s assertions of infringement have no merit, neither the outcome of any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

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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 Food and Drug Administration, or FDA, regulates as medical devices most test systems, kits and reagents that are marketed for human *in vitro* diagnostic use. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, safety, effectiveness, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of these products until we receive 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.

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If we are unable to manufacture products on a commercial scale, our business may suffer.

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 that we 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 agreements 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

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retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreements 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.

As of December 31, 2003, we had 30 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. As of December 31, 2003, this office employed 7 European-based sales executives and support personnel in Germany and The Netherlands.

Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by us and certain of our 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. We 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 us and our 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.

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We may lose money when we exchange foreign currency received from international sales into U.S. dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which we do business will cause foreign currency 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 product liability claim brought against us could be expensive to defend and could result in a diversion of management s attention from our core business. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations.

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, 2003, the turnover rate at all levels at Nanogen was 25%. For the years ended December 31, 2002 and 2001 the turnover rates at Nanogen were 29% and 31%, respectively. Turnover at these rates may, and if they continue, will adversely affect us.

The turnover rates above exclude the impact of reductions in workforce. In April 2003, we reduced our workforce by approximately 20% and incurred a severance charge of approximately $500,000 in the second quarter. Also, in October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately $290,000 during the fourth quarter of fiscal 2002. Continued layoffs could have an adverse effect on us.

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.

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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;

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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, nanotechnology stocks, and other stocks in general;

purchases by Nanogen pursuant to our 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 we use at our 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. Other than the agreement with SynX Pharma Inc. discussed below, 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.

Risks Related to Our Definitive Agreement with SynX

Failure to complete our proposed transaction with SynX Pharma Inc. could cause our stock price to decline and could harm our future business and operations.

Our definitive agreement with SynX Pharma Inc. contains conditions which we and SynX must meet in order to complete the proposed transaction. In addition, the definitive agreement may be terminated by us or by SynX under certain circumstances.

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If the proposed transaction is not completed, we may be subject to the following material risks, among others:

- The price of our common stock may decline to the extent that the current market price of our common stock reflects a market assumption that the proposed transaction will be completed;
- Certain of our costs incurred in connection with the proposed transaction, such as legal, accounting, financial printing and certain expenses of our financial advisor must be paid even if the proposed transaction is not completed; and
- The secured line of credit of CDN $2 million that we made available to SynX prior to entering into the definite agreement might not be repaid.

In addition, we have filed a current report on Form 8-K with the SEC containing a description of the pro forma financial impact of our proposed transaction with SynX. The SynX pro forma financial information disclosed therein is preliminary and is subject to change. The SynX pro forma financial information is for illustrative purposes only and is not necessarily indicative of the operating results or financial position that would have occurred if the proposed transaction had occurred as of the date or during the periods presented. Actual future operating results of the combined entity may differ materially from those described in our pro forma financial presentation of the proposed transaction.

We will incur a variety of costs and may never realize the anticipated benefits of our acquisitions.

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. In February 2004 we entered into a definitive agreement to acquire SynX Pharma Inc., a point-of-care diagnostic company. The transaction is valued at approximately CDN $16.3 million (US$12.2 million) and is expected to close in the second quarter of 2004. However, the acquisition is subject to the approval of holders of SynX common shares and debentures, court approval and other customary closing conditions. The process of integrating SynX or any other 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 the SynX acquisition or any other 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, 2003, 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	51,000	Administrative offices, research and development, sales and marketing and manufacturing for a term ending on March 31, 2010 (with an option to extend).
1		2,600	Administrative offices and sales and marketing.

	Helmond, Netherlands		
1	Frankfurt, Germany	9,500	Administrative offices and research and development.

Our leases expire at varying dates through 2010 not including renewals at our option. We believe that our facilities will be suitable and adequate for the present purposes, and that the productive capacity in the San Diego and Helmond 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.

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The facility in Franfurt relates to the operations of Nanogen Recognomics. In February 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sales transactions. As a result, this facility will no longer be necessary. Notice of intent to terminate the lease in accordance with a six month notice period defined in the lease was provided to the Nanogen Recognomics landlord in 2004.

Item 3. Legal Proceedings

In December 2002, Oxford Gene Technologies (OGT) filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with OGT pursuant to which the lawsuit was dismissed by OGT without prejudice. If the litigation were to be reinitiated, significant attorneys costs and fees could result. Although it is our position that Oxford Gene s assertions of infringement have no merit, neither the outcome of any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

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, 2003.

PART II

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

Market Information

Our common stock trades on the 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:

Year ended December 31, 2002:	High	Low
1st Quarter	$ 6.34	$ 3.95
2nd Quarter	$ 4.74	$ 2.49
3rd Quarter	$ 3.67	$ 1.50
4th Quarter	$ 2.23	$ 1.22

Year ended December 31, 2003:		
1st Quarter	$ 1.78	$ 1.00
2nd Quarter	$ 4.98	$ 1.16
3rd Quarter	$ 4.82	$ 2.60
4th Quarter	$ 10.29	$ 2.95

As of March 19, 2004 there were approximately 240 stockholders 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.

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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,				
	2003	2002	2001	2000	1999
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales	$ 2,762	$ 3,384	$ 2,245	$ 919	$
License fees	84	10,844			
Sponsored research	1,500	1,355	7,457	8,457	5,688
Contract and grant	2,367	1,596	1,467	1,856	2,431
Total revenues	6,713	17,179	11,169	11,232	8,119
Costs and expenses:					
Cost of product sales	3,176	2,466	1,606	599	
Research and development	19,038	21,020	18,597	18,905	25,284
Selling, general and administrative	15,114	20,540	22,032	15,267	9,097
Litigation and settlement of patent matters	205	(165)	6,900		
Total costs and expenses	37,533	43,861	49,135	34,771	34,381
Loss from operations	(30,820)	(26,682)	(37,966)	(23,539)	(26,262)
Interest income, net	489	2,119	4,390	5,257	2,059
Minority interest in loss of consolidated subsidiary	1,817	2,156	907		
Loss on sale of investments	(1,925)	197	116		
Other income (loss)	(157)	(36)	52		(996)
Net loss	$ (30,596)	$ (22,246)	$ (32,501)	$ (18,282)	$ (25,199)
Net loss per share basic and diluted	$ (1.38)	$ (1.02)	$ (1.54)	$ (0.92)	$ (1.39)
Number of shares used in computing net Loss per share basic and diluted	22,244	21,722	21,091	19,944	18,069
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 29,114	$ 52,729	$ 67,524	$ 95,089	$ 41,021
Working capital	30,872	53,050	71,516	92,700	33,508
Total assets	43,849	71,360	90,091	111,168	50,785
Other long term liabilities and capital lease obligations, less current portion	5,005	4,219	3,430	2,065	2,831
Accumulated deficit	(176,254)	(145,659)	(123,413)	(90,912)	(72,630)
Total stockholders equity	32,823	57,393	74,929	101,414	38,121

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

The following discussion should be read in conjunction with our audited financial statements, including the related notes, presented in this Annual Report on Form 10-K.

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

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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 (4) Nanogen s general purpose reagents and accessories used to facilitate assay and protocol development and validation 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, 2003, had an accumulated deficit of $176.3 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.

During the year ended December 31, 2003, product related revenue was the largest category of revenue. While we recognized revenue from product sales during the years ended December 31, 2002, and 2001, our main sources of revenues during these fiscal years 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, our revenue base will continue to be 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:

Hitachi Development Program In July 2000, the Company executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute additional potential products based on the parties proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute, toward the research and development efforts of the Company, up to $28.5 million in cash over the ten-year period. At a minimum, the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. In addition, the Company is liable to repay to Hitachi fifty percent of all funding provided by Hitachi over an indefinite period of time. Repayment amounts are determined as a percentage of the Company s gross NanoChip® Cartridge sales until the liability is paid in full. Furthermore, Hitachi made an equity investment in the Company by purchasing 74,590 shares of the Company s common stock worth approximately $2.0 million pursuant to a private sale by the Company based on a per share price of $26.813 (the fair market value as of the signing date of the Hitachi agreement). 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.

In August 2003, the Company received written notice from Hitachi to exercise its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi s exercise of its right to terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Neither Nanogen nor Hitachi has terminated any of the other agreements between the companies. Based

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on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new clinical instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new clinical instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

From inception of the collaboration agreement with Hitachi through December 31, 2003, we have received a total of $8.7 million in sponsored research funding. Half of this funding has been recorded as revenue or deferred revenue, and the remaining half has been recorded as a long-term liability. Payment amounts are determined as a percentage of the Company s gross NanoChip® Cartridge sales until the liability is paid in full. Our failure to achieve established remaining milestones under this collaboration could mean the forfeiture of approximately $1.1 million in payments otherwise due prior to termination.

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.

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 contract was completed in December 2003 and all milestones have been completed. 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.

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.

NIH Grants In July 2002, the Company was awarded a grant by National Institute of Allergy and Infectious Disease for the National Institutes of Health (NIH) in an amount totaling approximately $162,000 over a 14-month period. The purpose of the grant is to design a compact centrifugal microfluidics-based analyzer, a system to integrate sample preparation and allocation in an automated, easy to use detection format. The project was completed in September 2003 and all milestones were completed. In May 2003, a second NIH grant was awarded to Nanogen in an amount totaling approximately $147,000 over a 15 month period. The goal of the grant is to develop a new 3-D DEP cell/pathogen separation system capable of processing large volumes of samples with significantly improved collection efficiency. In September 2003, the Company was awarded a third NIH grant totaling $0.7 million over a two-year period. The grant is aimed at developing a new isothermal on-chip strand displacement amplification (SDA) assay on an electronically active micro array.

Combined sponsored research, contract and grant revenue increased during the fiscal year ended 2003 from 2002, but remains lower than for the year ended 2001. Revenues for the years ended December 31, 2003 and 2002 consisted of $2.4 million and $1.6 million, respectively, from government contracts and grant funding and $1.5 million and $1.4 million, respectively, from sponsored research, all pertaining to the development program entered into in July 2000 with Hitachi. The decline in combined revenue associated with sponsored research,

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contract and grants between 2001 and 2003 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 or strategic 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.

License revenue decreased to $0.1 million during the year ended 2003 from $10.8 million during the year ended 2002. The $10.8 million license revenue received in 2002 consisted entirely of a settlement payment from CombiMatrix Corp. over a patent matter. Additional minimum license payments are required as part of the settlement agreement; however, these payments are not expected to be significant in 2004.

Fiscal year 2003 included a number of highlights. 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 the Assay ToolBox, a product that is designed to assist research institutions develop and validate 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. In April 2003, the Company announced that it has launched three new products for detecting genetic mutations. The first product was ASRs relating to ApoE gene mutations linked to the detection of Alzheimer s disease. The second was ASRs for certain mutations in the ASPA gene associated with Canavan disease, a disease that has highest prevalence in the Ashkenazi Jewish community. The third product was for research agents for the detection of certain genes associated with beta thalassemia, a disease that is most prevalent in the Mediterranean regions of Europe. These research reagents have been initially marketed through a European distributor as an alternative method for testing beta thalassemia. In April 2003, we also announced staff reductions of 20% and cost reductions of up to $5 million per year. In September 2003, we entered into a collaboration agreement with Prodesse to develop automated, highly sensitive microarray products to detect a number of infectious disease agents, including influenza adenovirus, herpes, West Nile Virus, and SARS. The collaboration will integrate Prodesse s proprietary multiplex amplification technology with the automated NanoChip® and jointly develop and market gene-based testing products to health care and clinical reference labs. Additionally, during September, we closed on the first $7 million traunch of a financing that could result in a total of up to approximately $16.1 million if all related warrants are exercised. Subsequent to December 31, 2003, we received an additional $4.6 million representing the exercise of six-month warrants issued in the financing.

Recent Developments

Acquisition of SynX Pharma Inc.

In February 2004, the Company entered into a definitive agreement whereby the Company will acquire SynX Pharma Inc., a point-of-care diagnostics company, in an all-stock transaction by way of a Toronto, Canada court-approved plan of arrangement. The transaction is valued at approximately $12.2 million. In connection with this transaction, Nanogen is making available to SynX a secured line of credit of approximately $1.5 million to fund working capital needs prior to closing. The transaction is subject to the approval of holders of SynX common shares and debentures, court approval and other customary closing conditions. The acquisition is expected to close in the second quarter of 2004. The acquisition is expected to provide Nanogen with a pipeline of complementary products in order to expand its market share in the in vitro diagnostics market and augment our

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technology platform for developing advanced diagnostic products. SynX currently markets point-of-care diagnostic tests for myocardial infarction in Europe and Canada, and infectious diseases and drugs of abuse in Canada. SynX is preparing to commercialize a diagnostic product for congestive heart failure (CHF). Unless otherwise indicated, disclosures in this report relate to us as a stand-alone entity and do not reflect the impact of the proposed acquisition of SynX.

Sale of Common Stock

In March 2004, the Company sold 4.25 million shares of its common stock to institutional investors at a price of $7.94 per share, for gross proceeds of approximately $33.7 million. After deducting fees and expenses, the Company received approximately $31.5 million from the sale. The Company plans to use the net proceeds for working capital, including the pending SynX acquisition, and other general corporate purposes.

Critical Accounting Policies and Estimates

We prepare our financial statements in conformity with accounting principles generally accepted in the United States. These accounting principles 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 or strategic 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

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of years) after a normally brief validation period that varies from 60 to 120 days. 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 or strategic 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 generally for marketing purposes and last for a period normally between six and twelve months. Under some of the arrangements, customers may develop content or optimize assays that could result in the creation or enhancement of intellectual property that we may license in the future. In addition, the customer may decide 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 and is included 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 it within finished goods. We record a reserve for the refurbishment costs, recorded within SG&A, for each unit included in consignment inventory 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 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.

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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. In September 2003 we took an accounting charge of $829,000 to reduce product inventory to its estimated net realizable value. 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, 2003, 2002 and 2001

Revenues

For the year ended December 31, 2003, product sales revenue totaled $2.7 million compared to $3.4 million for the year ended December 31, 2002. Product sales primarily consist of revenue recognized from the sale of our NanoChip® Molecular Biology Workstations and NanoChip® Cartridges. We sold seventeen NanoChip® Systems in 2003, compared to twenty-four in 2002, and thirteen during 2001, respectively. In addition, we sold two NanoChip® Systems in of 2001 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, 2003, we had total placements of 100 instruments, which consists of 62 outright sales and 38 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 years ended December 31, 2003 and 2002, license fees contributed $100,000, and $10.8 million, respectively, to revenue as the result of a litigation settlement with CombiMatrix (see Note 4 of Notes to Financial Statements). The amount recorded in 2002 was based on the fair value of the CombiMatrix shares received in the settlement. We do not anticipate recognizing significant license fees in 2004. There were no license fee revenues earned for 2001.

For the year ended December 31, 2003, revenue from sponsored research totaled $1.5 million compared to $1.4 million, and $7.5 million for the years ended December 31, 2002, and 2001, respectively. Sponsored research revenue in 2003 consisted of revenue earned in connection with our

development program entered into in July 2000 with Hitachi. Due to the termination of this agreement in 2003 with Hitachi, we expect sponsored research revenue to be significantly less in 2004 versus 2003. The final Hitachi funding under this agreement is expected in the second quarter of 2004, the amount of which is subject to the achievement of certain milestones.

Sponsored research revenue for 2001 included $6.4 million earned in connection with our research and development agreement entered into in January 1998 and September 1999 with Aventis, which included the sale of 2 NanoChip® Molecular Biology Workstations in each year and $1.1 million earned in connection with our development program entered into in July 2000 with Hitachi.

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 expired. We do not expect to receive additional funding from Aventis.

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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 $3.2 million in 2003 compared to $2.5 million and $1.6 million in 2002 and 2001, respectively. Gross margins on product sales revenue were negative 16% in 2003, positive 27% in 2002, and positive 28% and in 2001. Cost of sales during the years ended December 31, 2003, 2002 and 2001 were 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. Cost of sales was further impacted by reserves for excess instrument inventory and obsolete raw material components totaling $831,000, $28,000, and $109,000 for the years ended December 31, 2003, 2002, and 2001, respectively. Gross margins in 2003 and 2002 were unfavorably impacted due to manufacturing scrap as a result of lower yields on new products released into production. 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. 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 2004. 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 $19.0 million, $21.0 million, and $18.6 million for the years ended December 31, 2003, 2002, and 2001, respectively. The decrease in research and development expenses from 2002 to 2003 in part is the result of a headcount reduction in April 2003, and as a result of the termination of a collaboration agreement resulting in a loss of $452,000 in 2002 representing the remaining carrying value of acquired technology rights obtained in 1999. The increase from 2001 to 2002 primarily related to Nanogen Recognomics GmbH, a majority-owned subsidiary of the Company, which began operations in the third quarter of 2001. The majority-owned subsidiary recorded losses of $1.8 million and $2.2 million in 2003 and 2002, respectively. In February 2004, a decision was made to wind down all operations at Nanogen Recognomics GmbH in accordance with provisions established in the joint venture agreement. As part of this wind down, a holding company with the same ownership structure will be created to house the joint technology developed. The wind down will result in reduced research and development expense for the Company as the joint venture s operating expenses will no longer be included in the Company s consolidated financial statements. Research and development expenses included the following during the years 2003, 2002, and 2001: costs of salaries and benefits for scientific, engineering and operations personnel; costs associated with improving and refining our current products as well as development of potential new products and protocols; lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities. We anticipate that we will continue to invest significant resources in research and product development for the foreseeable future.

Selling, general and administrative expenses

Selling, general and administrative expenses totaled $15.1 million in 2003 compared to $20.5 million in 2002 and $22.0 million in 2001. The decrease in expenses from 2002 to 2003 is primarily the result of a headcount reduction in April 2003 as well as other cost savings initiatives.

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. Selling, general and administrative expenses are expected to remain at approximately the current level for the foreseeable future as we continue to market and sell our current and potential future products.

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Litigation and Settlement of Patent Matter

The net expenses for litigation and settlement of patent matters totaled $205,000 for the year ended December 31, 2003 as compared to a net benefit of $165,000 for the year ended December 31, 2002 and net expenses of $6.9 million for the year ended December 31, 2001.

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 2003 or 2002.

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 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. During 2003, the Company sold all of the CombiMatrix tracking common stock for $8.9 million.

Interest income, net

We had net interest income of $489,000 in 2003 compared to $2.1 million in 2002 and $4.4 million in 2001, 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 2003 when compared to 2002 and 2001. Primarily as a result of higher cash and investment balances resulting from a $34 million financing secured in March 2004, it is anticipated that net interest income will increase in 2004.

Gain (loss) on the sale of short-term investments

A realized loss on the sale of short-term investments of $1.9 million was recorded for the year ended December 31, 2003 compared to realized gains of $197,000 and $116,000 for the years ended December 31, 2002 and 2001, respectively. The $1.9 million realized loss in 2003 is related to the sale of 4,016,346 shares of CombiMatrix stock. These shares were obtained through a settlement agreement with CombiMatrix in 2002.

As of December 31, 2003, the Company had sold all holdings in CombiMatrix.

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Other income (expense)

Other net expenses totaled $155,000 and $36,000 for the years ended December 31, 2003 and 2002, respectively. Other income totaled $52,000 for the year ended December 31, 2001. Other net expenses increased during the year ended December 31, 2003 primarily due to a loss on the sale of certain fixed assets totaling approximately $129,000.

Minority interest in loss of consolidated subsidiary

We had losses relating to our majority-owned subsidiary, Nanogen Recognomics GmbH, of $1.8 million in 2003 compared to $2.2 million in 2002 and $907,000 in 2001. These losses have been funded by an initial $5 million investment from the minority interest investor and are therefore offset against the minority interest balance in the respective balance sheet. In February 2004, a decision was made to wind down all operations at Nanogen Recognomics GmbH in accordance with provisions established in the joint venture agreement. As part of this wind down, a holding company with the same ownership structure will be created to house the joint technology developed. The wind down will result in reduced research and development expense for the Company as the joint venture s operating expenses will no longer be included in the Company s consolidated financial statements.

Liquidity and capital resources

At December 31, 2003, we had $29.1 million in cash, cash equivalents and short-term investments, compared to $52.7 million at December 31, 2002. This decrease is primarily due to cash used in operations of approximately $25.5 million and both realized and unrealized losses totaling approximately $5.7 million related to the sale of securities received from the CombiMatrix settlement. These reductions in cash and short-term investments were partially offset by a financing in September 2003 that resulted in a cash infusion of approximately $7.0 million. In the first quarter of 2004, the Company received an additional $4.6 million in proceeds from the exercise of warrants related to the September 2003 financing, as well as gross proceeds from another financing totaling approximately $33.7 million.

Net cash used in operating activities was $25.5 million, $28.5 million, and $33.1 million, for 2003, 2002, and 2001, respectively. The decline in cash used in operating activities from 2002 to 2003 was primarily due to a reduction in force that was implemented in April 2003. The decline in cash used in operating activities from 2001 to 2002 was primarily due to collection of receivables. Cash used for operations during 2003, 2002, and 2001 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 $15.4 million and $26.5 million in 2003 and 2002, respectively compared to cash used in investing activities of $17.1 million for 2001. Cash provided by investing activities in 2003 and 2002 related primarily to proceeds received from the sale of short-term investments. Cash used for investing activities during 2001 primarily related to the purchase of short-term securities in an effort to maximize our return while preserving our cash balance.

Net cash provided by financing activities was $8.9 million, $353,000, and $5.2 million for 2003, 2002 and 2001, respectively. Cash provided by financing activities in 2003 primarily related to proceeds received pursuant to our private placement of common stock in September 2003 and

the exercise of stock options. 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

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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.

We fund much of our equipment acquisitions and leasehold improvements through capital leasing facilities. During 2003, equipment and leasehold improvement financing totaled $282,000 compared to $400,000 and $1.1 million during 2002 and 2001, 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, 2003, we had approximately $1.9 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, 2003 (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	$ 1,329	762	567		$
Other long term liabilities (a)	4,419				4,419
Operating leases	7,223	989	2,253	3,663	318
Purchase commitments (b)	1,875	1,875			
Research and development funding commitments (c)	1,125	1,125			
Standby letters of credit (d)	14				14
Total contractual obligations & other commitments	$ 15,985	$ 4,751	$ 2,820	$ 3,663	$ 4,751

(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 approximately $8.7 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 our next generation NanoChip® workstations. As of December 31, 2003, we had commitments to purchase approximately $1.9 million of our next generation NanoChip® workstations through January 31, 2005. Future purchase commitments will be determined based on product demand and inventory levels.

(c) We are required to contribute on an annual basis funding for our 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, and subsequently terminated in 2003. Amounts included in the table above assume Hitachi will make all scheduled payments up to final termination of the agreement which is expected to occur in the second quarter of 2004.

(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.

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We expect that our existing capital resources, combined with $33.7 million in gross proceeds from the sale of the Company s common stock in March 2004, and 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, including an estimated investment of approximately $6-8 million related to the pending acquisition of SynX and wind down costs related to our joint venture, Nanogen Recognomics, discussed elsewhere herein, 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, 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, 2003, we had federal and state net operating loss, or NOL, carryforwards of approximately $157.5 million and $65.1 million, respectively, and $5.5 million and $4.0 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.

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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 approximately $3.0 million at December 31, 2003.

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.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures.

The Company s management, with the participation of the Company s Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness the Company s disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company s disclosure controls and procedures as of the end of the period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. The Company believes that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

(b) Change in Internal Control over Financial Reporting.

No change in the Company s internal control over financial reporting occurred during the Company s most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company s internal control over financial reporting.

PART III

Item 10. Directors and Executive Officers of the Registrant

The information required by this item concerning our directors, executive officers, Section 16 compliance and code of ethics is incorporated by reference to the information set forth in the sections titled Election of Directors, Executive Officers of the Company, Section 16(a) Beneficial Ownership Reporting Compliance and Code of Ethics in our 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 9, 2004 (the Proxy Statement).

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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. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the Proxy Statement under the heading Principal Accountant Fees and Services .

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.

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Exhibit Number	Description of Document
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**(16)**	Form of Securities Purchase Agreement between Registrant and investors described therein, dated September 17, 2003
10.10	Warrant to Purchase Common Stock between Registrant and Aventis Pharma Deutchland, GmbH, dated June 6, 2003.
10.11***(5)(+)***	Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement by and between Registrant and Hitachi, Ltd. dated as of December 15, 1999.
10.11***(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)
10.12***(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)
10.14***(7)***	Common Stock Purchase Agreement between Registrant and the Hitachi Parties, dated July 26, 2000. (10.8)
10.15***(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)
10.16***(1)***	Master Lease Agreement between Registrant and Mellon US Leasing, dated September 11, 1997. (10.19)
10.17***(1)***	Master Lease Agreement between Registrant and LMP Properties, Ltd., dated June 29, 1994 as amended on March 14, 2001. (10.20)
10.18***(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)
10.19***(1)(A)***	Form of Promissory Note between Registrant and certain of its executive officers, dated August 22, 1996. (10.23)
10.20***(1)(A)***	Form of Promissory Note between Registrant and certain of its executive officers, dated June 30, 1995. (10.24)
10.21***(1)(A)***	Form of Performance Stock Option Agreement. (10.26)
10.22***(11)(A)***	Amended and Restated Employment Agreement between Registrant and Howard C. Birndorf, dated as of June 3, 2001. (10.2)
10.23**(15)*(A)***	Separation Agreement between Registrant and Kieran T. Gallahue, dated as of January 2, 2003
10.24**(15)*(A)***	Separation Agreement between Registrant and Dr. Vance R. White, dated as of December 11, 2002
10.25***(A)***	Separation Agreement between Registrant and Ira Marks, dated August 15, 2003
10.26**(15)*(A)***	Employment Agreement between Registrant and Bruce A. Huebner, dated December 1, 2002
10.27**(15)*(A)***	Employment Agreement between Registrant and William Franzblau, dated January 24, 2003
10.28**(15)*(A)***	Employment Agreement between Registrant and David Macdonald, dated January 24, 2003
10.29**(15)*(A)***	Employment Agreement between Registrant and Graham Lidgard, dated January 24, 2003

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Exhibit Number	Description of Document
10.30***(A)***	Separation Agreement between Registrant and Gerard A. Wills, dated as of May 21, 2003.
10.31(**15**)***(A)***	Indemnification Agreement between Registrant and Bruce A. Huebner, dated effective as of December 1, 2002
10.32(**15**)***(A)***	Indemnification Agreement between Registrant and Graham Lidgard, dated effective as of January 24, 2003
10.33(**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).
10.34**(9)(A)(+)**	Contribution Agreement among Aventis R&T, Registrant and Nanogen Recognomics, dated June 27, 2001 (10.4).
10.35**(11)(+)**	Settlement Agreement between Motorola, Inc., Genometrix, Inc., the Massachusetts Institute of Technology and Registrant, dated July 20, 2001. (10.6)
10.36***(14)***	Settlement Agreement between CombiMatrix Corporation, Dr. Donald Montgomery, Acacia Research Corporation and Registrant, dated September 30, 2002
10.37***(4)***	Master Loan and Security Agreement between Registrant and Transamerica Business Credit Corporation, dated June 14, 1999.
14.1(**15**)	Nanogen, Inc. Ethics Policy (99.2)
23.1	Consent of Ernst & Young LLP, independent auditors.
31.1	Certifications of Chief Executive Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certifications of Chief Financial Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended. (This exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)
32.2	Certifications of Chief Financial Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended. (This exhibit shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Further, this exhibit shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.)

(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.

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(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.
(15) Incorporated by reference to Registrant s Annual Report on Form 10-K for the year ended December 31, 2002. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(16) Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on September 22, 2003.

(A) Indicates management compensatory plan or arrangement.
(+) Confidential treatment has been requested for certain portions of these agreements.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 31, 2003 other than a report announcing the third quarter earnings.

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SIGNATURES

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

NANOGEN, INC.

Date: March 29, 2004

By: /s/ HOWARD C. BIRNDORF

Howard C. Birndorf

Chairman of the Board,

and Chief Executive Officer

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

Signature	Title	Date
/s/ HOWARD C. BIRNDORF Howard C. Birndorf	Chairman of the Board, and Chief Executive Officer (Principal Executive Officer)	March 29, 2004
/s/ DAVID LUDVIGSON David Ludvigson	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 29, 2004
/s/ VAL BUONAIUTO Val Buonaiuto	Director	March 29, 2004
/s/ DAVID SCHREIBER David Schreiber	Director	March 29, 2004
/s/ STELIOS B. PAPADOPOULOS Stelios B. Papadopoulos	Director	March 29, 2004

/s/ ROBERT E. WHALEN	Director	March 29, 2004
Robert E. Whalen		

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NANOGEN, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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, 2003 and 2002, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2003. 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, 2003 and 2002 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States.

/s/ ERNST & YOUNG LLP

San Diego, California

February 6, 2004

except Note 15 as to which

the date is March 18, 2004

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NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	December 31,	
	2003	**2002**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,550	$ 9,353
Short-term investments	20,564	43,376
Receivables, net	1,415	1,754
Inventories, net	4,774	4,717
Other current assets	1,590	1,781
Total current assets	36,893	60,981
Property and equipment, net	4,276	4,982
Acquired technology rights, net	2,508	4,544
Other assets, net	158	789
Restricted cash	14	64
	$ 43,849	$ 71,360
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 290	$ 753
Accrued liabilities	4,519	5,901
Deferred revenue	469	472
Current portion of capital lease obligations	743	805
Total current liabilities	6,021	7,931
Capital lease obligations, less current portion	586	1,134
Other long-term liabilities	4,419	3,085
Total long-term liabilities	5,005	4,219
Minority interest in consolidated subsidiary		1,817
Commitments and contingencies		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2003 and 2002; no shares issued and outstanding at December 31, 2003 and 2002		
Common stock, $0.001 par value, 50,000,000 shares authorized at December 31, 2003 and 2002; 24,867,325 and 21,981,115 shares issued and outstanding at December 31, 2003 and 2002, respectively	25	22
Additional paid-in capital	209,014	199,483
Accumulated other comprehensive income	1,136	4,926
Deferred compensation	(175)	(156)
Notes receivable from officers		(513)

Accumulated deficit	(176,255)	(145,659)
Treasury stock, at cost, 500,189 and 366,857 shares at December 31, 2003 and 2002, respectively	(922)	(710)
Total stockholders equity	32,823	57,393
	$ 43,849	$ 71,360

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	Years Ended December 31,		
	2003	**2002**	**2001**
Revenues:			
Product sales	$ 2,762	$ 3,384	$ 2,245
License fees	84	10,844	
Sponsored research	1,500	1,355	7,457
Contract and grant	2,367	1,596	1,467
Total revenues	6,713	17,179	11,169
Costs and expenses:			
Cost of product sales	3,176	2,466	1,606
Research and development	19,038	21,020	18,597
Selling, general and administrative	15,114	20,540	22,032
Litigation and settlement of patent matters	205	(165)	6,900
Total costs and expenses	37,533	43,861	49,135
Loss from operations	(30,820)	(26,682)	(37,966)
Other income (expense):			
Interest income, net	489	2,119	4,390
Gain (loss) on the sale of short-term investments	(1,925)	197	116
Other income/(expense)	(157)	(36)	52
Minority interest in loss of consolidated subsidiary	1,817	2,156	907
Total other income (expense)	224	4,436	5,465
Net loss	$ (30,596)	$ (22,246)	$ (32,501)
Net loss per share basic and diluted	$ (1.38)	$ (1.02)	$ (1.54)
Number of shares used in computing net loss per share basic and diluted	22,244	21,722	21,091

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid-in	Treasury	Accumulated Other Comprehensive	Deferred	Notes Receivable From	Accumulated	Total Stockholders
	Shares	Amount	Capital	Stock	Income	Compensation	Officers	Deficit	Equity
Balance at December 31, 2000	20,913	$ 21	$ 193,459	$	$ 270	$ (325)	$ (1,099)	$ (90,912)	$ 101,414
Components of comprehensive loss:									
Net loss								(32,501)	(32,501)
Unrealized gain on short-term investments					892				892
Cumulative currency translation adjustment									91
					91				
Total comprehensive loss									(31,518)
Issuance of common stock	330		1,248						1,248
Repurchase of common stock	(47)		(282)			11			(271)
Issuance of common stock in settlement of litigation and patent matter	417	1	2,500						2,501
Issuance of warrant to development partner			1,200						1,200
Issuance of common stock in connection with defined benefit plan, net of forfeitures	25		297			(284)			13
Stock based compensation expense						367			367
Options issued to consultants			105			(105)			
Payments received and accrued interest on notes receivable from officers	(22)		(140)				115		(25)
Balance at December 31, 2001	21,616	22	198,387		1,253	(336)	(984)	(123,413)	74,929
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

Components of comprehensive loss:									
Net loss								(30,596)	(30,596)
Unrealized loss on short-term investments					(4,056)				(4,056)
Cumulative currency translation adjustment									266
					266				
Total comprehensive loss									(34,386)
Issuance of common stock	696	1	1,921			22			1,944
Issuance of common stock and warrants under private									
offering, net of expenses	2,121	2	6,543						6,545
Issuance of warrant to development partner			700						700
Options issued to Board			136						136
Acquisition of common stock				(212)					(212)
Issuance of common stock in connection with defined benefit plan, net of forfeitures	69		97			(44)			53
Stock based compensation expense			116						116
Revaluation of deferred compensation			6						6
Options issued to consultants			12			3			15
Settlement of notes receivable from officers							513		513
Balance at December 31, 2003	24,867	$ 25	$ 209,014	$ (922)	$ 1,136	$ (175)	$ 0	$ (176,255)	$ 32,823

See accompanying notes

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2003	**2002**	**2001**
Operating activities:			
Net loss	$ (30,596)	$ (22,246)	$ (32,501)
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	(1,817)	(2,156)	(907)
Depreciation and amortization	4,453	4,088	3,475
Asset impairment and other non-cash charges	1,029	452	
Loss on disposal of fixed assets	171		
Amortization (accretion) related to short-term investments	216	99	(53)
Stock-based compensation expense	333	68	367
Interest capitalized on notes receivable from officers		(58)	(63)
Loss (gain) on sale of short-term investments	1,925	(197)	(116)
Common stock received for upfront licensing fees		(10,844)	
Changes in operating assets and liabilities:			
Receivables	339	2,626	(3,058)
Inventories	(474)	(1,440)	(2,398)
Other assets	177	581	(919)
Accounts payable	(464)	(298)	(172)
Accrued liabilities	(761)	923	610
Deferred revenue	(3)	(50)	162
Net cash used in operating activities	(25,472)	(28,452)	(33,073)
Investing activities:			
Purchase of short-term investments	(25,276)	(16,661)	(26,941)
Proceeds from sale of short-term investments	41,891	44,205	10,692
Purchase of technology rights	(3)	(884)	(150)
Purchase of equipment	(1,170)	(135)	(652)
Net cash provided by (used in) investing activities	15,442	26,525	(17,051)
Financing activities:			
Proceeds from minority interest stockholder			4,794
Proceeds from development partner	1,325	1,371	1,125
Proceeds (payments) from restricted cash balances	51	235	(135)
Proceeds from leasing company		222	
Principal payments on capital lease obligations	(774)	(1,471)	(1,818)
Issuance of common stock, net	8,330	177	1,149
Payments to acquire treasury stock		(181)	
Note receivable payments from officers			38
Net cash provided by financing activities	8,932	353	5,153
Effect of exchange rate changes	295	472	96
Net decrease in cash and cash equivalents	(803)	(1,102)	(44,875)

Cash and cash equivalents at beginning of year	9,353	10,455	55,330
Cash and cash equivalents at end of year	$ 8,550	$ 9,353	$ 10,455
Supplemental disclosure of cash flow information:			
Interest paid	$ 156	$ 220	$ 340
Supplemental schedule of noncash investing and financing activities:			
Equipment acquired under capital leases	$ 282	$ 400	$ 1,062
Common stock issued for litigation settlement	$	$	$ 2,500
Common stock issued for technology	$	$ 750	$
Warrants issued for research and technology	$ 700	$ 122	$ 1,200
Common Stock issued to employees, accrued in prior period	$ 112	$	$
Assets and liabilities contributed by minority stockholder	$	$	$ 307
Unrealized gain (loss) on short-term investments	$ (3,217)	$ 2,909	$ 892
Common stock issued in connection with employee benefit plan, net of forfeitures	$ (15)	$ 138	$ 284
Cancellation of notes receivable related to unvested restricted stock, net of payments on notes receivable	$ 300	$	$ 139
Options issued to non-employees for services	$ 24	$ 42	$ 105
Cancellation of unvested restricted stock	$	$	$ 11
Acquisition of treasury stock in exchange for cancellation of officer note receivable	$ 212	$ 529	$
Inventory transferred to fixed assets	$ 541	$ 1,411	$ 661

See accompanying notes.

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NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

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 subsidiaries, Nanogen Europe B.V. and Nanotronics, Inc., 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.

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, 2003 include $2.3 million in net tangible assets, excluding intercompany balances, and an operating loss of $1.6 million for the year ended December 31, 2003 related to Nanogen Europe B.V.

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 remaining estimated period for which the $5 million in funding will provide for operating expenses. In June 2003, pursuant to the joint venture agreement, the Company accrued for the issuance of a second warrant to Aventis to purchase 323,850 shares of the Company s common stock exercisable through June 2008 at an agreed upon price of $5.618 per share. The value of this accrued warrant, as determined by the Black-Scholes valuation model, was $700,000 and is included in other assets in the accompanying consolidated financial statements and has been amortized to research and development expense over a seven-month period, the remaining estimated period for which the $5 million in funding will provide for operating expenses. The Company s consolidated financial statements at December 31, 2003 include $635,000 in net tangible assets, excluding intercompany balances, of which $590,000 consists of cash and cash equivalents, related to Nanogen Recognomics. An operating loss of $1.8 million for year ended December 31, 2003 related to Nanogen Recognomics is reflected as an offset to minority interest in consolidated subsidiary as included in the consolidated balance sheets herein.

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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, 2003, 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.

Concentrations 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. 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 related to investment of excess cash for the years ended December 31, 2003, 2002, and 2001.

As a result of a settlement agreement in September 2002 as discussed in Note 4, the Company received 4,016,346 shares of ComibMatrix common stock initially valued at $10.8 million. At December 31, 2002, the estimated value of the shares had increased to $14.6 million, resulting in an unrealized gain of $3.8 million for the year ended December 31, 2002. All of the CombiMatrix shares were sold during the year

ended December 31, 2003 for gross proceeds of $8.9 million which resulted in a realized loss of $1.9 million, and the elimination of the $3.8 million unrealized gain.

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 $14,000 at December 31, 2003.

Inventories

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

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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. Once commercialization of a technology begins, the related acquired technology rights are amortized over their estimated useful lives, generally 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 years ended December 31, 2003 and 2002, the Company recognized impairment losses related to acquired technology rights totaling $1.1 million and $452,000, respectively. These charges have been included in research and development expense for the respective periods.

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 the Securities and Exchange Commission s Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements and is 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 placed with potential customers under development site programs that may ultimately 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 includes the estimated cost of product warranty in deferred revenue and recognizes as revenue over the warranty period.

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

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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 six 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 $197,000 and $489,000 at December 31, 2003 and 2002, 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 non-cancelable 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.

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.

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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. As of December 31, 2003 and 2002, unrealized cumulative foreign currency translation gains totaled approximately $1.1 million and $855,000, respectively.

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, 2003, 2002 and 2001, 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,		
	2003	2002	2001
Stock options	4,861,366	4,459,428	2,951,564
Warrants outstanding	2,747,293	365,863	315,863
	7,608,659	4,825,291	3,267,427

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 2003, 2002 and 2001: a risk-free interest rate of 3.2%, 3.0% and 5.0%, respectively; a dividend yield of zero; volatility factors of the expected market price of the Company s common stock of 110%, 83% and 65%, respectively; and a weighted average expected life of the option of five years.

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

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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,		
	2003	2002	2001
Adjusted pro forma net loss	$ (35,319)	$ (28,372)	$ (38,438)
Adjusted pro forma net loss per share	$ (1.59)	$ (1.31)	$ (1.82)

The weighted average fair value of options granted during 2003, 2002 and 2001 was $2.37, $1.77 and $4.05 per share, respectively.

The pro forma effect on net loss for 2003, 2002 and 2001 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 values (using the Black-Scholes model) as determined in accordance with SFAS 123 and periodically re-measured 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.

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 2003, 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.

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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)
2003			
Obligations of U.S. government agencies	$ 5,007	$ 5,016	$ 9
Corporate debt securities	2,313	2,315	2
Asset backed securities	7,180	7,190	10
U.S. Treasuries	6,040	6,043	3
	$ 20,540	$ 20,564	$ 24
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

Within the net unrealized gain as of December 31, 2003, there was an unrealized loss of approximately $12,000 related to one asset backed security with a market value of $1,028,000 and an amortized cost of $1,040,000. Unrealized losses as of December 31, 2002 were insignificant.

The estimated fair value of available for sale securities, by contractual maturity at December 31, 2003 is as follows (in thousands):

	Amortized Cost	Market Value
Due in one year or less	$ 12,060	$ 12,072
Due between one and two years	6,416	6,439
Due between three and five years	2,064	2,053
	$ 20,540	$ 20,564

During 2003, a realized loss of approximately $1.9 million from the sale of short-term investments was recorded related to the sale of Combimartix shares received as part of a settlement agreement as discussed in Note 4. 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.

Receivables

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

	December 31,	
	2003	**2002**
Product	$ 1,379	$ 1,549
Contract and grant	141	246
	1,520	1,795
Allowance for doubtful accounts	(105)	(41)
	$ 1,415	$ 1,754

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Inventories

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

	December 31,	
	2003	**2002**
Raw materials	$ 1,469	$ 1,062
Work in process	1,745	1,485
Finished goods	4,043	4,428
	7,257	6,975
Reserve for obsolescence	(2,483)	(2,258)
	$ 4,774	$ 4,717

Finished goods includes $1.7 million, $3.2 million and $2.0 million of NanoChip® Systems at December 31, 2003, 2002 and 2001, respectively, that are installed at customer sites under development and strategic site agreements where title has not transferred to the customer.

Property and Equipment

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

	December 31,	
	2003	**2002**
Scientific equipment	$ 7,479	$ 7,165
Office furniture and equipment	3,436	3,323
Manufacturing equipment	921	387
Leasehold improvements	4,425	4,336
	16,261	15,211
Less accumulated depreciation and amortization	(11,985)	(10,229)
	$ 4,276	$ 4,982

For the years ended December 31, 2003, 2002, and 2001, depreciation expense totaled $2.3 million, $2.4 million, and $2.0 million, respectively.

Acquired Technology Rights

As of December 31, 2003, 2002 and 2001, acquired technology rights is presented net of accumulated amortization of $1.4 million, $2.6 million and $2.0 million respectively. For the years ended December 31, 2003, 2002 and 2001, amortization totaled $1.0 million, $1.2 million, $1.2 million, respectively. Amortization expense for the years ended December 31, 2004, 2005, and 2006 is estimated at $1.0 million per year and $375,000 for the year ended December 31, 2007.

Accrued Liabilities

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

	December 31,	
	2003	**2002**
Accrued compensation and benefits	$ 1,534	$ 2,683
Accrued legal fees	673	639
Other	2,312	2,579
	$ 4,519	$ 5,901

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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 $2.7 million, $2.8 million, and $2.3 million from Hitachi pursuant to this agreement during the years ended December 31, 2003, 2002, and 2001, respectively.

In August 2003, the Company received written notice from Hitachi to exercise its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi s exercise of its right to terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Neither Nanogen nor Hitachi has terminated any of the other agreements between the companies. Based on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new clinical instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new clinical instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

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. As of December 31, 2003 the Company had fulfilled its spending requirements under the agreements. During 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company.

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 license 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 and Next Generation Instruments. As of December 31, 2003, the Company had commitments to purchase approximately $1.9 million in Workstations through January 31, 2005. At December 31, 2003, 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 of the Company s gross NanoChip® Cartridge sales until the liability is paid in full. This liability is non-interest bearing

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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 $4.3 million and $3.0 million at December 31, 2003 and 2002, 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 and 2003. This expense was recorded during fiscal 2002 and 2003, over the relative service periods. In the fourth quarter of 2003, the agreement was modified to provide a new pricing schedule.

Leases

The Company leases its facilities and certain equipment under operating lease agreements that expire at various dates through 2010. Rent expense was $843,000, $927,000 and $783,000 in 2003, 2002 and 2001, respectively.

The Company leases certain equipment under capital lease obligations. Cost and accumulated amortization of equipment under capital leases were $16.1 million and $11.9 million at December 31, 2003, and $14.1 million and $9.7 million at December 31, 2002. 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, 2003 are as follows (in thousands):

	Operating Leases	Capital Lease Obligations
2004	$ 989	$ 855
2005	1,086	494
2006	1,167	110
2007	1,179	
2008	1,220	
Thereafter	1,582	
Total minimum lease payments	$ 7,223	1,459
Less amount representing interest		130
Present value of future minimum capital lease obligations		1,329
Less amounts due in one year		743
Long term portion of capital lease obligations		$ 586

As of December 31, 2003, the Company has approximately $1.9 million of available funding under equipment lease lines.

Litigation

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

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provisions of the Company s technology to Motorola, Genometrix or MIT. The lawsuit and the counterclaim have now been dismissed. For the year ended December 31, 2001 costs associated with the litigation and settlement of the Motorola patent matter totaled $6.3 million. Costs incurred during the year ended December 31, 2001, primarily consist of the settlement fee of $5.0 million in addition to legal fees incurred related to the litigation process.

In 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 and were initially valued upon receipt at $10.8 million, 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. The $1.0 million was received in two installments of $500,000, one in 2002 and the second in 2003. 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 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.

In December 2002, Oxford Gene Technologies (OGT) filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with OGT pursuant to which the lawsuit was dismissed by OGT without prejudice. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

5. Related Party Transactions

Included in other assets in the accompanying December 31, 2002 balance sheet was a full-recourse note receivable from the Company s former Chief Executive Officer, totaling approximately $150,000 which had accrued interest at a rate of 7%, compounded quarterly, and was due in 2005. This note receivable was secured by second trust deeds on the officer s personal residence. In addition, there were full-recourse notes receivable from certain officers collateralized by the common stock of the Company. During 2002, in lieu of cancellation of a note totaling approximately $529,000 due the Company and a cash payment totaling approximately $133,000, the Company acquired 339,857 shares of its own common stock from Mr. Birndorf, Chairman of the Board and an officer of the Company. All notes receivable have been repaid in full as of December 31, 2003.

In addition, there were full-recourse notes receivable from a certain officer totaling approximately $513,000 related to stock purchase agreements as of December 31, 2002. During 2003, the stock related notes were repaid through a combination of cash and the tender of Nanogen common shares. The value of shares received as partial repayment totaled approximately $212,000 and has been recorded as additional treasury stock.

In July 2002, the Company entered into an agreement with Graviton, Inc. to terminate and release (the July 2002 Release) Nanogen and Graviton of their obligations under a Collaboration and License Agreement dated December 15, 1999. The Company received compensation from Graviton for termination of this arrangement in

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the form of 50,000 shares of Graviton Series D-Prime Preferred Stock and a waiver of the exercise price of $1.00 per share for a warrant to purchase 23,076 shares of Graviton Series B Preferred Stock, which was exercised in July 2002. As Graviton was privately-held and did not maintain a market for its stock, the fair value of these securities was determined to be immaterial.

In September 2002, Graviton commenced a recapitalization and a new round of financing. In exchange for Nanogen s consent for the recapitalization and new round of financing, Graviton issued to Nanogen a ten-year warrant to purchase 440,000 shares of Series 1 Preferred Stock at a price of $2.00 per share, the price at which the September 2002 financing was completed. As a result of the termination of the collaboration agreement, the Company recorded a loss of approximately $452,000 (the remaining carrying value of acquired technology rights obtained in 1999) during 2002.

Mr. Birndorf, Chairman of the Board and an officer of the Company, was also a director of and investor in Graviton. Following Graviton s recapitalization and additional financing, Mr. Birndorf held an approximate 3.5% ownership interest in Graviton and Mr. Buonaiuto, a director of the Company, held less than 1% ownership interest in Graviton as of December 31, 2002. Given the interrelationship among the parties, the Company s Board appointed a committee of disinterested Board members to evaluate these transactions with Graviton. After full disclosure of the above-referenced interrelationships, the Committee determined that it was in the best interest of the Company to enter into the license agreement which was executed on December 15, 1999, and the subsequent July 2002 Release and September 2002 Settlement Agreement. During 2003, the Company was notified that Graviton was dissolved.

Mr. Birndorf owns an aircraft which was leased by a local charter aircraft company. For the years ended December 31, 2003, 2002 and 2001, the Company paid approximately $82,000, $175,000, and $420,000, respectively, to the local charter aircraft company for the Company s use of Mr. Birndorf s aircraft for business related travel. In 2003, Mr. Birndorf received $1,250 per hour of usage when his aircraft was leased to outside parties. In 2002 and 2001, the per hour charge was $1,500. Mr. Birndorf received approximately $44,000, $82,000, and $207,000 for the years ended December 31, 2003, 2002 and 2001, respectively, as a result of the Company s use of Mr. Birndorf s aircraft. The Company believes that the terms of the charter arrangements are no less favorable to the Company than those that could be obtained from unrelated third parties, based on review of lease fees published by other charter aircraft companies.

In May 2003, the Company entered into a separation agreement with its then Chief Financial Officer. Under the terms of the agreement, the Company made severance payments totaling approximately $121,000. In addition, 20,000 shares of unrestricted Company common stock were sold at par value ($0.001), and the vesting on his existing stock options was accelerated. Severance expense of approximately $82,000 related to the sale of common stock and acceleration of stock options was recorded.

In December 2002, the Company entered into a separation agreement with its then Chief Executive Officer. Under the terms of the agreement, the Company made a net severance payment of $58,000 in January 2003 to settle all outstanding obligations between the two parties, including indebtedness to the Company amounting to $167,000.

Also in December 2002, Nanogen s then President, resigned effective in January 2003. In connection with the resignation, the Company made a net payment of approximately $384,000 in January 2003 to settle all outstanding obligations between the two parties, including indebtedness to the Company amounting to approximately $300,000. The cost of this separation has been accrued in the Company s financial statements as of December 31, 2002.

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6. Employee Benefit Plans

401(k) Plan

The Company has a 401(k) defined contribution savings and retirement plan (the Plan). The Plan is for the benefit of all qualifying employees and permits employees to make voluntary contributions up to a maximum of 20% of base salary (as defined), subject to annual limits. The Board of Directors may, at its sole discretion, approve Company contributions. The Compensation Committee of the Board of Directors approved a Company match in the form of Company stock equal to 25% or approximately $188,000 of total employees contributions for the year ended December 31, 2001. No match was approved for the years ended December 31, 2003 and December 31, 2002.

Retirement Plans

The Company s foreign subsidiary maintains separate defined contribution retirement savings plans for each country in which its employees reside. Participants may contribute a portion of their annual salaries subject to statutory annual limitations in each country. The Company contributes to these plans as required by local statute and may make additional contributions at its discretion.

Stock Option Plans

Under the Company s 1993 Stock Option Plan, as amended in April 1995, 654,671 shares of common stock were reserved for issuance upon exercise of stock options granted by the Company. In April 1995, the Board of Directors adopted the 1995 Stock Option/Stock Issuance Plan under which 333,333 shares of common stock were reserved for issuance. In April 1996, an additional 650,000 shares of common stock were reserved for issuance under the 1995 Plan. The plans provide for the grant of stock options to officers, directors, employees and consultants to the Company.

In August 1997, the Board of Directors adopted the 1997 Stock Incentive Plan, under which 1,641,341 shares of common stock were reserved for issuance upon exercise of stock options granted by the Company. In November 1997, June 1999, June 2000, June 2001, June 2002 and June 2003, an additional 600,000 shares, 925,000 shares, 1,000,000 shares, 1,500,000 shares, 750,000 shares and 1,000,000 shares, respectively, were reserved for issuance under the 1997 Plan.

The exercise price of incentive stock options to be granted under the stock option plans shall not be less than 100% of the fair value of such shares on the date of grant. The exercise price of nonqualified stock options to be granted under the plans shall not be less than 85% of the fair value of such shares on the date of grant. Options granted prior to April 13, 1998 (the date of the Company s initial public offering) are generally exercisable immediately; however, options granted subsequent to the initial public offering are generally exercisable only as they vest. Shares granted under the Stock Option Plans generally vest at the rate of one fourth after one year and the remainder ratably over the remaining three years. Options granted have a term of up to ten years.

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As of December 31, 2003, 610,872 shares are available for future grant under the stock option plans. The following table summarizes stock option activity through December 31, 2003:

	Number of Shares	Price Per Share	Weighted Average Exercise Price Per Share
Outstanding at December 31, 2000	2,292,424	$ .02 to $45.81	$ 21.50
Granted	2,000,641	$ 3.70 to $12.09	$ 7.55
Exercised	(259,258)	$ .02 to $ 8.00	$ 3.34
Cancelled	(1,082,243)	$ .15 to $45.81	$ 24.36
Outstanding at December 31, 2001	2,951,564	$ .90 to $45.81	$ 12.61
Granted	2,857,325	$ 1.68 to $ 6.06	$ 3.01
Exercised	(6,725)	$ 3.78 to $ 5.41	$ 3.45
Cancelled	(1,342,736)	$ .90 to $45.81	$ 8.12
Outstanding at December 31, 2002	4,459,428	$ .90 to $45.81	$ 7.82
Granted	1,963,923	$ 1.03 to $ 5.74	$ 3.15
Exercised	(571,871)	$ 1.95 to $ 9.27	$ 2.91
Cancelled	(990,114)	$ .90 to $45.81	$ 9.71
Outstanding at December 31, 2003	4,861,366	$ 1.03 to $45.81	$ 6.12

The Company has the option to repurchase, at the original issue price, unvested shares issued pursuant to early exercise of options in the event of termination of employment or engagement. There were 2,290, 9,483 and 18,063 shares issued under the stock option plans subject to repurchase by the Company at December 31, 2003, 2002 and 2001, respectively.

On January 26, 2001, the Compensation Committee of the Board of Directors authorized a plan for certain option holders whereby each holder could cancel certain of his or her vested and unvested options on February 28, 2001 and receive a written promise from the Company to issue, on a one-for-one basis, new options which would be granted and priced at the fair market value on August 29, 2001. This plan applied only to options granted to employees of the Company (excluding executive officers and directors) between January 1, 2000 and February 27, 2001. These options were exercisable on August 29, 2001 or when they vest, whichever is later. The new options granted contain similar vesting schedules as the cancelled options. A total of 389,900 option shares were cancelled on February 28, 2001 and 281,600 option shares were subsequently granted on August 29, 2001 related to this plan.

In July 2002, the Compensation Committee of the Board of Directors (the Compensation Committee) approved the issuance of employee retention options for 969,500 shares of the Company s common stock. The options were issued to the Company s employees and the employees of the Company s subsidiary, Nanogen Europe B.V. pursuant to the Company s 1997 Stock Incentive Plan, as amended. Each incentive stock option grant will be 50% vested on January 1, 2003 and 50% will vest ratably over the period January 1, 2003 through July 26, 2004. On July 18, 2003, the Compensation Committee of the Board of Directors (the Compensation Committee) approved the issuance of employee retention options for 1,437,500 shares of the Company s common stock. The options were issued to the Company s US employees pursuant to the Company s 1997 Stock Incentive Plan, as amended. Each incentive stock option grant will be 50% vested 6 months from date of grant and 50%

will vest ratably over the period of January 18, 2004 through July 18, 2005.

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Following is a further breakdown of the options outstanding as of December 31, 2003:

Range of Exercise Prices		Options Outstanding	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
$ 1.03	$ 1.72	281,530	8.86	$ 1.56	37,394	$ 1.53
$ 1.73	$ 1.90	550,219	8.59	$ 1.89	405,235	$ 1.90
$ 1.92	$ 3.05	577,383	8.92	$ 2.18	156,161	$ 2.31
$ 3.10	$ 3.10	112,175	8.44	$ 3.10	45,552	$ 3.10
$ 3.11	$ 3.45	1,450,834	9.55	$ 3.44	85,002	$ 3.44
$ 3.47	$ 5.11	581,405	8.05	$ 4.41	252,233	$ 4.59
$ 5.14	$ 7.00	597,610	7.10	$ 6.32	501,350	$ 6.37
$ 7.12	$21.85	490,260	6.99	$ 11.29	428,955	$ 11.16
$ 24.44	$41.75	19,950	6.42	$ 33.68	18,836	$ 33.81
$ 45.81	$45.81	200,000	6.10	$ 45.81	195,833	$ 45.81
$ 1.03	$45.81	4,861,366	8.41	$ 6.13	2,126,551	$ 9.58

Restricted Stock Awards

On July 27, 1999, the Board of Directors authorized the issuance of an aggregate of 251,000 shares of the Company s common stock to certain officers and key employees at a price per share of par value ($0.001). All of these shares were purchased by the respective officers and key employees and were subject to repurchase if the officer or key employee terminated employment with the Company prior to July 26, 2001. Deferred compensation aggregating $1.8 million has been recorded for the excess of the fair market value of the stock on the date of the award over the purchase price per share and has been fully amortized as of December 31, 2001.

Compensation expense related to options granted prior to the effective date of the Company s initial public offering, as mentioned above, and restricted stock awards, was $327,000 for the year ended December 31, 2001.

These restricted shares have been included in the summary of stock option activity under the caption ***Stock Option Plans*** above.

Stock Bonus Plan

In April 2002, the Board of Directors adopted a Stock Bonus Plan. This plan was approved by the Company s stockholders in June 2002 under which 250,000 shares of common stock were authorized for issuance under the plan. The purpose of this plan is to promote the long-term success of the Company and the creation of stockholder value by (a) encouraging key employees to focus on critical long-range objectives, (b) encouraging the attraction and retention of key employees with exceptional qualifications and (c) linking key employees directly to stockholder interest through increased stock ownership. This plan seeks to achieve this purpose by providing for payment of some or a portion of annual bonuses in the form of restricted shares. Amount of payout is based on Board approval. As of December 31, 2002, there were no shares issued or outstanding under this plan. In January 2003, 71,610 common shares were issued out of the Stock Bonus Plan to various key employees as an annual bonus for the year ended December 31, 2002. There are 178,390 shares available for grant as of December 31, 2003.

Employee Stock Purchase Plan

In November 1997, the Board of Directors approved the Employee Stock Purchase Plan (the Purchase Plan), under which 300,000 shares of common stock were authorized for issuance under the Purchase Plan. In June 2001, an additional 150,000 shares were reserved for issuance under the Purchase Plan. The Purchase Plan

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permits eligible employees of the Company to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the participant s base salary subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the stock at either the beginning of the applicable offering period or the last day of the accumulation period. Each offering period is 24 months long, with new offering periods commencing every six months, and an accumulation period is six months in duration. During the years ended December 31, 2003, 2002 and 2001, there were 79,250, 75,009 and 70,329 shares, respectively, issued under the Purchase Plan.

Shares Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at December 31, 2003:

Stock options outstanding	4,861,366
Stock options available for grant	610,872
Stock bonus plan	178,390
Employee stock purchase plan	87,640
Warrants outstanding	2,747,293
	8,485,561

Shares reserved for future issuances related to warrants outstanding include: 639,713 related to a joint venture agreement (Note 1); 50,000 related to a license agreement entered into in April 2002; and 2,057,580 related to a private financing in September 2003. The warrants related to the private financing include: 1,103,032 shares at $4.14 per share expiring in March 2004; 530,305 shares at $4.75 per share expiring in September 2004; and 424,243 shares at $4.75 expiring in September 2008.

7. Stockholder Rights Plan

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

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

8. Stock Repurchase Plan

In November 2002, the Board of Directors authorized a limited stock repurchase program under which the Company may purchase up to an aggregate of ten percent (10%) of its outstanding Common Stock from time to time. Any purchases under the Nanogen stock repurchase program may be made by the Company during certain periods in the open market or in privately negotiated transactions and may be initiated and discontinued at any time. For the year ended December 31, 2002, Nanogen had acquired 366,857 shares of the Company s

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outstanding common stock for treasury at a cost of $710,000. In January 2003 an additional 133,332 shares of the Company s outstanding common stock was acquired through privately negotiated transaction with a former officer in exchange for related notes receivable. As of December 31, 2003, the Company held a total of 500,189 treasury shares at a cost of $922,000.

9. Income Taxes

Significant components of the Company s deferred tax assets and liabilities as of December 31, 2003 and 2002 are shown below (in thousands). A valuation allowance of $72.3 million has been established to offset the deferred tax assets as realization of such assets is uncertain.

	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 58,144	$ 49,181
Research and development credits	8,126	7,603
Capitalized research expenses	2,494	1,772
Accrued expenses	354	788
Amortization	1,306	440
Other, net	2,120	1,106
Total deferred tax assets	72,544	60,890
Valuation allowance for deferred tax assets	72,351	(60,603)
Net deferred tax assets	193	287
Deferred tax liabilities:		
Depreciation	(193)	(287)
Net deferred tax assets	$	$

At December 31, 2003, the Company has federal, state and foreign net operating loss carryforwards of approximately $157.5 million, $65.1 million and $5.7 million, respectively. The difference between the federal and state tax loss carryforwards is primarily attributable to the capitalization of research and development expenses for state tax purposes and the 60% percent limitation on state loss carryforwards. The federal tax loss carryforwards will begin expiring in 2006 unless previously utilized. The state tax loss carryforwards will begin to expire in 2004, unless previously utilized. The foreign tax loss carryforwards will carryforward indefinitely, unless previously utilized. The Company also has federal and state research and development tax credit carryforwards of approximately $5.5 million and $4.0 million, respectively, which will begin expiring in 2007 unless previously utilized.

A portion of the deferred tax assets include a future tax benefit related to stock option deductions, which, if recognized, will be allocated to additional paid-in capital.

Under Sections 382 and 383 of the Internal Revenue Code, the annual use of the Company s net operating loss and credit carryforwards may be limited because of a cumulative change in ownership of more than 50% within a three-year period.

10. Collaborative Alliances

Hitachi, Ltd.

Manufacturing Agreement

In January 2000, the Company executed an agreement with Hitachi, Ltd., effective as of December 15, 1999, for the full-scale commercial manufacturing and distribution of the NanoChip® Molecular Biology Workstation in specified research markets. Hitachi, Ltd. s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip® Molecular Biology Workstation s components.

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Hitachi, Ltd. has the right to be the sole distributor of NanoChip® Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip® Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip® Molecular Biology Workstations sold by Hitachi, Ltd. in Japan. The Company retains the right to distribute, directly or through others, NanoChip® Molecular Biology Workstations outside of Japan. In addition, the Company manufactures NanoChip® Cartridges at its San Diego, California facility for distribution worldwide. The Company also retains the right to form other manufacturing and distribution agreements.

In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of a new clinical instrument being developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the new clinical instrument, when development is completed, exclusively for the Company for worldwide distribution. Once production instruments are received by the Company, the Company is required to meet certain annual purchase commitments for the new instrument.

Pursuant to our manufacturing agreements with Hitachi, the Company is required to provide annual purchase commitments to Hitachi for NanoChip® Workstations. As of December 31, 2003, the Company had a commitment to purchase approximately $1.9 million in Workstations from Hitachi through January 31, 2005.

Research Collaboration Agreement

In July 2000, the Company executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute additional potential products based on the parties proprietary technologies, potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. The agreement provides that the parties will jointly determine which projects to prioritize over the term of the agreement. The agreement may be terminated before its expiration by either party, subject to certain restrictions. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute, toward the research and development efforts of the Company, up to $28.5 million in cash over the ten-year period. At a minimum the Company is required to contribute on an annual basis funding for its own general technology development in an amount equal to or greater than payments made by Hitachi. In addition, the Company is liable to repay to Hitachi fifty percent of all funding provided by Hitachi over an indefinite period of time. Repayment amounts are determined as a percentage of the Company s gross NanoChip® Cartridge sales until the liability is paid in full. Furthermore, Hitachi made an equity investment in the Company by purchasing 74,590 shares of the Company s common stock worth approximately $2.0 million pursuant to a private sale by the Company based on a per share price of $26.813 (the fair market value as of the signing date of the Hitachi agreement). 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.

Sponsored research revenue recognized under this agreement totaled $1.5 million, $1.4 million and $1.1 million for the years ended December 31, 2003, 2002 and 2001, respectively. In accordance with SFAS No. 68, the Company records sponsored research revenue under this arrangement as expenses are incurred not exceeding scheduled payments under the agreement. The Company records a long-term liability for fifty percent of the funds received from Hitachi upon the receipt of such funds. The amount owed to Hitachi for proceeds received under this agreement was $4.3 million, $3.0 million and $1.6 million at December 31, 2003, 2002 and 2001, respectively. The current portion of the long-term liability remains immaterial as payment amounts due under this obligation are determined as a percentage of the Company s gross NanoChip® Cartridge sales which have not been significant to date. As such, the Company has classified the entire balance of this liability as long-term.

In August 2003, the Company received written notice from Hitachi to exercise its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi s exercise of its right to

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terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Neither Nanogen nor Hitachi has terminated any of the other agreements between the companies. Based on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new clinical instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new clinical instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

Service Agreement

In October 2000, the Company entered into an agreement with Hitachi for the service by Hitachi of the NanoChip® Molecular Biology Workstations in the United States after their sale or placement by the Company with the Company s customers. The Company pays an agreed-upon amount (as specified in the agreement) to Hitachi for annual service for each Workstation covered under the agreement. Nanogen amortizes the cost of the warranty agreement over the service period. As the Company provides the first year of warranty at no charge to the customer, the Company defers the portion of the Workstation sale revenue that relates to the warranty agreement. This deferred revenue is then amortized into revenue ratably over the annual service period. In subsequent years, the customer can pay an annual service fee to the Company and the Company will in turn pay Hitachi the annual service amount as specified in the agreement. The amount charged to the customer by the Company is based upon the cost of the service (i.e. the payment to Hitachi) plus an industry accepted profit margin for comparable service on similar types of products. Both the service revenue and the service expense are amortized ratably over the service period, generally one year.

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 warranty service in fiscal 2002 and 2003 and the expense was recorded over the relative service periods during fiscal 2002 and 2003. The agreement was modified in the fourth quarter of 2003 to provide a revised pricing schedule.

Aventis Research and Technologies

In December 1997, the Company entered into an agreement with Aventis Research and Technologies, an affiliate of Hoechst AG (Aventis) for, among other things, an exclusive research and development collaboration relating to the development of molecular recognition arrays. In December 1998, the Company and Aventis entered into a Collaborative Research and Development Agreement which, among other things, extended the guaranteed term of the research program from two to three years. In conjunction with this agreement, the Company issued to Aventis a warrant to purchase 120,238 shares of common stock exercisable through December 2003, which was exercised by Aventis in October 2000 at an agreed-upon exercise price of $6.17 per share.

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

Revenue is primarily recognized under these agreements as expenses are incurred, and totaled $6.4 million for the year ended December 31, 2001. No revenue was recorded in 2003 or 2002 as these projects were completed as of December 31, 2001.

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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. Nanogen Recognomics is sixty percent owned by the Company and forty percent owned by Aventis and is based in Frankfurt, Germany. Aventis provided the first $5 million of funding for the operations of Nanogen Recognomics and also contributed intellectual property in the form of eighteen patents. The Company is also 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. This funding is recorded as research and development expense in the Company s statement of operations as incurred. As of December 31, 2003, the Company had fulfilled its spending obligations under the agreements. The amounts contributed by Aventis are spent by the joint venture and reported in the operating results of the joint venture. Aventis has no further commitments to provide funding beyond the first five years of operation. In addition, Nanogen Recognomics will own several patent applications filed jointly by the Company and Aventis. The Company has licensed certain aspects of its NanoChip® technology to Nanogen Recognomics and will seek to commercialize new products and applications developed by Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics. In conjunction with the agreement to form Nanogen Recognomics, the Company issued a warrant to Aventis to purchase 315,863 shares of common stock exercisable through July 17, 2006 at an agreed upon price of $9.828 per share. The value of this warrant, as determined by the Black-Scholes valuation model, was $1.2 million, is included in other assets in the accompanying consolidated financial statements and is being amortized over a two and a half year period, the estimated period for which the $5 million in funding will provide for operating expenses. Assumptions used in determining the value of the warrant were as follows: dividend yield of 0%, expected volatility of 70%, risk-free interest rate of 6.5%, expected life of 5 years, stock price of $6.79 per share, and an exercise price of $9.828 per share. In June 2003, pursuant to the joint venture agreement, the Company accrued for the issuance of a second warrant to Aventis to purchase 323,850 shares of the Company s common stock exercisable through June 2008 at an agreed upon price of $5.618 per share. The value of this warrant, as determined by the Black-Scholes valuation model, was $700,000 and was included in other assets and was amortized over a seven month period, the remaining estimated period for which the $5 million in funding will provide for operating expenses. Assumptions used in determining the value of the warrant were as follows: dividend yield of 0%, expected volatility of 84%, risk-free interest rate of 2.3%, expected life of 5 years, stock price of $3.70 per share, and an exercise price of $5.618 per share. In 2004, the shareholders of Nanogen Recognomics decided to reorganize into a non-operating holding company. The Company is required pursuant to the agreement to take over reorganization costs and the Company may restructure Nanogen Recognomics to hold the original patents contributed by Aventis and any jointly owned patents. The restructured company will collect royalties, if any, and pay the equity owners accordingly. Our exclusive commercialization license will continue for 10 years after restructuring.

The results of operations for Recognomics are fully consolidated in the Company s financial statements. The total operating loss of Recognomics is reflected as a reduction of the minority interest in consolidated subsidiary liability account and totaled $1.8 million, $2.2 million and $907,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

11. Licensed Technology

The Company has acquired various licenses to technologies which are incorporated into certain of the Company s current products or products under development. The Company capitalizes the cost (which includes cash and equity consideration) in conjunction with the acquisition of these licenses and amortizes the cost over the expected life of the product. In June 2002, the Company issued 254,151 shares of the Company s common stock in a private stock transaction valued at $750,000, based on the closing price of the Company s stock at the effective date, to a licensor in exchange for license rights. In April 2002, the Company issued a warrant to a licensor which is exercisable through April 12, 2007 to purchase 50,000 shares of the Company s common stock at a per share price of $4.10, the fair market value on the effective date of the agreement. The value of the

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warrant was determined to be $122,000 using the Black-Scholes valuation model. Assumptions used in determining the value of the warrant were as follows: dividend yield of 0%, expected volatility of 65%, risk-free interest rate of 5.5%, expected life of 5 years, stock price of $4.10 per share, and an exercise price of $4.10 per share. The warrant has a term of five years, and was issued in return for license rights.

In July 2002, the Company and Graviton, Inc. entered into an agreement to terminate and release Nanogen and Graviton of their obligations under the Collaboration and License Agreement dated December 15, 1999 (see footnote 9 for further discussion of this transaction) which originally resulted in acquired technology rights of $1 million by the Company in fiscal 1999. In September 2002, the Company and Graviton, Inc. entered into a subsequent agreement to terminate and release Nanogen and Graviton of their obligations under the Collaboration and License Agreement dated December 15, 1999 and the termination and release agreement entered into in July 2002. As a result of the termination of this collaboration arrangement, the Company recorded a loss of approximately $452,000 included in research and development expenses (the remaining value of the acquired technology rights obtained in 1999) during 2002. During 2003, the Company was notified that Graviton has been dissolved.

12. Contract and Grant Revenue

In August 2000, a Defense Advanced Research Projects Agency (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. The contract is focused on developing an electronic sample preparation chip for the detection of biowarfare agents from blood samples. Revenue is recognized under these agreements as expenses are incurred and totaled $601,000, and $737,000, for the years ended December 31, 2002, and 2001, respectively.

In October 2000, the Company entered into a cooperative agreement with the U.S. Army Medical Research Acquisition Activity (USAMRAA) in an amount totaling approximately $1.1 million over a three-year period. The objective of the USAMRAA agreement is to develop an arrayable electronic system for the identification of biological warfare or infectious disease agents. In October 2001, the Company entered into an additional cooperative agreement with USAMRAA in the amount totaling $1.5 million over a three-year period. The second cooperative agreement is to develop miniaturized electronic devices for isolation and detection of biological warfare and infectious disease agents. In conjunction with the agreements, funding provided by the agency is matched dollar-for-dollar with Nanogen funds. Revenue is recognized under these agreements as expenses are incurred and totaled $1,093,000, $688,000, and $340,000 for the years ended December 31, 2003, 2002, and 2001, respectively.

The National Institute of Justice, U.S. Department of Justice, provides funding for the development of a chip based genetic detector for rapid DNA-based identification of individuals. Revenue is recognized under these agreements as expenses are incurred and totaled $979,000, $232,000, and $383,000, for the years ended December 31, 2003, 2002, and 2001, respectively.

The National Institute of Allergy and Infectious Diseases for the National Institutes of Health (NIH), provides funding for several grants. In July 2002, the Company was awarded a grant which focused on the development of a compact centrifugal micro fluidics based BWA analyzer. In May and September of 2003, Nanogen was awarded a second and third grant. The second grant is for the development of a dieletrophorectic (DEP) separator for cell/pathogen separation. The third grant is aimed at developing an on-chip real-time DNA amplification for biological warfare agent (BWA) detection. Revenue is recognized under these grants as expenses are incurred and totaled $188,000 and $25,000 for the years ended December 31, 2003 and 2002, respectively.

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13. Geographic Sales and Significant Customers

The Company has determined that, in accordance with SFAS No. 131, it operates in one segment as it only reports operating results on an aggregate basis to chief operating decision makers of the Company. The Company had product sales and license fees revenues by region as follows for the years ended December 31, 2003, 2002, and 2001 (in thousands):

	2003	2002	2001
Customer Location:			
United States	$ 1,500	$ 12,554	$ 1,097
Europe	1,329	1,664	943
Mexico/Canada	17	10	205
Total	$ 2,846	$ 14,228	$ 2,245

Revenue from customers representing 10% or more of total revenue during 2003, 2002 and 2001 is as follows:

	2003	2002	2001
Sponsored research:			
Customer A	22%	%	57%
Customer B	%	%	10%
License fees:			
Customer C	%	63%	%

14. Quarterly Financial Data (unaudited)

Summarized quarterly financial data for fiscal 2003 and 2002 are as follows (in thousands, except per share data):

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Fiscal 2003				
Revenues	$ 1,200	$ 1,694	$ 1,741	$ 2,078
Costs and expenses (2)	9,050	9,137	10,159	9,187
Loss from operations	(7,850)	(7,443)	(8,418)	(7,109)
Net loss	(10,680)	(6,893)	(7,079)	(5,943)
Net loss per share basic and diluted (1)	$ (0.50)	$ (0.32)	$ (0.33)	$ (0.25)
Fiscal 2002				
Revenues	$ 1,533	$ 1,951	$ 1,551	$ 12,144
Costs and expenses (2)	10,392	11,609	10,932	10,928
Income (loss) from operations	(8,859)	(9,658)	(9,381)	1,216
Net income (loss)	(7,532)	(8,521)	(8,224)	2,031
Net income (loss) per share basic and diluted (1)	$ (0.35)	$ (0.39)	$ (0.38)	$ 0.09

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly net loss per share will not necessarily equal the total for the year.
(2) Since a significant portion of the Company s revenues are derived from sponsored research and contracts and grants and the related costs are reported as research and development expense, the Company chose to disclose total costs and expenses rather than cost of sales as required.

15. Subsequent Events

Acquisition of SynX Pharma Inc.

In February 2004, the Company entered into a definitive agreement whereby the Company will acquire SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. The transaction is valued at Canadian $16.3 million (approximately U.S. $12.2 million). Nanogen will also make available to SynX a secured line of credit of Canadian $2.0 million (approximately U.S. $1.5 million) to fund

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working capital needs prior to closing. Outstanding options and warrants to acquire SynX common shares will convert into obligations of the Company at closing and will represent options and warrants to acquire shares of Nanogen common stock based on the transaction exchange ratio and the existing terms of the SynX stock option plan and warrants.

The transaction is subject to the approval of holders of SynX common shares and debentures, court approval and other customary closing conditions. The acquisition is expected to close in the second quarter of 2004.

Sale of common Stock

In March 2004, the Company sold 4.25 million shares of its common stock to institutional investors at a price of $7.94 per share, for gross proceeds of approximately $33.7 million. After deducting fees and expenses, the Company received approximately $31.5 million from the sale. The Company plans to use the net proceeds for working capital, including the pending SynX acquisition, and other general corporate purposes.

Reorganization of Joint Venture

In March 2004, the shareholders of Nanogen Recognomics decided to reorganize into a non-operating holding company. The Company is required pursuant to the joint venture agreement with Aventis to take over reorganization costs and the Company may restructure Nanogen Recognomics to hold the original patents contributed by Aventis and any jointly owned patents. The restructured company will collect royalties, if any, and pay the equity owners accordingly. Our exclusive commercialization license will continue for 10 years after restructuring.

Warrant Exercises

During the first quarter of 2004, warrants for 1,103,032 common shares related to a September 2003 private financing were exercised for gross proceeds to the Company of $4.6 million.

In addition, a 50,000 share warrant issued in April 2002 related to a license agreement was exercised utilizing a cashless exercise provision resulting in the net issuance of 32,463 shares.