NANOGEN INC
Form 10-K
March 15, 2005
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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, 2004

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 x NO ¨

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, 2004 (the last day of the registrant s most recently completed second fiscal quarter), as reported on the Nasdaq National Market was approximately $198,412,160. Shares of common stock held by each executive officer and director and by each person (including shares beneficially owned by Citigroup, Inc.) who owns 10 percent or more of the outstanding common stock have been excluded in such calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares outstanding of the registrant s common stock was 47,708,407 as of March 1, 2005.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its annual meeting of stockholders to be held in 2005 are incorporated by reference in Part III of this Form 10-K.

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For the Year Ended December 31, 2004

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PART I

Trademarks and trade names

NANOGEN®, NanoChip, Eclipse® MGB, MGB Eclipse, Eclipse® Dark Quencher, Super A, Super T, Super G, Redmond Red, Yakima Yellow, Smarter DNA, DxPress, Nexus D_x, StatusFirst and our other logos and trademarks are the property of Nanogen Incorporated. All other brand names or trademarks appearing in this Annual Report on Form 10-K are the property of their respective holders. Use or display by us of other parties trademarks, trade dress or products in this Annual Report is not intended to, and does not imply a relationship with, or endorsements or sponsorship of, us by the trademark or trade dress owners.

Forward Looking Statement

This Form 10-K and the information incorporated herein by reference contain forward-looking statements that involve a number of risks and uncertainties, as well as assumptions that, if they never materialize or prove incorrect, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Although our forward-looking statements reflect the good faith judgment of our management, these statements can only be based on facts and factors currently known by us. Consequently, forward-looking statements are inherently subject to risks and uncertainties, and actual results and outcomes may differ materially from results and outcomes discussed in the forward-looking statements.

Forward-looking statements can be identified by the use of forward-looking words such as believes, expects, hopes, may, will, plan, inte estimates, could, should, would, continue, seeks, pro forma or anticipates, or other similar words (including their use in the negativ discussions of future matters such as the development of new products, technology enhancements, possible changes in legislation and other statements that are not historical. In addition, to the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flows, balance sheet items or any other guidance for future periods, these statements are forward looking statements. These statements include but are not limited to statements under the captions Business, Risk Factors, and Management s Discussion and Analysis of Financial Condition and Results of Operations as well as other sections in this report. You should be aware that the occurrence of any of the events discussed under the heading Item 1. Business Risk Factors and elsewhere in this Annual Report could substantially harm our business, results of operations and financial condition. If any of these events occurs, the trading price of our common stock could decline and you could lose all or a part of the value of your shares of our common stock.

The cautionary statements made in this Annual Report are intended to be applicable to all related forward-looking statements wherever they may appear in this Annual Report. We urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this Annual Report.

Item 1. ***Business***

Overview

We were founded with an enduring vision to improve the quality of healthcare by introducing advanced human diagnostic products that will provide higher quality of information in a shorter period of time to our customers in the research, clinical laboratory or point-of-care markets. We intend to turn this vision into reality by continuing to develop new diagnostic products or by acquiring other companies and complementary products that will expand and accelerate our entry into rapidly growing diagnostic markets. We began a targeted acquisition strategy during 2004 that is expected to result in a broad product line of advanced diagnostic products. The combination of internally developed products plus acquired products addressing large markets should provide the stimulus for significant revenue acceleration in 2005 and beyond.

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The company has historically generated revenues through contract research, grants and licenses and through commercializing molecular diagnostic research tools, such as the Molecular Biology Workstation and NanoChip® Cartridge (collectively, the NanoChip® System) and related Analyte Specific Reagents (ASRs) for the clinical and laboratory research market. In November 2004 we introduced our second generation molecular diagnostic instrument, the NanoChip® 400. This platform is expected to ship in 2005 and is designed to serve the clinical laboratory market by offering faster throughput and simpler operating procedures. The new system offers a 400-site cartridge utilizing our unique and patented micro-array technology that will allow customers the flexibility to adjust panels from single-to-multiple arrays to fit their requirements.

We expanded both our product lines and addressable markets during the past year with the acquisitions of SynX Pharma in April 2004 and of Epoch Biosciences in December 2004. These combinations will accelerate our entry into the point-of-care market and deepen our penetration of the research and clinical laboratory markets, respectively.

SynX Pharma is developing a product that will test for congestive heart failure (CHF) by measuring levels of NT-proBNP in patients. FDA submission of this product for a 510k approval is expected during 2005. SynX researchers are continuing research and development work in the cardiovascular field including development of a test for the diagnosis of stroke. SynX received patents during 2004 in both the US and in Europe for the diagnosis of stroke. SynX is also developing a test for diagnosis of traumatic brain injury. We expect that the SynX product line will accelerate our entry into the point-of-care market place by providing time-sensitive information to emergency room or urgent care settings.

The acquisition of Epoch Biosciences late in 2004 will have an immediate effect on revenues during 2005. Epoch has a number of proprietary products for genomic analysis as well as molecular and infectious disease diagnostics for the real-time polymerase chain reaction (PCR) market. We also acquired Epoch s revenue stream of royalties from companies in the research, diagnostics and industrial markets that have licensed Epoch technologies.

Collectively, our existing products along with the products acquired from SynX and Epoch, are expected to significantly increase our revenues during 2005 and provide us with a strong revenue base for the following years. One of our key goals in broadening our product line both organically and through acquisition is to have a definable path to profitability that will help us emerge as a leader in the growing field of advanced diagnostics.

We were incorporated under the laws of the state of Delaware and our stock is listed on the Nasdaq National Market under the symbol NGEN . Our corporate offices are located at 10398 Pacific Center Court, San Diego, California 92121. Our main telephone number is 858-410-4600.

We make available through our internet website our code of business conduct and ethics, annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. Our Internet address is www.nanogen.com. The information contained in, or that can be accessed through, our website is not part of this Annual Report.

Technology

Increased awareness of the role of genes in regulating the functions of living organisms has generated a worldwide effort to identify and sequence genes and genomes of many organisms, including the estimated three billion nucleic acid base pairs that comprise 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.

Genomics research investigates the role of specific genes and gene expression in disease. This research will ultimately lead to a new healthcare paradigm where disease is understood at the molecular level. We believe that

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this change 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 be increasingly proactive as well as being increasingly specific to the individual patient. Therefore, we have developed tools for both simple and complex testing that render genetic information accessible to researchers and clinicians.

The Molecular Biology Workstation and NanoChip® 400 product platforms are advanced diagnostic systems designed for complex genetic testing with the ability to perform multiple tests on multiple gene markers at the same time. Molecular and infectious disease products developed by Epoch use the real-time, PCR format that is more applicable for simpler, single-test analysis. These tests run on platforms that are sold by other companies. The two product lines address different, yet complimentary needs of the research and clinical laboratory market thereby providing the company with a broader product line to offer its customers.

The company s technologies are also being applied to infectious disease diagnostic products. The area of infectious disease includes bacteria, fungi, and viruses that all contain nucleic acids detectable by the molecular diagnostic methods we have developed for human genes. With our acquisition of Epoch, we currently offer multiple infectious disease ASRs to the real-time PCR clinical laboratory marketplace. Further, through our collaboration with Prodesse, Inc., we are working to commercialize multiplexed ASRs for infectious disease detection.

SynX Pharma has discovered or licensed a series of proteomic markers related to cardiovascular, stroke, brain injury and various metabolic diseases. Their research is expected to result in a pipeline of immunoassay products that we may develop or licensed to others for development in specific markets.

Customers

The market for our molecular diagnostic systems and reagents includes customers in research institutions, clinical research laboratories and high complexity CLIA certified laboratories. In the United States, the Food and Drug Administration (the FDA) regulates most diagnostic tests and *in vitro* reagents marketed as test kits as medical devices. The FDA also considers ASRs to be medical devices. ASRs are exempt from pre-market approval requirements; however, the FDA restricts the sale of these products to those clinical laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988, known as CLIA. Customers for our diagnostics technology and products therefore include:

Research customers These customers develop and create test reagents to detect various SNPs or other genetic changes in order to correlate these genetic changes with certain disease states. These customers are most interested in highly flexible equipment on which they can design and operate their specialized tests.

High complexity certified clinical diagnostics laboratories These customers offer validated tests to aid physicians in the diagnosis of patients conditions. They may either develop reagents internally or may purchase ASRs manufactured under the Good Manufacturing Practices regulations. Ease of use and through-put is important to these customers.

With our acquisition of SynX Pharma, we are entering the point-of-care diagnostic market with devices that detect the levels of proteins that may cause or be correlated with diseases. Our technology is moving these tests from the clinical reference lab to near patient settings such as the hospital lab or emergency room. Ease of use and rapid availability of information is critical to these customers. Our point-of-care customers are reached through a network of distributors.

Products

We have three categories of advanced diagnostic products: 1) real-time ASRs, 2) microarray instrument platforms and related ASRs, and 3) point-of-care tests.

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1) Real-time ASRs

Real-time PCR analysis is widely used in a variety of research and clinical laboratories to test for single markers or mutations. The products, assumed in our acquisition of Epoch, operate on instrument systems sold by other companies.

MGB Eclipse Detection Reagents MGB Eclipse *Detection Reagents* consist of ready-to-use 20X probe and primer mixes for amplifying and detecting disease-specific genetic sequences. For MGB Eclipse *Detection Reagents* targeting infectious disease agents, pathogen-specific probe and primer mixes are bi-plexed with a probe and primers specific for an Internal Control. Internal Control and disease-specific Positive Control template products are sold separately as an option for incorporation into laboratory-defined assay quality assurance protocols. MGB Eclipse *Detection Reagents* targeted to disease-associated gene expression are bi-plexed with a probe and primers for amplifying and detecting a reference gene for increased accuracy. MGB Eclipse *Detection Reagents* for disease-associated single nucleotide polymorphisms (SNPs) consist of a bi-plexed mix of probes specific for each of two genetic variants along with primers for amplification and detection using post-PCR dissociation or melt curve analysis.

We currently offer MGB Eclipse Detection Reagents for infectious disease and genetic testing targets.

2) Microarray Instrument Platforms and related ASRs

Microarray-based testing is preferred in applications involving multiple gene markers or mutations. The largest markets for these products involve testing for respiratory viruses, mutations associated with cystic fibrosis, Factor V/II and pharmacogenomic tests. Our Molecular Biology Workstation and the recently announced NanoChip® 400 (our second generation product) are designed to address the requirements of this market.

Despite recent advances in technology, many molecular testing methodologies are too specialized or inflexible to be used for the varied needs of the diagnostics or research laboratory. Many of the current tools were designed for large-scale data generation and the automation of repetitious tasks required for high throughput discovery research. These technologies fall primarily into three categories: high-density arrays; high throughput sequencing and SNP discovery tools; and gel-based methods. While these technologies have certain advantages, they also have significant drawbacks that inhibit their broad applicability across the life sciences market, particularly in the molecular diagnostics market. Therefore, we are seeking to establish the NanoChip® System as the preferred platform for complex detection of genetic mutations and to develop applications for clinical laboratory use.

Both the NanoChip® 400 and Molecular Biology Workstation consist of a consumable cartridge containing a proprietary semiconductor microchip (the NanoChip® Electronic Microarray), a fluidic and optical instrument, and imbedded software that can be programmed by the end-user to control all aspects of microchip operations including 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.

Our first generation platform, the Molecular Biology Workstation has an installed base of approximately 100 units. It provides research-oriented customers with the ability to electronically control up to 100 tests per cartridge. Electronic control enables rapid transport, concentration and hybridization on our arrays and will permit unused test sites to be saved for future assays, enabling full chip utilization. This feature represents a

significant differentiator over other microarrary technologies.

Our next generation NanoChip® 400 System, now in early customer testing, will streamline user workflow and should permit the testing of up to 400 sites per cartridge. The NanoChip® 400 has a new architecture which eliminates the need for user handling of cartridges and reagents during instrument operation. It also offers a significantly smaller footprint that is more attractive to clinical lab customers. We believe the automation and ease-of-use of the NanoChip® 400 System better meets the requirements of the clinical diagnostic market.

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We sell not only the NanoChip® System and Cartridges, but also ASRs and other reagents that our customers can use to develop, validate and perform specific molecular tests. We have developed multiple ASRs that enable researchers and high complexity CLIA certified laboratory customers to develop, validate and run specific assays on our Molecular Biology Workstation system. The ASRs available include Factor V/II, ApoE, CFTR, and in the European market: Connexin26 and beta thalmassemia.

3) Point-of-care market

Our point-of-care product development pipeline is primarily focused on cardiac and central nervous system disorders such as Congestive Heart Failure (CHF) and Stroke. Heart and stroke related disorders are the number one and three causes of death in the United States, respectively. Nearly 5 million Americans have congestive heart failure and 550,000 new cases are diagnosed each year; the estimated direct and indirect cost of heart failure is $26.5 billion. About 700,000 Americans will have a stroke this year, of which 500,000 are first attacks and 200,000 are recurrent attacks. Stroke is a leading cause of severe, long-term disability; in 2004 the estimated direct and indirect cost of stroke was $53.6 billion[1]. When a physician can specifically diagnose CHF or stroke at the point-of-care facility, more effective treatment may be administered.

With our acquisition of SynX in 2004, we acquired a pipeline of potential diagnostic products based on detecting proteins associated with CHF, stroke or other conditions. From this pipeline we are developing point-of-care diagnostic tests for highly specific protein markers that play a role in assisting the early diagnosis and monitoring of the diseases. Our technology is moving these tests from the clinical reference lab to near patient settings such as the hospital laboratory or emergency room. Our current products in the point-of-care market include:

Nexus D_x Myocardial Infarction/LifeSign MI® The Nexus D_x Myocardial Infarction (heart failure) product line provides qualitative analytical results. The diagnostic device is a simple to use, rapid one-step immunoassay for the simultaneous qualitative detection of CK-MB, Myoglobin and/or cardiac Troponin I in human whole blood, serum or plasma. The Nexus Dx myocardial infarction test allows for efficient triaging of chest pain patients, while providing accurate diagnostic test results. This product is produced by Princeton Biomeditech (PBM) and is distributed in Canada and Europe.

Nexus D_x we manufacture and sell a Central Nervous System ELISA product line with a unique combination of markers: S-100, NSE (Neuron Specific Enolase), MBP (Myelin Basic Protein) and Tm (Thrombomodulin). These markers have been recognized as helpful in the early assessment of acquired brain injuries (stroke, non inflicted trauma), and inflicted trauma such as Shaken Baby Syndrome.

In addition, SynX is the exclusive Canadian distributor of LifeSign® and Status POC diagnostics produced by Princeton Bio-meditech Corporation (PBM). The extensive PBM product line complements SynX s own point-of-care diagnostic line, Nexus D_x, and includes a broad range of tests for infectious diseases, drugs of abuse, fertility and cardiac markers.

Point-of-care products in the commercialization / launch phase 2005

StatusFirst Congestive Heart Failure The Status First Congestive Heart Failure point-of-care test will give a quantitative reading of NT-proBNP, a marker for CHF. Using the Status First NT-proBNP CHF test in conjunction with a reader in an emergency room or near patient setting will enable physicians to diagnose patients who present with CHF symptoms according to class 1 through IV (NYHA guidelines) and differentiate between heart failure and other disorders in patients who present with shortness of breath. With

[1] American Heart Association. *Heart Disease and Stroke Statistics 2005 Update.* Dallas, Texas.: American Heart Association; 2005. 2005, American Heart Association

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this information the physician can more quickly determine the ideal treatment regimen for a particular patient. The StatusFirst product will provide a 15 minute quantitive test. We will distribute this product in Canada, Europe and several countries in Asia. PMB will distribute in the United States.

DxPress Reader The diagnostic reader is manufactured by an OEM supplier and has been designed to provide quantitative results for lateral flow immunochemistry membrane tests such as NT-proBNP for the diagnosis of CHF. We will distribute the reader in Canada, Europe and several countries in Asia. PBM will distribute the reader in the United States. The DxPress Reader features user-friendly software with easy to read menus. A bar code wand quickly loads in test information, patient and user identification. An on-board printer provides hard copy test and QC results for filing and reporting. The combination of the StatusFirst Congestive Heart Failure test and DxPress diagnostic reader provides a system for placement in near patient settings such as the hospitals emergency room and physician s offices for the triaging and diagnosing patients exhibiting congestive heart failure symptoms.

Our Growth Strategy

We will continue to develop and market advanced diagnostic products that address large and growing markets. We plan to establish our leadership position in the advanced diagnostics arena by leveraging our technologies and knowledge base to identify business opportunities that will allow us to increase our critical mass and accelerate our progress in the marketplace. We will continue to invest in the internal development of new diagnostic products as well as seek to acquire additional entities or product lines which are complementary to our existing product portfolio.

New products expected to contribute significantly to product revenue during 2005 include the NanoChip® 400 and related ASRs for infectious disease and for testing for mutations in the CFTR gene, the StatusFirst congestive heart failure product, and several real-time ASRs. In addition, the Epoch acquisition will contribute significant royalty revenues from existing relationships. Unlike previous years where revenue was derived from a single product family, revenue in 2005 is expected to result from multiple product families and sources in multiple markets.

We have two different approaches to address the molecular diagnostics market. First, we have focused on penetrating the high value, complex testing requirements of the molecular diagnostics market by creating an open platform that can help automate laboratory testing. We continually seek to increase the installed base of the NanoChip® Systems and to establish our platform as the preferred system 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 by our customers and collaborators, driving the growth in assay development far beyond our internal capacities. The NanoChip® System could transform molecular diagnostics by delivering speed, efficiency and accuracy on a robust platform. As this market area grows and our market share increases, the NanoChip® System could generate multiple revenue sources that will fuel next generation systems and revenue growth. Second, we develop and offer single marker ASRs in a real-time format. These products address genetic as well as infectious disease tests and run on instruments sold by other companies. Often times, our clinical laboratory customer already owns the real-time testing instrument needed to run our test. By offering both of these approaches to molecular diagnostics, we can provide the clinical research laboratory or CLIA laboratory with the range of products they need to perform simple to complex genetic and infectious disease tests.

We believe point-of-care products offer a strong growth opportunity. Emergency rooms and urgent care units represent a significant market for rapid point-of-care testing for cardiovascular and neurological conditions. With our recent acquisition of SynX, we plan to obtain European, Canadian and U.S. regulatory clearance for our NT-pro BNP CHF diagnostic product and enter the point-of-care market. Together with our partner, PBM, we plan to launch the CHF product in major markets around the world.

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Products and Applications in Research and Development

Below is a brief description of some of our future products and applications currently in research and development by us or with our collaborators.

Array-based ASRs:

The Next Generation of NanoChip® System

We have developed the second generation of the NanoChip® System, the NanoChip® 400, which is expected to be released in 2005. The second generation system will be more compact, have increased test density, have improved functionality and accuracy and be less costly in order to access a broader market for molecular-based testing. Our scientists will pursue opportunities to 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 NanoChip® 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.

We believe there is potential for our technology in the field of infectious disease diagnostics. Our plan is 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 empirically. 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.

Because a particular infectious episode may be caused by one of many microorganisms or several microorganisms together, multiple tests are required to determine the correct diagnosis. Single analyte (one at a time) DNA probe diagnostic tests, which were first introduced to the marketplace in the mid-1980 s, have been unsuccessful in displacing many 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.

Point-of-care

We are currently developing, and expect to launch in 2005, our Status First Congestive Heart Failure (CHF) point-of-care test which will give a quantitative reading of NT-proBNP, a marker for CHF, a chronic disease that affects millions of patients each year. Using the Status First NT-proBNP CHF test in conjunction with a reader in an emergency room or near-patient setting will enable physicians to diagnose patients presenting with CHF symptoms according to class 1 through IV (NYHA guidelines) and differentiate between heart failure and other disorders in patients who present with shortness of breath. With this information the physician can more quickly determine the ideal treatment regimen for a particular patient. The StatusFirst product will provide a 15 minute test.

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During 2004 we received both a United States and a European patent related to the detection of stroke and the differentiation of stroke types. We are currently developing a product for the diagnosis of stroke with the intent to commercialize it in the future. We believe that the stroke product will address a significant market in the emergency room and urgent care setting.

We are also developing the Nexus D_X Traumatic Brain Injury point-of-care test that measures several protein markers which are released into the blood stream following traumatic brain injury. Currently, there is no reliable biochemical test available for traumatic brain injury. The Nexus D_X Traumatic Brain Injury test results could provide important information to assist clinicians in determining the appropriate management of brain trauma patients.

Biodefense

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

Specific development efforts have included a prototype portable field-based detection device and an integrated micro-laboratory and assay protocol to analyze simulated biowarfare targets. We also developed assays aimed at detection of specific biowarfare agents and infectious diseases and a self-contained portable system capable of performing on-chip non-PCR amplification and detection of potential biowarfare threats. We currently do not anticipate significant additional development work in the area of Biodefense although we continue to evaluate potential government grant projects.

Nanotechnology

Our proprietary nanotechnology and molecular tools may provide a technological foundation for the effective use of nanocomponents in many diverse applications. We currently have nanotechnology patents that were assembled through the pioneering research of Dr. Michael Heller, a founder of Nanogen and currently at the University of California, San Diego. We plan to realize value from our nanotechnology patents through use in biomedical applications or through licensing or partnering opportunities. We have been issued several key nanotechnology patents that relate to the electronic fabrication of micro and nanoscale devices including the following patents that were issued during 2004:

In January 2004 we receive U.S. Patent No. 6,682,936, Addressable Biologic Electrode Array, by the U.S. Patent and Trademark Office. The 936 patent relates to electrode-based array devices and methods of operation in which individual electrodes contained within the array can be selectively addressed or manipulated. The technology enables high-density electrode arrays to be produced and has applications for the hybridization as well as combinatorial synthesis and self-assembly of biological molecules, such as nucleic acids and peptides. The technology also enables the production of smaller and more compact arrays, while at the same time minimizing the utilization of off-chip control circuitry, even for large numbers of electrodes.

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.

In May 2004 we received U.S. Patent No. 6,726,880, Electronic Devices for Performing Active Biological Operations and Method of Using Same, by the U.S. Patent and Trademark Office. The 880 patent relates

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to new devices that enable increased sensitivity of active, programmable electronic matrix (APEX) devices and perform actions such as concentration and assembly of biological materials on a substrate. DNA, RNA, proteins and other biologics can be electronically concentrated at collection electrodes and then re-distributed to reaction or detection electrodes. With alternating manipulation of the collection and reactive electrodes, molecular nanostructures can be assembled for more sensitive detection or used to manufacture molecular structures such as DNA hybrids or Protein/Protein complexes.

In June 2004 we received U.S. Patent No. 6,753,148, Methods and Apparatus for Detecting Variants Utilizing Base Stacking, by the U.S. Patent and Trademark Office. The 148 patent is a continuation of patents issued to us that cover methods and apparatus that are particularly useful for detecting varying lengths of genetic variants. The patent covers the application of base stacking technologies that use specific types of oligonucleotides, both capture and probe oligonucleotides, to bind and discriminate nucleic acid sequences of differing lengths. Historically, variations in nucleic acid sequences had to be detected by using electrophoresis, a tedious and multi-step process, to determine fragment sizes. With this new and novel approach, the nucleic acid sequence variants can be detected by hybridization and be included in DNA/RNA array panels.

Forensics

Short terminal repeats (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 European customers working on forensic applications.

Our research collaborations in the area of forensic applications have allowed us to further develop existing technology and explore new technology. Prior 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 amplification. We do not currently anticipate spending significant additional development resources in the forensics area. However, several of our customers may continue to develop their own applications using our technology.

Pharmacogenomics

Pharmacogenomics is the science of individualizing therapy based on genetic differences among patients. Certain genes have been shown to be required for the breakdown and elimination of drugs in the body (pharmacokinetics). Changes in these genes can result in an inability to process certain kinds of drugs, which can lead to a buildup of toxic chemicals in the body. Other genetic changes can result in extremely rapid breakdown of a drug, limiting the drug s effectiveness. By determining a patient s genetic profile prior to prescribing a drug, a physician can reduce the potential for serious or fatal side effects. We believe that the ability of our technology to screen simultaneously for various changes in a patient s DNA has wide applicability to pharmacogenomics.

Increasingly, pharmaceutical and biotechnology companies are developing therapeutics by targeting specific biological molecules. This approach contrasts traditional pharmaceutical development, in which therapeutics were developed against disease models rather than against specific genetic targets. Changes in the genetic sequence of these target molecules may enable segregation of patient populations into likely responders and non-responders. Such segregation could decrease the cost of clinical trials during drug development, and decrease the likelihood of adverse events once a drug is approved and commercialized. Our NanoChip® System may provide pharmaceutical and biotechnology companies with the ability to identify important genetic variations early in the drug development process, and create companion diagnostic assays that could be used to identify those likely to receive the maximum benefit from treatment.

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Research and Development

As of January 31, 2005, we had 78 full-time and temporary employees in research and development. Our research and development expenses were $18 million in 2004, $18 million in 2003 and $21 million in 2002. These research and development expenses have been directed toward developing innovative new products in areas of significant market opportunity. Most of our research and development has been conducted at our facilities in San Diego CA, Bothell WA, or Toronto, Canada or in collaboration with various partners.

Sales and Marketing

Molecular diagnostic products

We sell our molecular diagnostic products including our microarray platforms, array-based ASRs and real-time ASRs in the United States through our own direct sales force. As of January 31, 2005, our sales force consisted of a staff of approximately 44 sales, marketing and technical support representatives. These representatives principally focus on large CLIA certified laboratories including clinical research laboratories, reference laboratories and public health laboratories. We continually educate our sales representatives on the technical, clinical and economic merits of our products.

We sell custom real-time MGB Eclipse Probe Systems directly to the research market through a specialized direct sales force into the United States. Our MGB Eclipse Online Design and Ordering consists of assay design and order processing software to facilitate delivery of custom assays starting with the submission of a customer s target genetic sequence of interest. MGB Eclipse Online Design and Ordering is also used to identify new potential customers for MGB Eclipse By Design. Products that incorporate our MGB Eclipse Probe Systems for the gene expression market are also sold on a worldwide basis by QIAGEN N.V., who offer their customers custom and catalogue probe systems as part of its QuantiTect Gene Expression Assays product line.

Our sales representatives are able to recommend the appropriate business solution to meet the needs of our customers by presenting multiple technology and instrumentation options. Sales representatives are trained to find new market opportunities, provide diagnostic solutions to address unmet customer needs, and to provide comprehensive after-sale product support. In addition, our field technical support group provides thorough training and ongoing technical support for our products.

All sales to customers outside the United States are made through distributors or agents. We currently have 12 distributors addressing the European and middle-east markets. In the future, we plan to add additional distributors to address the major Asian markets. To support our 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, marketing and technical support office. In December 2004, we terminated our agreement with Transgenomic, Inc. for the distribution of our array-based products in certain European countries. We have since appointed new distribution partners to replace Transgenomic.

We are building our own internal services organization. This field service organization will provide initial installation, on going technical support and warranty and maintenance work as needed.

Point-of-care

All sales to customers for point-of-care products are made through distributors or agents. We currently have distributors addressing 28 European and middle east countries. In the future, we plan to add additional distributors to address the major Asian markets. Nanogen Europe B.V., our wholly-owned subsidiary, operates as our primary European sales, marketing and technical support office for point-of-care customers. In North America, initial distribution of the CHF product will be managed by our partner, PBM. They will develop a

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distribution network that complements their current sales capabilities to access hospital and emergency laboratories. We select distributors based on their prior experience in the point-of-care medical diagnostic device sector and their knowledge of cardiovascular products. We believe each distributor will be responsible for the distribution and marketing of the full range of our point-of-care products.

Collaborations and Strategic Arrangements

We intend to continue to enter into collaborations to expand applications of our technology platforms 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 technologies and resources of our partners with our technologies, while allowing us to pursue diagnostics and other opportunities outside the scope of these collaborations.

We are currently involved in the following corporate collaborations:

Prodesse

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, and atypical pneumonia agents. The collaboration will integrate Prodesse s proprietary multiplex amplification technology with the automated NanoChip® System; we will jointly develop and market gene-based testing products to health care and clinical reference labs.

Hitachi Manufacturing Agreement

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

Pursuant to the agreement, Hitachi, Ltd. has the right to be the sole distributor of NanoChip® Molecular Biology Workstations 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 had been required to provide annual purchase commitments to Hitachi for the first generation NanoChip® Workstations. As of December 31, 2004, the Company had fulfilled its purchase commitments for the first generation NanoChip® Workstations.

In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of the NanoChip® 400, the second generation instrument, which was developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the NanoChip® 400 exclusively for the Company for worldwide distribution. Hitachi has the right to

distribute the NanoChip® 400 in Japan on a royalty bearing basis. The Company is required to meet certain annual purchase commitments for the new instrument. As of December 31, 2004, the Company had a purchase obligation of $590,000 through February 28, 2005.

Hitachi 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

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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. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute cash over the ten-year period toward the research and development efforts of the Company. 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).

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, which is reflected as a $4.9 million long-term obligation in our December 31, 2004 balance sheet. Based on joint discussions, we and Hitachi have determined to focus their joint efforts on the development and manufacture of the NanoChip® 400. We and Hitachi continue to be jointly responsible for development of the NanoChip® 400. Hitachi is responsible for world-wide manufacturing of the instrument. We are responsible for development of assays and for marketing and sales except in Japan.

Princeton Biomeditech (PBM)

SynX Pharma and PBM have a long standing relationship that includes the joint development and marketing of point-of-care tests. Under this arrangement, PBM is responsible for the development and manufacturing of the CHF product including the management of the OEM development of a quantitative reader. SynX Pharma is responsible for the development of reagents and clinical data. PBM will distribute the CHF product and reader in the United States and SynX will distribute the CHF product and reader outside the United States. The parties will divide revenues based on sales levels in the specific geographies. The parties may jointly develop future products.

Government Grants

In 2004, we continued work under a number of biodefense-related technology grants for the United States Government. 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. The first grant for $147,000 is for the development of a 3-D DEP cell/pathogen separation system, and the second grant for $711,000 is for the development of a new isothermal on-chip SDA assay.

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.

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Patents and Proprietary Technology Rights

We consider the protection of our proprietary technologies and products to be important element in the success of our business. As of December 31, 2004, we had 111 issued U.S. patents and numerous foreign patents expiring at varying dates 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 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.

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.

Competition

The medical diagnostics and biotechnology industries are subject to intense competition. Our competitors in the United States and abroad are numerous and include, among others, diagnostic, health care, pharmaceutical and biotechnology companies.

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Many of our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than we do. Moreover, many of our competitors offer broader product lines and have greater brand recognition than we do, and offer price discounts as a competitive tactic. In addition, there can be no assurance that competitors, many of which have made substantial investments in competing technologies, will not prevent, limit or interfere with our ability to make, use or sell our products either in the United States or in international markets.

In the markets for clinical molecular diagnostic products, a number of companies including Roche, ABI, Celera Diagnostics and Third Wave compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. In markets outside of the United States, other factors, including local distribution systems, complex regulatory environments and differing medical philosophies and product preferences, influence competition as well. In the congestive heart failure (CHF) market, for which we plan to begin selling product in 2005, Biosite, Inc. currently has a competitive FDA-approved test. Although we believe that our CHF product will have commercial advantages over the competing test, they may be able to develop technologies that are as effective as, or more effective, or easier to interpret or less expensive than, those offered by us, which would render our product uncompetitive or obsolete.

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 us and our 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

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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. 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.

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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. 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.

Manufacturing and raw materials

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. In June 2003, we entered into another manufacturing agreement with Hitachi for the manufacture of our second generation clinical instrument. Hitachi has exclusive manufacturing rights and distribution rights in Japan. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges.

Pursuant to the manufacturing agreements 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 Workstations and other products 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 revenues from NanoChip® product sales.

We manufacture MGB Eclipse Probe Systems, modified bases, fluorescent dyes, quencher, and chemical intermediate products in our facility in Bothell, Washington. We have registered the facility used for manufacturing our diagnostics products with the United States Food and Drug Administration, or FDA, as a Device Manufacturer and we believe we are in compliance with the FDA s quality system requirements.

Additionally, we use contract manufacturers to synthesize component chemical reagents when appropriate.

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We purchase raw materials essential to our business in the ordinary course of business from numerous suppliers. Substantially all the raw materials used for our commercial manufacturing of oligonucleotides, assay systems and other reagent products are available from multiple sources; however, other raw materials for supply contract and OEM manufacturing are proprietary products of other companies. Raw materials may be rejected if they do not meet manufacturing specifications, are contaminated and/or have other failures. A material shortage, contamination, or failure could adversely impact the commercial manufacturing of our products and related revenues.

Quality Systems

We have implemented modern quality systems and concepts throughout the organization. Our regulatory department supervises our quality systems and is responsible for assuring compliance with all applicable regulations, standards and internal policies. Our senior management team is actively involved in setting quality policies and managing internal regulatory and monitoring external quality performance.

Our regulatory, quality and government affairs department has successfully led us through multiple quality and compliance audits by the FDA, foreign governments and customers.

Geographic Area Financial Information

For financial information concerning the geographic areas in which we operate, see Note 14, Geographic Sales and Significant Customers to the consolidated Financial Statements.

Employees

As of December 31, 2004, we had 202 employees of whom 40 hold Ph.D. degrees and 22 hold other advanced degrees. Approximately 78 are involved in research and development, 48 in operations, manufacturing and quality assurance, 44 in sales and marketing, and 32 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, 2004, 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, various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis, general purpose reagents and accessories to facilitate assay and

protocol development and validation on the NanoChip® Platform and through our acquisition of SynX, point-of-care diagnostic tests for myocardial infarction and drugs of abuse. We announced our second-generation instrument, the NanoChip® 400, in October 2004. This new instrument is expected to begin shipping in 2005. 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.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a NanoChip® System at a customer site with no upfront cost to the customer. The value of

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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, 2004 require customer acceptance of our CFTR ASRs as a pre-condition to the customer s commitment to purchase reagents. 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 products and 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 the years ended December 31 2004, 2003 and 2002 we took accounting charges of approximately $3.7 million, $908,000 and $1.1 million, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those currently 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.

Performance issues with our products may also harm market acceptance of our products and reduce our revenues. During the year ended December 31, 2004, we experienced performance issues with our CFTR ASR which negatively impacted our revenue. Certain of the clinical research laboratories using our CFTR ASR experienced validation rates and repeat rates which were not satisfactory, increasing their costs and labor associated with the tests. We are in the process of making improvements to our CFTR ASR to address these issues. Nonetheless, we may not be able to address these issues to the satisfaction of our clinical laboratory customers and they may decide to adopt alternative products or may not resume purchases of our CFTR ASR.

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

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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.

Our NanoChip® System instruments, including Molecular Biology Workstation and the second-generation NanoChip® 400, are manufactured by Hitachi. As such our success in the micro-array based diagnostics market is largely dependent upon Hitachi s ability to perform under our manufacturing agreement. In October 2001, SynX entered into a development and manufacturing agreement with Princeton BioMeditech Corporation (PBM) which granted PBM exclusive rights to develop and manufacture certain point-of-care products of SynX, as well as rights to share in the profits of such products. As a result, our success in the point-of-care market is dependent upon PBM s ability to perform under the agreement.

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 recently announced our second-generation instrument system. The transition to new products subjects us to risks and uncertainties, including increased risks of excess or obsolete inventory and inventory related write-downs.

In October 2004, we announced our second-generation instrument system, the NanoChip® 400. This new instrument is expected to begin shipping in 2005. Risks inherent in the transition to our second-generation system and other new products we may release in the future include:

- potential delays in initial shipments of new products,
- the possibility that new products may erode demand for our current products, including those under reagent rental agreements, causing a decline in sales of current products and an excessive, obsolete supply of inventory,
- potential delays in customer purchases in anticipation of new product releases or a decision by customers to evaluate new products for longer periods of time before making a purchase,
- uncertainties in product pricing and market acceptance,
- additional costs related to providing customer support and service for both first generation and second generation systems, and
- unexpected technical or operational problems with the new products.

If any of these risks occur, our revenues could decline and our financial condition could be harmed.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to complement our internally developed products. We expect that acquisitions will remain a part of our growth strategy going forward. Acquisitions involve numerous risks, including the following:

The possibility that we will pay more than the value we derive from the acquisition;

Difficulties in integration of the operations, technologies, and products of the acquired companies;

The assumption of certain known and unknown liabilities of the acquired companies;

Difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired company;

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Any of these factors could have a negative impact on our business, results of operations or financing position.

Future acquisitions could also 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. In addition, to the extent that the economic benefits associated with any of our acquisitions diminish in the future, we may be required to record additional write downs of goodwill, intangible assets or other assets associated with such acquisitions, which would adversely affect our operating results.

We may not realize the benefits that we anticipate from our recent acquisitions of Epoch Biosciences, Inc. and SynX Pharma Inc. due to integration and other challenges.

We completed two significant acquisitions in 2004: the acquisition of SynX Pharma Inc. in April 2004 and Epoch Biosciences, Inc. in December 2004. We expect that the SynX product line will accelerate our entry into the point-of-care market and we expect that the acquisition of Epoch will have an immediate effect on our revenues during 2005. However, we cannot be certain that we will achieve these and other benefits which we currently expect from these acquisitions. The process of integrating these acquired companies requires significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Combining our product offerings is a complex and lengthy process involving a number of steps in which we will seek to achieve increasing degrees of integration of our products. Additionally, SynX is located in Canada and Epoch is located in Washington, and because our facilities are physically separated, it may be difficult for us to communicate effectively with, manage and integrate these employees and operations with the rest of the Company. If we are not able to integrate the operations of these acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations.

Factors that will affect the success of these acquisitions and any future acquisitions include:

- our ability to manage a more complex corporate structure that requires additional resources for such responsibilities as tax planning, foreign currency management, financial reporting and risk management;
- our ability to retain key employees of acquired companies; and
- our ability to increase revenues due to the integration of the products and technologies of the acquired companies; and
- our ability to operate efficiently following the completion of acquisitions and to achieve cost savings.

Even if we are able to successfully integrate our acquired operations, we may never realize the anticipated benefits of the SynX and Epoch acquisitions, or any other acquisition. Our failure to achieve these benefits and synergies could have a material adverse effect on our business, results of operations and financial condition.

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, 2004, total approximately $215.2 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. 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 second generation NanoChip® 400 System, acquisitions, and potential other products under development, including the CHF product and diagnostics related to infectious disease, the type of acquisition program our potential customers may choose, whether and when

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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.

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.

Changes in financial accounting standards related to stock option expenses are expected to have a significant effect on our reported results.

The FASB recently issued a revised standard that requires that we record compensation expense in the statement of operations for employee stock options using the fair value method. The adoption of the new standard is expected to have a significant effect on our reported earnings, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to establish the value of stock options. As a result, the adoption of the new standard in the third quarter of fiscal 2005 could negatively affect our stock price and our stock price volatility.

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 can not 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 (QSRs) and obtaining necessary domestic and international regulatory clearances or approvals;
- filing, prosecuting, defending and enforcing patent claims and litigation; and

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

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

Competing technologies may adversely affect us.

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

health care and other companies that manufacture laboratory-based tests and analyzers;

diagnostic and pharmaceutical companies;

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companies developing drug discovery technologies;

companies developing molecular diagnostic tests; and

companies developing point-of-care 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 (FDA) or marketing technologies or products that are more effective or commercially attractive than our current or potential products or that render our technologies and current or potential products obsolete.

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

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

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

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

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

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

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action

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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. One such interference has recently been declared between U.S., Patent 6,461,828 owned by our Canadian subsidiary, SynX, and a patent application owned by Biosite Incorporated (Biosite). The count of the interference is directed to a method for predicting cardiac mortality in a patient using pairs of biological markers. Among the markers within the scope of the count are pro-BNP and troponin I, markers which are the basis of a product being developed by SynX for the prognosis of congestive heart failure. Even though Biosite is the senior party in the interference because of its earlier filing date, we believe that we will be able to prove an earlier date of invention and thus prevail in the interference. However, if Biosite prevails it may obtain a patent having claims corresponding exactly or closely to the count of the interference. If that were to occur, we would be precluded from marketing in the United States a product for predicting cardiac mortality using the markers within the scope of any claim obtained by Biosite. We may in the future become subject to other 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 (Oxford Gene). 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 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 pursuant to which the lawsuit was dismissed by Oxford Gene 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 or maintaining required approvals for the commercialization of our products.

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

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

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

the loss of previously received approvals or clearances;

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

failure to comply with existing or future regulatory requirements.

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

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

recall or seizure of products;

total or partial suspension of production; and

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

The FDA also has the authority to request the recall, repair, replacement or refund of the cost of any regulated device that may eventually be manufactured or distributed by us. Any devices manufactured or distributed by us pursuant to FDA clearance or approvals are subject to thorough and continuing regulation by the FDA and certain state agencies, including the California Department of Health Services.

Our dependence on suppliers for materials could impair our ability to manufacture our products.

Outside vendors provide key components and raw materials used by us, Hitachi and PBM 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, Hitachi or PBM or incompatible with our, Hitachi or PBM s manufacturing processes, could harm our, Hitachi or PBM s ability to manufacture our products. We, Hitachi or PBM 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, Hitachi or PBM fail to obtain a supplier for the manufacture of components of our products, we may be forced to curtail or cease operations.

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

Hitachi manufactures our NanoChip® System, including the second-generation NanoChip® 400, we manufacture our NanoChip® Cartridges, our ASRs and most of our other products, and PBM manufactures our

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point-of-care products. We, Hitachi and PBM 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, Hitachi or PBM either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We, Hitachi or PBM 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, Hitachi or PBM 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 PBM 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, PBM 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, one manufacturer for our point-of-care 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 second generation NanoChip® 400 workstations and other hardware products to be developed. We have 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.

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The number of our sales and marketing employees may not result in corresponding numbers of sales or placements of the NanoChip® System, the sale of ASRs, point-of-care diagnostic products or other products

As of December 31, 2004, we had 44 total employees in our worldwide sales and marketing group.

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, point-of-care diagnostic products or other products. We may be required to increase or decrease the size of the 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;
- additional costs resulting from deploying the NanoChip® System, including the second-generation NanoChip® 400, ASRs, point-of-care diagnostics, and other products in foreign countries due to ;
- licenses, tariffs and other trade barriers;
- political and economic instability, including the war on terrorism;
- difficulties in staffing and managing foreign offices;
- costs and difficulties in establishing and maintaining foreign distribution partnerships;

potentially adverse tax consequences; and

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

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

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

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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 years ended December 31, 2004, 2003 and 2002 we experienced turnover rates of 27%, 25% and 29%, 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 of 2003. Also, in October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately $290,000 during the fourth quarter of 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.

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.

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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 diagnostic testing in general;
- evidence of the safety or efficacy of our potential products or the products of our competitors;
- the announcement by us or our competitors of technological innovations or new products;
- the announcement by us of acquisitions by customers of our NanoChip® System, ASRs or our other products;
- announcements by us of government grants or contracts or of failure to obtain such government grants or contracts;
- announcements by us of involvement in litigation;
- developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;
- loss of key board, executive, management or other personnel or the increase or decrease in size of our sales and marketing staff;
- governmental regulatory actions or the failure to gain necessary clearances or approvals;
- the ability to obtain necessary licenses;

changes or announcements in reimbursement policies;

developments with our subsidiaries and collaborators;

changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;

period-to-period fluctuations in sales, inventories and our operating results;

market conditions for life science stocks, nanotechnology stocks and other stocks in general;

purchases by us 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;

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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.

Investor confidence and share value may be adversely impacted if our independent auditors are unable to provide us with the attestation of the adequacy of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the Securities and Exchange Commission adopted rules requiring public companies to include a report of management on our internal controls over financial reporting in our annual reports on Form 10-K that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must attest to and report on management s assessment of the effectiveness of our internal controls over financial reporting. This requirement first applies to this Annual Report on Form 10-K. How companies are implementing these new requirements including internal control reforms, if any, to comply with Section 404 s requirements, and how independent auditors are applying these new requirements and testing companies internal controls, remain subject to uncertainty. The requirements of Section 404 of the Sarbanes-Oxley Act of 2002 are ongoing and also apply to future years. We expect that our internal controls will continue to evolve as our business activities change. Although we will continue to diligently and vigorously review our internal controls over financial reporting in order to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. If, during any year, our independent auditors are not satisfied with our internal controls over financial reporting or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management s assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares.

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.

Our business is subject to changing regulation of corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board, the SEC and Nasdaq, have recently issued new requirements and regulations and continue to develop additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002 (SOX). Our efforts to comply with these new regulations have resulted in, and are likely to

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continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

We will be dependent upon our agreement with Applied Biosystems for a significant portion of our revenues for 2005 and future periods, and a reduction of sales under or early termination of this agreement would seriously harm our revenues and operating results and would likely cause our stock price to decline

In January 1999, Epoch and Applied Biosystems entered into a License and Supply Agreement pursuant to which we licensed some of our technology to Applied Biosystems for use in its TaqMan® 5 - nuclease real-time PCR assays, (TaqMan® is a registered trademark of Roche Molecular Systems, Inc.). In July 1999, Epoch licensed its proprietary software, which speeds the design of oligonucleotide probes used in the study of genes, to Applied Biosystems. In August 2000, the agreement was amended to, among other things, provide for Epoch manufacturing product for Applied Biosystems. In July 2002 this agreement was further amended to remove the manufacturing rights from the contract effective October 2002, redefine product categories, increase the minimum royalties and royalty rates, and establish that minimum royalties are measured and paid quarterly. We will depend upon product sales and royalties from Applied Biosystems sales of its TaqMan® assays under this agreement for a significant portion of our revenues in 2005 and future periods.

The technology licenses and Applied Biosystem s obligation to pay us royalties on their sale of products that incorporate Epoch s technologies continue until the expiration of the underlying patents. Since the July 2002 amendment that increased the minimum royalty levels, quarterly royalties earned based on actual sales by Applied Biosystems have been less than the contractual minimum royalty levels. As a result, the royalty payments have been in the amount of the specified quarterly minimum level. The current agreement calls for quarterly royalty minimums through the third quarter 2005. Thereafter, we will receive royalty payments based on actual sales.

Either party may terminate the agreement upon 180 days written notice. In the event that this agreement is terminated, our revenues, financial condition and operating results would be adversely affected and our stock price would likely decline.

Item 2. Properties

At December 31, 2004, 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		30,000	

	Bothell, Washington		Research and development, sales and marketing and manufacturing for a term ending in 2012.
1	Toronto, Canada	50,000	Administrative offices, research and development, and sales and marketing for a term ending in 2012.
1	Helmond, Netherlands	2,600	Administrative offices and sales and marketing.

Our leases expire at varying dates through 2012 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

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Diego, Bothell and Helmond facilities is substantially being utilized. We have excess capacity in our Toronto facility, and have therefore sublet a portion of the facility to help offset the facility cost. In the future, we may need to purchase, build or lease additional facilities to meet the requirements projected in our long-term business plan.

Item 3. Legal Proceedings

In December 2002, Oxford Gene Technologies (OGT) filed a complaint against 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

Our stockholders voted on the following matters at the Special Meeting of Stockholders on December 15, 2004 (which was postponed from an original date of December 8, 2004):

	FOR	AGAINST	ABSTAIN
To approve the issuance of shares of our common stock pursuant to the Agreement and Plan of Merger and Reorganization, dated as of September 7, 2004, by and among Nanogen, Empire Acquisition Corp., a wholly owned subsidiary of Nanogen, and Epoch Biosciences, Inc.	17,847,052	542,401	191,266
To amend our certificate of incorporation to increase the authorized shares of Nanogen common stock from 50,000,000 to 135,000,000.	17,361,797	1,1001,972	216,950

PART II

Item 5. Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

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, 2003:	High	Low
1st Quarter	$ 1.78	$ 1.00
2nd Quarter	$ 4.98	$ 1.16
3rd Quarter	$ 4.82	$ 2.60
4th Quarter	$ 10.29	$ 2.95

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Year ended December 31, 2004:	High	Low
1st Quarter	$ 13.20	$ 6.60
2nd Quarter	$ 9.54	$ 5.39
3rd Quarter	$ 7.25	$ 3.18
4th Quarter	$ 7.86	$ 3.82

As of March 1, 2005 there were approximately 324 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.

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,				
	2004[1]	2003	2002	2001	2000
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales	$ 2,690	$ 2,762	$ 3,384	$ 2,245	$ 919
License fees	490	84	10,844		
Sponsored research	500	1,500	1,355	7,457	8,457
Contract and grant	1,694	2,367	1,596	1,467	1,856
Total revenues	5,374	6,713	17,179	11,169	11,232
Costs and expenses:					
Cost of product sales	5,642	3,176	2,466	1,606	599
Research and development	18,117	18,014	21,020	18,597	18,905
Selling, general and administrative	18,232	15,319	20,375	28,932	15,267
Charge for acquired in-process research and development	3,758				
Impairment of acquired in-process technology rights		1,024			
Total costs and expenses	45,749	37,533	43,861	49,135	34,771
Loss from operations	(40,375)	(30,820)	(26,682)	(37,966)	(23,539)
Interest income, net	517	489	2,119	4,390	5,257
Other income (loss)	(221)	(141)	(15)	30	
Warrant valuation adjustment	(74)				
Gain (loss) on sale of investments	(47)	(1,925)	197	116	
Gain (loss) on foreign currency translation	1,293	(16)	(21)	22	
Minority interest in loss of consolidated subsidiary		1,817	2,156	907	
Net loss	$ (38,907)	$ (30,596)	$ (22,246)	$ (32,501)	$ (18,282)
Net loss per share basic and diluted	$ (1.21)	$ (1.38)	$ (1.02)	$ (1.54)	$ (0.92)

Number of shares used in computing net loss per share basic and diluted	32,203	22,244	21,722	21,091	19,944
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 51,934	$ 29,114	$ 52,729	$ 67,524	$ 95,089
Working capital	44,999	30,872	53,050	71,516	92,700
Total assets	176,024	43,849	71,360	90,091	111,168
Other long-term liabilities and debt obligations, less current portion	6,065	5,005	4,219	3,430	2,065
Accumulated deficit	(215,162)	(176,255)	(145,659)	(123,413)	(90,912)
Total stockholders equity	$ 157,516	$ 32,823	$ 57,393	$ 74,929	$ 101,414

(1) 2004 includes the results of operations of SynX and Epoch as of April 21, 2004 and December 16, 2004, respectively, the date of acquisitions, which affects comparability of the Selected Financial Data.

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

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. These risks and uncertainties include those included herein under the caption Factors That May Affect Results in Item 1. Business. We assume no obligation to update any forward-looking statements. The audited financial statements and this Management s Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the Consolidated Financial Statements and Notes thereto for the years ended December 31, 2004, 2003 and 2002 in this Annual Report on Form 10-K.

Overview

Nanogen, Inc. is headquartered in San Diego, California and was founded on the vision of providing higher quality of healthcare by introducing advanced diagnostic medical products that will improve the quality of information in a shorter period of time to our customers in the research, clinical laboratory or point-of-care markets. We intend to turn this vision into reality by continuing to develop new diagnostic products or by acquiring other companies and complementary products that will expand and accelerate our entry into rapidly growing diagnostic markets. We expanded both our product lines and addressable markets during the past year with the acquisition of SynX Pharma in April 2004 and the acquisition of Epoch Biosciences in December 2004. These combinations will accelerate our entry into the point-of-care market and deepen our penetration of the research and clinical laboratory markets, respectively. The combination of internally developed products plus acquired products addressing large markets should provide the stimulus for significant revenue acceleration in 2005 and beyond.

We have historically generated revenues through contract research, grants and licenses and through commercializing molecular diagnostic research tools, such as the Molecular Biology Workstation and related Analyte Specific Reagents (ASRs) for the genetic and clinical research market. In November 2004 we introduced our second generation molecular diagnostic instrument, the NanoChip 400. This platform is expected to ship in 2005 and is designed to serve the clinical laboratory market by offering faster throughput and simpler operating procedures. The new system offers a 400-site cartridge utilizing Nanogen s unique and patented micro-array technology that will allow customers the flexibility to adjust panels from single-to-multiple arrays to fit their requirements. Since commencing operations in 1993, we have applied substantially all of our resources to our research and development programs on the technology associated with our NanoChip® System. With the acquisition of SynX, in 2004, we began investing in research and development related to future point-of-care products. We have incurred losses since inception and, as of December 31, 2004, had an accumulated deficit of $215.2 million.

We have focused on the advanced diagnostics market by commercializing products that enhance, bring cost saving and value to our laboratory testing customers. In 2004, we generated $5.4 million in revenues with a net loss of $38.9 million. Of this revenue approximately $2.3 million was associated with product sales that consist of the sale and rental of our NanoChip® systems and associated consumables to the worldwide molecular diagnostic research market. We sell our products to our customers FOB shipping, and in the case of the NanoChip® system we offer our products under various commercial arrangements, some of which transfer title of the instrument to the customer and some of which do not transfer title to the customer. An additional $353,000 of product sale revenue was generated from our recent acquisitions, which resulted in sales of various molecular chemistries, reagent products and point-of-care diagnostic tests. The remainder of our revenue was through

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various contractual research agreements such as license fees of our patented technologies, sponsored research through our Hitachi development agreement (terminated in 2004) and contracts and grants revenue with governmental or commercial organizations. Revenues for the years ended December 31, 2004 and 2003 were as follows (dollars in thousands):

	2004	2003	Year over year growth or (decline)	Year over year growth or (decline) as a %
Product sales	$ 2,690	$ 2,762	$ (72)	(2.6)%
License fee and royalty income	490	84	406	483.3%
Sponsored research	500	1,500	(1,000)	(66.7)%
Contracts and grants	1,694	2,367	(673)	(28.4)%
Total	$ 5,374	$ 6,713	$ (1,339)	(19.9)%

Product sales: Developments

We have focused on creating product sales revenue through internally developed products as well as through acquisitions. We initially entered the molecular diagnostics market by selling our first generation NanoChip® System, the Molecular Biology Workstation, into the research market with a goal of becoming the industry s preferred platform for molecular testing. We recognized prior to launching our first generation NanoChip® System in 2000, that sales to the research market alone would not produce sufficient revenue to support our goals. As a result, we have been working to enhance the initial product to enter the clinical laboratory market, and ultimately expect to address the point-of-care market with a micro-array product in the future. During 2003 we launched seven ASRs, that can be used by clinical laboratories to assist them in developing diagnostic tests that can be run on our system. Additionally, in 2005 we expect to launch a second generation system, the NanoChip 400, that should help broaden our reach into the clinical market place. This new system is smaller, is expected to be easier to operate by laboratory personnel and its level of automation does not required continuous monitoring by a technician during production testing. We also plan to expand our ASR products for the NanoChip 400 during 2005.

Through the acquisition of Epoch, we also provide real-time ASR products to clincial laboratories for simpler, lower cost tests than those addressed by our NanoChip® System, thus expanding the product portfolio available to our customers. We also believe that Epoch will provide additional revenue through providing custom products and services to research customers.

Finally, we have been working on products that will allow us to begin addressing point-of-care customer needs. Specifically, through the acquisition of SynX, we obtained the Nexus D_x Myocardial Infarction (heart failure) product line and are preparing to launch our StatusFirst product for congestive heart failure in 2005.

We also believe that Epoch will provide us additional revenue through the chemistry, design, and synthesis of DNA probes and optimization of real-time PCR assays for our molecular diagnostic customers. In addition to the acquisitions we believe we will generate additional revenue when we launch our second generation of the NanoChip® System in mid-2005 that is targeted at both the research and diagnostic markets with such products as our infectious disease diagnostics systems.

License fee and royalty income: Developments

While we currently own 111 issued U.S. patents we have strategically limited the licensing of much of this technology to protect our intellectual property position in all areas of our business including the NanoChip® System, real-time products and point-of-care markers. We are now evaluating our intellectual property position in light of our recent acquisitions. We may choose to license our technology in the future, if we believe the terms and conditions are acceptable given our investment into the research and development and its

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relationship to our future product pipeline. In addition, with our acquisition of Epoch we obtained a royalty agreement with Applied Biosystems, Inc. with contractual minimum royalties through the third quarter of 2005 and thereafter we will receive royalty payments based on actual sales.

Sponsored research: Developments

In July 2000 we executed a ten-year agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute potential products based on the parties proprietary technologies. The agreement provides that we work together to jointly determine which projects to prioritize over the term of the agreement. Both Hitachi and we may contribute cash toward our research and development over a ten-year period. At a minimum, we were required to match the Hitachi contribution to our research and development on an annual basis. In addition, we are required to repay to Hitachi 50% of their contributions to research and development over an indefinite period of time. The repayment amount is determined as a percentage of our gross NanoChip® Cartridge sales until the liability is paid in full.

In August 2003, we 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 did not accelerate the repayment due Hitachi. From inception of the collaboration agreement with Hitachi through December 31, 2004, we have received a total of $9.8 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. We recognized the last $500,000 in revenue from Hitachi in 2004 and do not expect any revenue from this agreement in the future.

Contracts and grants: Developments

We fund some of our research and development efforts through contracts and grants awarded by various federal and state agencies. Revenue is recognized under these contracts and grants as expenses are incurred. We do not believe these grants will be our primary source of on-going revenue but provide us additional revenue while offsetting our research and development costs. We will continue to seek new contracts and grants that are aligned with our internal research and development goals. In 2004, we entered into no new contract and grants; however, we continued to receive revenue from the following on-going grants.

U.S. Army Medical Research Acquisition Activity

In October 2000, we entered into a cooperative agreement with the U.S. Army Medical Research Acquisition Activity (USAMRAA) in an amount totaling approximately $1.1 million over a 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, we 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 our funds. We recognized revenue under these agreements of $466,000, $1,093,000, and $688,000 for the years ended December 31, 2004, 2003, and 2002, respectively. These agreements were completed in this year and do not expect any additional funding.

The National Institute of Justice

In April 1997, we entered into an agreement with The National Institute of Justice, U.S. Department of Justice, which provides funding for the development of a chip based genetic detector for rapid DNA-based identification of individuals in an amount totaling approximately $4.4 million over a 9-year period. We recognized revenue under this agreement of $747,000, $979,000, and $232,000, for the years ended December 31, 2004, 2003, and 2002, respectively.

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National Institutes of Health (NIH)

The National Institute of Allergy and Infectious Diseases for the National Institutes of Health (NIH), provides funding for several grants. In July 2002, we were awarded a grant which focused on the development of a compact centrifugal micro fluidics based biological warfare agent (BWA) analyzer. In May and September of 2003, we were 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 BWA detection. The awards under these grants totaled approximately $1.0 million over a 4-year period. We recognized revenue under these agreements of $415,000, $188,000 and $25,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

Acquisitions: Developments

We actively and selectively seek to acquire companies with complementary products and strong intellectual property positions to allow us to penetrate emerging markets. We anticipate using our common stock as the primary currency to purchase future companies or product lines. In 2004, we acquired in all stock transactions, SynX and Epoch to obtain new product lines for the point-of-care and advanced diagnostic markets, respectively. We believe that these acquisitions are important to our long-term strategy and are an example of our ongoing efforts to build a stronger company with products to serve the advanced diagnostic marketplace.

Acquisition of SynX Pharma Inc.

On April 21, 2004, we acquired all the outstanding common stock of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests. As a result of this acquisition, we have entered the point-of-care diagnostic market. We believe that the future markets for advanced diagnostics will include research and clinical reference labs as well as the point-of-care market.

Acquisition of Epoch Biosciences, Inc.

On December 16, 2004, we acquired all the outstanding common stock of Epoch Biosciences, Inc. (Epoch). Based in Bothell, Washington, Epoch develops and sells proprietary products with commercial applications in the genomics and molecular diagnostics fields. As a result of the acquisition, we expect to broaden our product offerings to research institutions and clinical reference labs and further leverage our existing sales, marketing infrastructure and expand our customer reach.

Sale of Common Stock: Developments

In March 2004, we sold 4.25 million shares of our common stock to institutional investors at a price of $7.94 per share, for gross proceeds of approximately $33.7 million. In April 2004, we sold an additional 900,000 shares to institutional investors at a price of $8.60 per share for gross proceeds of approximately $7.7 million. After deducting fees and expenses, we received approximately $39.4 million from the sales. We believe that it is beneficial to maintain a significant amount of cash and short-term investments on hand to ensure we have adequate resources to fund

future research and development, to create and expand sales distribution channels, to support future acquisitions, to provide working capital and assuage legal risks and challenges to our business model.

Critical Accounting Policies and Estimates

Our discussion and analysis of our results of operations and liquidity and capital resources are based on our consolidated financial statements which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and

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judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, valuation of inventory, intangible assets and investments, income taxes, and litigation. We base our estimates on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. By their nature, estimates are subject to an inherent degree of uncertainty. Actual results that differ from our estimates could have a significant adverse effect on our operating results and financial position. We believe that the following significant accounting policies and assumptions may involve a higher degree of judgment and complexity than others.

Revenue Recognition

We have historically derived revenue principally from sales agreements and reagent rental/cost per test agreements of the NanoChip® Molecular Workstation and related consumables, chemical, reagent products, molecular diagnostic products, from royalties for our intellectual property, sponsored research, contract and grant agreements and from license fees for intellectual property. The timing of revenue recognition and the amount of revenue actually recognized in each case depends upon a variety of factors, including the specific terms of each arrangement and the nature of our deliverables and obligations. Determination of the appropriate amount of revenue recognized involves judgments and estimates that we believe are reasonable, but it is possible that actual results may differ from our estimates.

Valuation of Intangible Assets and Investments

Our business acquisitions typically result in goodwill and other intangible assets, and the recorded values of those assets may become impaired in the future. As of December 31, 2004, our goodwill and intangible assets, net of accumulated amortization was approximately $108 million. The determination of the value of such intangible assets requires management to make estimates and assumptions that affect our consolidated financial statements. We assess potential impairments to intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recovered. Our judgments regarding the existence of impairment indicators and future cash flows related to intangible assets are based on operational performance of our acquired businesses, market conditions and other factors. Although there are inherent uncertainties in this assessment process, the estimates and assumptions we use are consistent with our internal planning. If these estimates or their related assumptions change in the future, we may be required to record an impairment charge on all or a portion of our goodwill and intangible assets. Furthermore, we cannot predict the occurrence of future impairment-triggering events nor the impact such events might have on our reported asset values. Future events could cause us to conclude that impairment indicators exist and that goodwill or other intangible assets associated with our acquired businesses is impaired. Any resulting impairment loss could have an adverse impact on our results of operations.

Inventory

We estimate and evaluate obsolescence or non-marketability of our inventory and reduce the carrying value of our inventory to the lower of cost or market by considering future purchase commitments based upon assumptions about future demand and market conditions. In 2004, we took accounting charges of $3.7 million to reduce our inventory to its estimated net realizable value. Theses charges primarily related to our first generation micro-array instrument, the Molecular Biology Workstation. As of December 31, 2004, the net carrying value of our first generation instrument was $210,000, which we expect to be realizable in 2005. If actual future demand or market conditions are less favorable than those projected by us, either generation of our micro-array instrument, or any other component of our inventory, additional inventory write-downs may be required.

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Income Taxes

We regularly review our established valuation allowance against our potential tax assets that is based on historical taxable income, projected future taxable income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies. As of December 31, 2004, our valuation allowance was $123.5 million.

Results of Operations

Years ended December 31, 2004, 2003 and 2002

Revenues

The following table summarizes our revenues for the years ended December 31, 2004, 2003 and 2002:

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
	(in thousands)			(in thousands)		
Product sales	$ 2,690	$ 2,762	$ (72)	$ 2,762	$ 3,384	$ (622)
License fee and royalty income	490	84	406	84	10,844	(10,760)
Sponsored research	500	1,500	(1,000)	1,500	1,355	145
Contracts and grants	1,694	2,367	(673)	2,367	1,596	771
Total	$ 5,374	$ 6,713	$ (1,339)	$ 6,713	$ 17,179	$ (10,466)

Product Sales

With our acquisitions of SynX and Epoch we have expanded our sources of product sales revenue from the NanoChip® System and associated consumables to include real-time reagent products and molecular diagnostic point-of-care products. In 2004, we had approximately $2.3 million from the direct sale and reagent rental/cost per cartridges of the NanoChip® System and $353,000 of revenue associated with chemical, regent products and molecular diagnostic point-of-care products.

The downward trend in product sales revenue relates to the decreased sales of our first generation NanoChip® System. This is partially due to the limited size of the molecular research market. In 2003, we began to address the much larger clinical diagnostic lab market; however, as the first generation of our product was designed for research applications and not diagnostic use, the clinical diagnostic customer s acceptance of our initial product has been limited. Our revenue was negatively impacted when we announced in the fourth quarter of 2004 our second-generation molecular diagnostic system, which was designed specifically to meet the needs of the clinical diagnostic user, would be available in 2005. We

believe that potential future diagnostic customers may be waiting for the next generation of our NanoChip® System, the NanoChip® 400.

The future: We expect to continue to generate revenue from the NanoChip® System and associated consumables in the research market and are expanding into the molecular diagnostic and point-of-care markets. A core element of this expansion strategy included the mergers with the point-of-care and molecular diagnostic companies, SynX and Epoch, respectively, to provide us revenue growth in 2005. We believe SynX will allow us to penetrate the point-of-care market and provide us with additional revenue in 2005 through a new product for the diagnosis of congestive heart failure which is scheduled to begin shipping in 2005. The SynX congestive heart failure product is expected to provide a 15 minute test result and it will be offered with a point-of-care quantitative reader. We also believe that Epoch will provide additional revenues through the sale of real-time ASRs to clinical laboratories and the sale of custom products and services to research customers. In addition to revenue from acquisitions, we believe we will generate additional revenue when we release in the NanoChip® 400 in 2005. The NanoChip® 400 is targeted at both the research and clinical laboratory markets. We also plan to offer ASRs including those for use in detection of respiratory viruses or for detection in the CFTR gene associated with Cystic Fibrosis.

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License fees include nonrefundable fees generated from the licensing of our technology with third parties. License fees increased in 2004 from 2003 primarily due to contractual minimum royalties from CombiMatrix. In addition, in 2002 the $10.8 million was a result of a litigation settlement with CombiMatrix (see Note 5 of Notes to Consolidated Financial Statements). The amount recorded in 2002 was based on the fair value of the CombiMatrix shares received in the settlement.

The future: We are now focusing on evaluating our intellectual property in light of our recent acquisitions and anticipate having additional licensing opportunities of our intellectual property. Through our acquisition of Epoch we obtained a royalty bearing licensing agreement with Applied Biosystems, Inc. for the TaqMan® 5 -nuclease real-time PCR assays with contractual minimums through the third quarter 2005 and thereafter we will receive royalty payments based on actual sales. We expect license fee revenue to significantly increase as a result of including a full year of revenue under Epoch s royalty agreement for the TaqMan® 5 -nuclease real-time PCR assays.

Sponsored research revenue is nonrefundable money generated through the development agreement with Hitachi (see Note 11 to the Consolidated Financial Statements). The decrease in sponsored research revenue directly relates to the termination of the Hitachi collaborative research agreement in August 2003. Funding through this agreement was completed in the second quarter of 2004.

The future: With the termination of our sponsored research agreement with Hitachi completed in the second quarter of 2004 we do not expect any revenue from Hitachi in 2005 or thereafter. We may enter into additional sponsored research projects in the future.

Contracts and grants revenue is nonrefundable payments by various federal and state agencies for our research and development efforts awarded through contracts and grants. Contracts and grants revenue is recorded as the costs and expenses to perform the research are incurred, if the amount is reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Under certain arrangements where funding is provided for contractually on a scheduled basis, revenue is recorded ratably over the term of the arrangement. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. The decrease in contract and grant revenue in 2004 as compared to 2003 is a result of the completion of certain contracts and grants. No new contracts or grants were entered into during 2004 to replace those that were completed.

The future: The recognition of revenue under contracts and grants may vary from quarter to quarter and may result in significant fluctuations in operating results from year to year depending on the timing and quantity of agreements and contracts. In the future, we expect contract and grant revenue to become a decreasing portion of our overall revenues. We expect the majority of our revenue growth to be generated through an increase in product revenue.

Cost and expenses

Cost of product sales:

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
	(in thousands)			(in thousands)		
Cost of product sales	$ 5,642	$ 3,176	$ 2,466	$ 3,176	$ 2,466	$ 710

Cost of product sales includes the material, manufacturing labor, overhead costs and inventory impairment charges related to the cost of manufacturing our products. In 2003 and 2002 all of our manufacturing costs related to the manufacturing of our NanoChip® System and the associated consumables. In 2004, approximately $5.5 million of our manufacturing costs relates to the cost of manufacturing the NanoChip® System and associated consumables. The NanoChip® System s gross margin has on a per unit basis remained low relative to our sales price, as our volume of production relative to the available capacity has remained low. Included in the cost of product sales in 2004, 2003 and 2002 were charges of $3.7 million,

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$908,000 and $1.1 million respectively, relating to underutilized capacity, excess instrumentation inventory and obsolete components. The increase in charges in 2004 related to a large inventory build up that stemmed from purchase commitments from Hitachi for the first generation of the NanoChip® System. Gross margins during 2004 and 2003 were also impacted by sales to certain customers under discount programs and by discounted sales to distributors. In 2004, we incurred approximately $164,000 of manufacturing costs for the products we acquired with the acquisition of SynX and Epoch.

The future. As we are still in the early stages of commercialization of our product lines, we are still developing our models for accurately predicting the cost of our second generation of the NanoChip® System, point-of-care testing and the single analytic real time PCR-products. We currently believe that point-of-care testing and the single analytic real time PCR products will positively effect our gross margins. We use outside vendors to manufacture our point-of-care Nexus D_x Myocardial Infarction product line, and our StatusFirst congestive heart failure line. We expect to continue to incur significant costs associated with excess production capacity within our manufacturing facility in 2005 as we transition from the first to second generation NanoChip® System. Because we are anticipating a significantly lower sale price per unit of our second generation NanoChip® System our cost of manufacturing will greatly depend on the number of units sold or rented to absorb our excess capacity and therefore lower the overhead and labor costs. Gross margins in future periods may additionally be impaired by minimum product royalties or potential adjustments made to reflect the impairment of inventory or intangible assets related to products sold.

Research and development expenses:

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
	(in thousands)			(in thousands)		
Research and development	$ 18,117	$ 18,014	$ 103	$ 18,014	$ 21,020	$ (3,006)

Research and development expenses include the associated 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. In 2003 and 2002 our research and development primarily focused on the NanoChip® System and the associated consumables. In 2004, with our acquisition of SynX, we added research and development related to point-of-care diagnostic systems as well as continued our research and development efforts on the second generation of the NanoChip® System and associated consumables. In 2004, research and development expenses related to our NanoChip® System and associated consumables remained consistent with 2003. The increase in research and development expenses related to our acquisitions of SynX and Epoch were offset by a general reduction in historical expense levels as well as a decision in 2004 to wind down all operations at Nanogen Recognomics GmbH. Of the total 2004 research and development expenses, approximately $3.6 million is the result of our entry into the point-of-care market through the acquisition of SynX in April 2004. Research and development expenses in 2004 from the acquisition of Epoch were not significant.

The future. We expect our research and development expenditures to increase modestly from 2004 levels. The increase is primarily the result of including a full year of research and development from our recent acquisitions of Epoch and SynX, partly offset by reduced expenditures from our Nanogen Recognomics subsidiary which ceased operations in 2004. In addition, 2004 included a $3.8 million one-time charge to write-off in-process research and development acquired from SynX.

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Selling, general and administrative expenses:

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
	(in thousands)			(in thousands)		
Selling, general and administrative	$ 18,232	$ 15,319	$ 2,913	$ 15,319	$ 20,375	$ (5,056)

Selling, general and administrative expenses include sales and marketing personnel, tradeshows, promotional activities and materials, administrative personnel, legal, other professional expenses and general corporate expenses. The increase in expenses in 2004 as compared to 2003 primarily relates to $1.8 million in additional expenditures related to operating expenses related to the acquisition of SynX, which had not been consolidated until April 21, 2004 (the date of acquisition), approximately $450,000 related to the costs of Sarbanes-Oxley Act compliance and a $467,000 non-cash charge related to a modification to extend the exercise period from 90 days to 180 days for vested options relating to a separation agreement with the Company s then President and Chief Operating Officer. In addition, 2004 included $164,000 in operating expenses of Epoch beginning December 16, 2004 (the date of acquisition). The decrease in expenses in 2003 as compared to 2002 is primarily the result of a headcount reduction in April 2003 as well as other cost savings initiatives.

The future. We expect that our selling, general and administrative expenditures on a percentage basis will trend lower than the increases in our revenue. We expect to incur integration costs, and ongoing operational costs related to the acquisitions of Epoch and SynX for a full year in 2005, rather than only a portion of the year as occurred in 2004. On a consolidated basis, however, we expect to achieve significant synergies and savings by consolidating many of the general and administrative functions. The savings from consolidation of general and administrative activities are expected to be offset by increased sales and marketing expenses required to support the various new product launches expected in 2005. Expenses may also be further impacted by potential future business combinations or corporate development transactions.

Charges for acquired in-process research and development & impairment for acquired technology:

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
	(in thousands)			(in thousands)		
Charge for acquired in-process research and development	$ 3,758	$	$ 3,758	$	$	$
Impairment for acquired technology rights	$	$ 1,024	$ (1,024)	$ 1,024	$	$ 1,024

We incurred a non-cash charge of $3.8 million related to the write-off of acquired in-process research and development or IPR&D, related to the SynX acquisition in 2004. The amount expended for IPR&D represents the estimated fair value of purchased in-process technology for projects that, as of the acquisition date, had not reached technological feasibility and had no alternative future use.

The future. We do not expect to incur any additional charges for acquired in-process research and development related to the SynX or Epoch acquisitions. However, if we acquire other companies in the future, we may incur additional material in-process research and development charges.

The impairment of acquired technology rights relates to the difference between two of our license agreements assets carrying values and their estimated fair values. In 2003, we decided to restructure certain license agreements and it resulted in a $1.0 million impairment expense.

The future. As of December 31, 2004, we have approximately $11.8 million in net book value remaining associated with acquired technology rights related to in-licensing of various technologies. We regularly review these assets for impairment and it is possible that additional impairment charges may be necessary in future periods.

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Other income

The following table summarizes our other income for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	Year ended December 31,			Year ended December 31,		
	2004	2003	Difference	2003	2002	Difference
Interest income, net	$ 517	$ 489	$ 28	$ 489	$ 2,119	$ (1,630)
Other expense	(221)	(141)	(80)	(141)	(15)	(126)
Warrant valuation adjustment	(74)		(74)			
Gain (loss) on sale of investments	(47)	(1,925)	1,878	(1,925)	197	(2,122)
Gain (loss) on foreign currency translation	1,293	(16)	1,309	(16)	(21)	5
Minority interest in loss of consolidated subsidiary		1,817	(1,817)	1,817	2,156	(339)
Total other income	$ 1,468	$ 224	$ 1,244	$ 224	$ 4,436	$ (4,212)

Interest income, net

Interest income primarily relates to the interest we receive on our cash, cash equivalents, and short-term investments. Our interest income slightly increased in 2004 as a result of the financing we secured during 2004 and the resulting higher balances of cash and investment balances during the year. The $1.6 million decrease in 2003 as compared to 2002 was a result of lower average cash and investment balances as well as lower yields on outstanding cash and investment balances.

Warrant expense

Warrant expense relates to our acquisition of Epoch in 2004 where we assumed warrants convertible into 381,317 shares of our common stock that contain a cash redemption feature which may be triggered under certain conditions. We accounted for the fair value of these warrants in our purchase accounting, with a portion of the value assigned to the cash redemption liability, and the remaining portion recorded as additional paid-in capital. We are required to revalue the cash redemption liability related to these warrants quarterly using the Black-Scholes valuation model with the changes in value accrued in the balance sheet and the associated non-cash income or expense recorded in the income statement.

Gain (loss) on the sale of investments

The gain (loss) on the sale of investments in 2004 and 2002 primarily relate to the normal sales of our short-term investments for operating capital. In 2003, however, when we sold 4,016,346 shares of CombiMatrix stock, obtained through a settlement agreement, we realized a loss on the sale of short-term investments of $1.9 million.

Gain on Foreign Currency Translation

Gain on foreign currency translation in 2004 primarily relates to the February 2004 decision to reorganize and discontinue all business activities of our majority owned subsidiary, Nanogen Recognomics GmbH. In accordance with Statement of Financial Accounting Standards No. 52, Foreign Currency Translation, and its related interpretations, when the business activity at this entity was discontinued we were required recognize a gain of $1.2 million related to previously unrealized gains from foreign currency translation.

Minority interest in loss of consolidated subsidiary

Minority interest in loss of consolidated subsidiary related to our majority-owned subsidiary, Nanogen Recognomics GmbH that was funded by an initial $5 million investment from a minority interest investor. Through 2003, we accounted for the minority interest in the subsidiary s expenditures in the cost and

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expenses section of the income statement. To record the offset against the minority interest recorded in our balance sheet we recorded a gain in the other income section in the income statement. The net effect of these entries was to reflect actual expenditures in the cost and expense section of our income statement while recognizing the contribution of the minority investor as a gain in the other income section of the income statement. Therefore, the effect on our net loss was eliminated. In 2003, when the minority interest investors funds were expended we recorded the expenditures in our cost and expense section of the income statement. Therefore, in 2004 the minority interest in loss of consolidated subsidiary was $0.

Liquidity and capital resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures for the years ended December 31, 2004, 2003 and 2002 (in thousands):

	December 31, 2004	December 31, 2003	December 31, 2002
Cash and cash equivalents	$ 15,372	$ 8,550	$ 9,353
Short-term investments, available for sale	36,562	20,564	43,376
Total cash and cash equivalents and short-term investment, available for sale	$ 51,934	$ 29,114	$ 52,729
Current assets	$ 57,442	$ 36,893	$ 60,981
Current liabilities	(12,443)	(6,021)	(7,931)
Working capital	$ 44,999	$ 30,872	$ 53,050

We believe that existing funds and existing sources of and access to financing are adequate to satisfy our working capital, capital expenditures and debt service requirements at least through December 31, 2005. However, to provide greater flexibility, additional liquidity, ability to complete strategic mergers and acquisition and commercialize our products in development we anticipate raising additional funds through the sale of our common stock and/or the issuance of debt.

From inception to December 31, 2004, we have financed our operations primarily by:

Issuing our stock

Generating revenues

Using proceeds from our litigation settlement with CombiMatrix

Obtaining a modest amount of capital equipment long-term financing

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash.

We invest excess funds in short-term investments that are classified as available for sale. We believe that it is important to maintain a significant amount of cash and short-term investments on hand to ensure that we have adequate resources to fund future research and development, provide working capital and assuage legal risks and challenges to our business model.

We expect that our existing capital resources, combined with anticipated product revenues, license fees and contract and grant funding, will be sufficient to support our planned operations, through at least the next twelve months. However, this estimate is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. Our future liquidity and capital funding requirements for 2005 will depend on numerous factors including, but not limited to: potential business combinations, potential corporate development transactions, commercial success of our products, or lack thereof, the extent to which our products under

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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.

Cash provided by (used in) operating, investing and financing activities of the years ended December 31, 2004, 2003 and 2002 is as follows (in thousands):

	December 31, 2004	December 31, 2003	December 31, 2002
Net cash used in operating activities	$ (29,495)	$ (25,456)	$ (28,431)
Net cash (used in) provided by investing activities	(13,791)	15,442	26,525
Net cash provided by financing activities	$ 49,971	$ 8,932	$ 353

Operating activities

Net cash used in operating activities for the years ended December 31, 2004, 2003, 2002 primarily related to our adjusted net losses, changes in working capital due to the product shipments and payments in liabilities. The net cash used 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 costs associated with patent litigation. The decline in cash used in operating activities in 2003 as compared to 2002 was primarily due to a reduction in force that was implemented in April 2003. The increase in 2004 as compared to 2003 is primarily the result of including the operations of SynX beginning April 21, 2004 and Epoch beginning on December 16, 2004, the respective dates of acquisition and an increase in our net loss.

Investing activities

Net cash used in investing activities in 2004 related to reinvesting the cash we realized from our common stock sales into purchasing available-for-sale short-term investments. Net cash provided by investing activities in 2003 and 2002 related to net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we utilized short-term investments to fund our operating and financing activities).

In 2004, we issued 15.1 million shares of common stock for the acquisition of SynX and Epoch and received $3.5 million in cash, net of acquisition expenses.

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore, in 2004, 2003 and 2002 we used cash to purchase $800,000, $1.2 million and $135,000 in property and equipment to support the development of our product lines.

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Financing activities

Net cash provided by equity financing activities in 2004 related to:

- The issuance of 5.1 million common stock shares in two registered direct placements for net proceeds of $39.4 million,
- The issuance of 1.1 million common stock shares, related to the exercise of warrants issued in the 2003 private placement, for net proceeds of $4.4 million, and
- Proceeds from the exercise of stock options of approximately $6.3 million.

Net cash provided by equity financing activities in 2003 related to:

- The issuance of 2.1 million common stock shares and warrants in a private placement for net proceeds of approximately $6.5 million, and
- Issuance of 696,000 common stock shares for $1.9 million.

Under our development agreement with Hitachi we received $556,000, $1.3 million and $1.4 million in 2004, 2003 and 2002, respectively. We received our last payment under this agreement in 2004. In addition, we received $486,000 and $222,000 in 2004 and 2002, respectively, in equipment financing. As of December 31, 2004 we did not have any available funding under financing lines.

Net cash provided by financing activities was offset by payments related to our debt obligations of $846,000, $774,000 and $1.5 million in 2004, 2003 and 2002, respectively, and the acquisition of treasury stock in 2003 and 2002.

We have no significant contractual obligations not fully recorded on our Consolidated Balance Sheets or fully disclosed in the Notes to our Condensed Consolidated Financial Statements. We have no off-balance sheet arrangements as defined in S-K 303(a)(4)(ii).

At December 31, 2004, our outstanding contractual obligations included (in thousands):

	Payments Due by Period				
Contractual Obligations & Other Commitments	**Total**	**Less Than 1 year**	**1 2 years**	**3 5 years**	**Thereafter**

Debt obligations	$ 1,598	$ 988	$ 610	$	$
Other long term liabilities (a)	4,857				4,857
Operating leases	19,236	2,658	2,799	8,897	4,882
Purchase commitments (b)	590	590			
Standby letters of credit (c)	1,411				1,411
Total contractual obligations & other commitments	$ 27,692	$ 4,236	$ 3,409	$ 8,897	$ 11,150

(a) In connection with the agreement entered into with Hitachi in July 2000 and since terminated in 2003, 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. 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, we have classified the entire balance of this liability as long-term. This liability is non-interest bearing and survives the termination of the agreement in 2003. We have received a total of approximately $9.8 million since July 2000 under this arrangement, of which approximately $4.9 million is reflected as a long-term liability.

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(b) Our manufacturing agreement with Hitachi, Ltd. (Hitachi) requires that we provide annual purchase commitments to Hitachi for our next generation NanoChip® workstations, the NanoChip® 400. As of December 31, 2004, we had commitments to purchase approximately $590,000 of NanoChip® 400 workstations through February 28, 2005. Future purchase commitments will be determined based on product demand and inventory levels.

(c) 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.

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

Future Accounting Requirements

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment , which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123R). SFAS 123R supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS 95, Statement of Cash Flows. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We expect to adopt SFAS 123R on July 1, 2005.

As permitted by SFAS 123, we currently accounts for share-based payments to employees using Opinion 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123R s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the assumptions for the variables which impact the computation. However, had we adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share elsewhere in Note 2 to our consolidated financial statements. We cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options).

Net operating loss carryforwards

As of December 31, 2004, we had federal, state and foreign net operating loss, or NOL, carryforwards of approximately $231.3 million, $70.1 million and $26.2 million, respectively, and $8.0 million and $4.4 million of research and development 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 2005, unless previously utilized, and the state tax loss carryforwards will continue to expire in 2005, 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. In 2004, we acquired SynX s and Epoch s NOLs. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the our net operating losses and credit carryforwards may be limited due to cumulative changes in ownership of more than 50% over a 3-year period. We may be subject to similar limitations on its Canadian losses acquired from SynX. We have not performed a formal analysis to quantify the amount of possible limitations. Currently the net operating losses reflected above have not been reduced by potential limitations, however, a full valuation allowance has been placed on all deferred tax assets and, therefore, there is no material impact on our financial statements. Similar

limitations may also apply to utilization

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of R&D tax credits to offset taxes payable. However, such limitations may have a material impact on our ability to utilize the NOLs. See Note 10 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. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments. Recent downgrading of issuers of such securities we believe, have had no material impact on our investment portfolio.

The functional currency for our Canadian and Netherlands subsidiaries is the U.S. dollar. The functional currency of our majority owned subsidiary in Germany is the euro. 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, 2004.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements as of December 31, 2004 and 2003 and for the three years in the period ended December 31, 2004 and the Report of Ernst and Young LLP, Independent Registered Public Accounting Firm, are included in this Annual Report on Form 10-K on pages F-1 through F-33.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

Based on our evaluation during the most recent quarter, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) were effective as of December 31, 2004 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal controls over financial reporting during the fourth quarter ended December 31, 2004 that have materially affected or are reasonably likely to materially affect our internal control over financial reporting.

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Management s Report on Internal Control over Financial Reporting

MANAGEMENT STATEMENT

RESPONSIBILITY FOR PREPARATION OF THE FINANCIAL STATEMENTS AND ESTABLISHING AND MAINTAINING ADEQUATE INTERNAL CONTROL OVER FINANCIAL REPORTING

We are responsible for the preparation of the financial statements included in this Annual Report. The financial statements were prepared in accordance with accounting principles generally accepted in the United States of America and include amounts that are based on the best estimates and judgments of management. The other financial information contained in this Annual Report is consistent with the financial statements.

Our internal control system is designed to provide reasonable assurance concerning the reliability of the financial data used in the preparation of Nanogen s financial statements, as well as to safeguard the Company s assets from unauthorized use or disposition.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement presentation.

REPORT OF MANAGEMENT ON NANOGEN, INC. S INTERNAL CONTROL OVER FINANCIAL REPORTING

We are also responsible for establishing and maintaining adequate internal control over financial reporting. We conducted an evaluation of the effectiveness of the Company s internal control over financial reporting as of December 31, 2004. In making this evaluation, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. Our evaluation included reviewing the documentation of our controls, evaluating the design effectiveness of our controls and testing their operating effectiveness. Our evaluation did not include assessing the effectiveness of internal control over financial reporting at our recently acquired SynX and Epoch subsidiaries, which are included in the 2004 consolidated financial statements of the Company and constituted: $19.5 million and $14.3 million of total and net assets, respectively, as of December 31, 2004 and: $590,000 and $5.4 million of total revenues and net loss, respectively, for the year then ended. We did not assess the effectiveness of internal control over financial reporting at these newly acquired entities due to the insufficient time between the dates acquired and year-end and the complexity associated with assessing internal controls during integration efforts, thus making the process impractical. Based on this evaluation we believe that, as of December 31, 2004, the Company s internal controls over financial reporting were effective.

Ernst and Young LLP, an independent registered public accounting firm, has issued their report on our evaluation of Nanogen s internal control over financial reporting. Their report appears on page 49 of this Annual Report.

Date: March 15, 2005

/s/ HOWARD BIRNDORF
Howard Birndorf
Chairman and Chief Executive Officer

Date: March 15, 2005

/s/ ROBERT SALTMARSH
Robert Saltmarsh
Chief Financial Officer

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Report of Independent Registered Public Accounting Firm on Internal Controls over Financial Reporting

To the Shareholders and the

Board of Directors of Nanogen, Inc.

We have audited management s assessment, included in the accompanying Report of Management on Nanogen s Internal Control over Financial Reporting, that Nanogen, Inc. (the Company) maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment about the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management s assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As indicated in the accompanying Report of Management on Nanogen s Internal Control over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of SynX Pharma, Inc. and Epoch Biosciences, Inc. which were acquired in 2004 and are included in the 2004 consolidated financial statements of the Company and constituted: $19.5 million and $14.3 million of total and net assets, respectively, as of December 31, 2004 and $590,000 and $5.4 million of revenues and net loss, respectively, for the year then ended. Management did not assess the effectiveness of internal control over financial reporting at these newly acquired entities due to insufficient time between the dates acquired and year-end and the complexity associated with assessing internal controls during integration efforts, thus making the process impractical. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of SynX Pharma, Inc. and Epoch Biosciences, Inc.

In our opinion, management s assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the COSO criteria.

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Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of the Company as of December 31, 2004 and 2003 and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004, and our report dated March 14, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California

March 14, 2005

Item 9B. Other Information

None.

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, 2005 (the Proxy Statement).

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 .

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(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

Schedule II Valuation and Qualifying Accounts

For the Years Ended December 31, 2004, 2003 and 2002

(in thousands)

	Balance at Beginning of Period	Acquired in acquisitions	Additions (charges to expenses)	Deductions	Balance at end of year
Allowance for doubtful accounts					
Year ended December 31, 2004	$ 105	$ 53	$ 239	$ (221)	$ 176
Year ended December 31, 2003	41		100	(36)	105
Year ended December 31, 2002	$ 199	$	$ 200	$ (358)	$ 41
Inventory reserve for obsolescence					
Year ended December 31, 2004	$ 2,483	$	$ 3,746	$ (369)	$ 5,860
Year ended December 31, 2003	2,258		908	(683)	2,483
Year ended December 31, 2002	$ 1,500	$	$ 1,101	$ (343)	$ 2,258

(3) Exhibits

Exhibit Index

Exhibit Number	Description of Document

2.1***(20)***	Plan of Arrangement between Nanogen, Inc. and SynX Pharma Inc. dated February 9, 2004.
2.2***(19)***	Agreement and Plan of Merger and Reorganization dated September 7, 2004, by and among Nanogen, Inc., Empire Acquisition Corp. and Epoch Biosciences.
3.1***(3)***	Restated Certificate of Incorporation. (3.(i)1)
3.2***(17)***	Certificate of Amendment to Restated Certificate of Incorporation.
3.3***(3)***	Certificate of Designations, as filed with the Delaware Secretary of State on November 23, 1998. (3.(ii)2)
3.4***(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***(21)(A)***	Amended and Restated 1997 Stock Incentive Plan of Nanogen, Inc. (1997 Plan).
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***(21)(A)***	Amended and Restated Nanogen, Inc. Employee Stock Purchase Plan. (99.2)
10.5***(13)(A)***	Nanogen, Inc. 2002 Stock Bonus Plan.

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Exhibit Number	Description of Document
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***(18)***	Warrant to Purchase Common Stock between Registrant and Aventis Pharma Deutchland, GmbH, dated June 6, 2003. (10.10)
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***(18)(A)***	Separation Agreement between Registrant and Ira Marks, dated August 15, 2003. (10.25)
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.
10.30***(18)(A)***	Separation Agreement between Registrant and Gerard A. Wills, dated as of May 21, 2003. (10.30)

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Exhibit Number	Description of Document
10.31***(22)(A)***	Employment Agreement between Registrant and David Ludvigson dated April 30, 2004. (10.1)
10.32***(23)(A)***	Employment Agreement between Registrant and Dr. William L. Respess dated January 28, 2004. (10.42)
10.33***(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.
10.34***(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).
10.35***(9)(+)***	Contribution Agreement among Aventis R&T, Registrant and Nanogen Recognomics, dated June 27, 2001. (10.4).
10.36***(11)(+)***	Settlement Agreement between Motorola, Inc., Genometrix, Inc., the Massachusetts Institute of Technology and Registrant, dated July 20, 2001. (10.6)
10.37***(14)***	Settlement Agreement between CombiMatrix Corporation, Dr. Donald Montgomery, Acacia Research Corporation and Registrant, dated September 30, 2002.
10.38***(4)***	Master Loan and Security Agreement between Registrant and Transamerica Business Credit Corporation, dated June 14, 1999.
10.39***(22)(+)***	Cross License Agreement on NT-pro BNP dated July 17, 2003 between SynX Pharma Inc. and Roche Diagnostics GmbH. (10.2)
10.40***(22)(+)***	Development and Manufacturing Agreement dated October 9, 2001 between SynX Pharma Inc. and Princeton BioMeditec Corporation. (10.3)
10.41***(24)***	SynX Pharma Inc. Stock Option Plan.
10.42***(24)***	Form of Stock Option Agreement (SynX Stock Option Plan).
10.43***(25)***	Epoch Biosciences 2003 Stock Incentive Plan.
10.44***(25)***	Epoch Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan 1991.
10.45***(25)***	Epoch Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan 1993.
10.46	Form of Stock Option Agreement Epoch Biosciences 2003 Stock Incentive Plan.
10.47***(25)***	Form of Stock Option Agreement Epoch Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan 1991.
10.48***(25)***	Form of Stock Option Agreement Epoch Pharmaceuticals, Inc. Incentive Stock Option, Nonqualified Stock Option and Restricted Stock Purchase Plan 1993.
10.49***(++)***	Second Amended and Restated Collaboration, License and Supply Agreement Between Epoch and Applera Corporation (formerly PE Corporation) dated August 17, 2000.
10.50***(++)***	First Side Agreement dated October 31, 2001 by and between Epoch and Applera Corporation (formerly PE Corporation).
10.51***(++)***	Amendment No. 1 to Second Amended and Restated Collaboration, License and Supply Agreement between Epoch and Applera Corporation (formerly PE Corporation) dated July 26, 2002.
14.1***(15)***	Nanogen, Inc. Ethics Policy. (99.2)
21.1	List of Subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
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.

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Exhibit Number	Description of Document
32.1	Certifications of Chief Executive Officer Required by Rule 13a-14(b) of 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.

(1) Incorporated by reference to Registrant s Registration Statement on Form S-1 (File No. 333-42791). Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(2) Incorporated by reference to Exhibit 4.2 to the Registrant s Registration Statement on Form 8-A, filed on November 24, 1998.
(3) Incorporated by reference to Registrant s Annual Report on Form 10-K for the year ended December 31, 1998. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(4) Incorporated by reference to Exhibit 10.38 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 1999.
(5) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
(6) Incorporated by reference to the Registrant s Form S-8 filed on June 15, 2000. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(7) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2000. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(8) Incorporated by reference to Exhibit 10.1 to the Registrant s Form 8-K filed on December 12, 2000.
(9) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(10) Incorporated by reference to Exhibit 10.1 to the Registrant s Form S-8 filed on June 20, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(11) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2001. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(12) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2002. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(13) Incorporated by reference to Exhibit 10.1 to the Registrant s Form S-8 filed on August 16, 2002.
(14) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 31, 2002.
(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.
(17) Incorporated by reference to Exhibit 3.1 to the Registrant s Form 8-K filed on December 21, 2004.
(18) Incorporated by reference to the Registrant s Form 10-K for the year ended December 31, 2003. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
(19) Incorporated by reference to Exhibit 2.1 of the Registrant s Form 8-K filed on September 8, 2004.
(20) Incorporated by reference to Exhibit 2.1 of the Registrant s Form 8-K filed on May 6, 2004.

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(21) Incorporated by reference to the Registrant s Form S-8 (File No. 333-116605) filed June 18, 2004. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.

(22) Incorporated by reference to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.

(23) Incorporated by reference to Exhibit 10.42 of the Registrant s Form S-4 (File No. 333-119558) filed on October 6, 2004.

(24) Incorporated by reference to Registrant s Registration Statement on Form S-8 (File No. 333-115629), filed on May 19, 2004.

(25) Incorporated by reference to Registrant s Registration Statement on Form S-8 (File No. 333-121508) filed on December 21, 2004.

(A) Indicates management compensatory plan or arrangement.

(+) Confidential treatment has been granted for certain information contained in this document pursuant to an order of the Securities and Exchange Commission. Such information has been omitted and filed separately with the Securities and Exchange Commission.

(++) Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.

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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 15, 2005

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 15, 2005
/s/ ROBERT SALTMARSH Robert Saltmarsh	Chief Financial Officer (Principal Financial and Accounting Officer)	March 15, 2005
/s/ VAL BUONAIUTO Val Buonaiuto	Director	March 15, 2005
/s/ DAVID SCHREIBER David Schreiber	Director	March 15, 2005
/s/ STELIOS B. PAPADOPOULOS Stelios B. Papadopoulos	Director	March 15, 2005
/s/ ROBERT E. WHALEN Robert E. Whalen	Director	March 15, 2005

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NANOGEN, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the

Board of Directors of Nanogen Corporation

We have audited the accompanying consolidated balance sheets of Nanogen, Inc., as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15(a)(2). These consolidated financial statements and the financial statement schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (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, 2004 and 2003 and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2004, in conformity with United States generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Nanogen Inc. s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2005 expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California

March 14, 2005

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NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	As of December 31,	
	2004	**2003**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,372	$ 8,550
Short-term investments	36,562	20,564
Receivables, net of allowance for doubtful accounts of $176 and $105 in 2004 and 2003, respectively	2,023	1,415
Inventories, net	1,744	4,774
Other current assets	1,741	1,590
Total current assets	57,442	36,893
Property and equipment, net	8,500	4,276
Acquired technology rights, net	11,819	2,508
Restricted cash	1,411	14
Other assets, net	780	158
Goodwill	96,072	
Total assets	$ 176,024	$ 43,849
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 9,923	$ 4,809
Deferred revenue	420	469
Common stock warrants	1,112	
Current portion of debt obligations	988	743
Total current liabilities	12,443	6,021
Debt obligations, less current portion	610	586
Other long-term liabilities	5,455	4,419
Total long-term liabilities	6,065	5,005
Commitments and contingencies		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2004 and 2003; no shares issued and outstanding at December 31, 2004 and 2003		
Common stock, $0.001 par value, 135,000,000 and 50,000,000 shares authorized at December 31, 2004 and 2003, respectively; 47,765,581 and 24,867,325 shares issued and outstanding at December 31, 2004 and 2003, respectively	48	25
Additional paid-in capital	374,910	209,014
Accumulated other comprehensive income (loss)	(174)	1,136
Deferred compensation	(1,184)	(175)
Accumulated deficit	(215,162)	(176,255)
Treasury stock, at cost, 500,189 shares at December 31, 2004 and 2003, respectively	(922)	(922)

Total stockholders equity	157,516	32,823
Total liabilities and stockholders equity	$ 176,024	$ 43,849

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share data)

	For the Years Ended December 31,		
	2004	**2003**	**2002**
Revenues:			
Product sales	$ 2,690	$ 2,762	$ 3,384
License fees and royalty income	490	84	10,844
Sponsored research	500	1,500	1,355
Contracts and grants	1,694	2,367	1,596
Total revenues	5,374	6,713	17,179
Costs and expenses:			
Cost of product sales	5,642	3,176	2,466
Research and development	18,117	18,014	21,020
Selling, general and administrative	18,232	15,319	20,375
Charge for acquired in-process research and development	3,758		
Impairment of acquired technology rights		1,024	
Total costs and expenses	45,749	37,533	43,861
Loss from operations	(40,375)	(30,820)	(26,682)
Other income (expense):			
Interest income, net	517	489	2,119
Other expense	(221)	(141)	(15)
Warrant valuation adjustment	(74)		
Gain (loss) on sale of investments	(47)	(1,925)	197
Gain (loss) on foreign currency translation	1,293	(16)	(21)
Minority interest in loss of consolidated subsidiary		1,817	2,156
Total other income	1,468	224	4,436
Net loss	$ (38,907)	$ (30,596)	$ (22,246)
Net loss per share basic and diluted	$ (1.21)	$ (1.38)	$ (1.02)
Number of shares used in computing net loss per share basic and diluted	32,203	22,244	21,722

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY

(in thousands)

	Common Stock		Additional Paid-in	Treasury Stock		Accumulated Other		Notes Receivable		Total
	Shares	Amount	Capital	Shares	Amount	Comprehensive Income (Loss)	Deferred Compensation	From Officers	Accumulated Deficit	Stockholders Equity
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				(27)	(47)					(47)
Acquisition of common stock from officer				(340)	(663)			529		(134)
Issuance of common stock in connection with defined contribution 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	(367)	(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				(133)	(212)					(212)
Issuance of common stock in connection with defined contribution 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	(500)	$ (922)	$ 1,136	$ (175)	$	$ (176,255)	$ 32,823
Components of comprehensive loss:										
Net loss									(38,907)	(38,907)
Unrealized loss on short-term investments						(154)				(154)
Cumulative currency translation adjustment						(1,156)				(1,156)
Total comprehensive loss										(40,217)
Issuance of common stock for acquisitions	15,064	15	115,278				(964)			114,329
Issuance of common stock in a direct placement, net of expenses	5,150	5	39,405							39,410
Issuance of common stock in a private placement, net of expenses	1,103	1	4,394							4,395
Issuance of common stock for a net warrant exercise	32									
Issuance of common stock to Board	17		100							100
Issuance of common stock in connection with defined contribution plan	110		244				6			250
Issuance of common stock, subject to repurchase	121									
Proceeds from the exercise of options	1,302	2	5,867							5,869
Stock-based compensation			470							470
Options issued to consultants			138				(51)			87
Balance at December 31, 2004	47,766	$ 48	$ 374,910	(500)	$ (922)	$ (174)	$ (1,184)	$	$ (215,162)	$ 157,516

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	For the Years Ended December 31,		
	2004	**2003**	**2002**
Operating activities:			
Net loss	$ (38,907)	$ (30,596)	$ (22,246)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	4,377	4,453	4,088
Inventory impairment charges	3,746	908	424
Charge for acquired in-process research and development	3,758		
Other asset impairment and non-cash charges		121	28
Loss on disposal of fixed assets	43	171	
Accretion related to short-term investments	301	216	99
Foreign currency translation (loss) gain	(1,293)	16	21
Stock-based compensation expense	645	333	68
Minority interest in loss of consolidated subsidiary		(1,817)	(2,156)
Realized loss (gain) on sale of short-term investments	47	1,925	(197)
Warrant valuation adjustment	74		
Interest capitalized on notes receivable from officers			(58)
Common stock received for upfront licensing fees			(10,844)
Increase (decreases) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions:			
Receivables	1,264	339	2,626
Inventories	(748)	(474)	(1,440)
Other current and long-term assets	269	177	581
Accounts payable and accrued liabilities	(3,022)	(1,225)	625
Deferred revenue and other long-term liabilities	(49)	(3)	(50)
Net cash used in operating activities	(29,495)	(25,456)	(28,431)
Investing activities:			
Purchase of short-term investments	(64,683)	(25,276)	(16,661)
Proceeds from sale and maturities of short-term investments	48,183	41,891	44,205
Acquisition of businesses, net of cash acquired	3,509		
Purchase of equipment	(800)	(1,170)	(135)
Purchase of patent and technology rights		(3)	(884)
Net cash (used in) provided by investing activities	(13,791)	15,442	26,525
Financing activities:			
Principal payments on capital lease obligations	(846)	(774)	(1,471)
Proceeds from development partner	556	1,325	1,371
Proceeds (payments) from restricted cash balances	(78)	51	235
Issuance of common stock, net	49,853	8,330	177
Proceeds from long-term obligations	486		222
Payments to acquire treasury stock			(181)
Net cash provided by financing activities	49,971	8,932	353

Effect of exchange rate changes	137	279	451
Net increase (decrease) in cash and cash equivalents	6,822	(803)	(1,102)
Cash and cash equivalents at beginning of year	8,550	9,353	10,455
Cash and cash equivalents at end of year	$ 15,372	$ 8,550	$ 9,353
Supplemental disclosure of cash flow information:			
Interest paid	$ 97	$ 156	$ 220
Supplemental schedule of noncash investing and financing activities:			
Inventory transferred to fixed assets	$ 633	$ 541	$ 1,411
Unrealized (loss) gain on short-term investments	$ (154)	$ (3,217)	$ 2,909

See accompanying notes.

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NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2004

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 s vision is to create an advanced diagnostic company with products aimed at the clinical research and point-of-care market places.

Basis of Consolidation

The accompanying consolidated financial statements include the accounts of: Nanogen, Inc.; its wholly-owned subsidiaries: SynX Pharma Inc. (SynX), Epoch Biosciences, Inc. (Epoch), Nanogen Europe B.V. and Nanotronics, Inc.; as well as its majority-owned subsidiary, Nanogen Recognomics GmbH (collectively, the Company). SynX and Epoch s accounts and operating results are included from the date of acquisition which was April 21, 2004 for SynX and December 16, 2004 for Epoch. Both acquisitions were accounted for using the purchase method of accounting and all significant intercompany transactions have been eliminated in consolidation.

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 $9.828 per share. The value of this warrant, as determined by the Black-Scholes valuation model, was $1.2 million, and was fully amortized to research and development expense by December 31, 2003. In 2003, pursuant to the joint venture agreement, the Company issued a second warrant to Aventis to purchase 323,850 shares of the Company s common stock exercisable through June 2008 at $5.618 per share. The value of this accrued warrant, as determined by the Black-Scholes valuation model, was $700,000 and was fully amortized to research and development expense by December 31, 2003.

The consolidated financial statements include all of the assets and liabilities of Nanogen Recognomics. As of December 31, 2003, the ownership interest of minority participant, Aventis Inc, which was equal to their cash contribution of $5.0 million and had historically been recorded as Minority interest in consolidated subsidiary, had been depleted. During 2004 all of the operating loss of Nanogen Recogomics were included in the Company s net loss.

The Company adopted the revised interpretation of Financial Accounting Standards Board (FASB) Interpretation No. 46, Consolidation of Variable Interest Entities, (FIN 46-R). FIN 46-R requires that certain variable interest entities be consolidated by the primary beneficiary of the entity if the equity investors in the entity do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. The Company does not have any investments in entities it believes are variable interest entities for which the Company is primary beneficiary.

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2. Summary of Significant Accounting Policies

Financial Statement Preparation

The preparation of the 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 and the disclosure of contingent amounts in the Company s financial statements and the accompanying notes. Actual results could differ from those estimates. Certain prior year amounts have been reclassified to conform to the current year presentation.

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

The Company invests excess cash in highly liquid debt instruments of financial institutions and corporations with strong credit ratings and in United States government obligations. The Company has established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

The Company has evaluated its investments in accordance with the provisions of SFAS No. 115, Accounting for Certain Investments in Debt and Equity Securities. Based on such evaluation, the Company s management has determined that all of its investment securities are properly classified as available-for-sale. Based on the Company s intent, investment policies and its ability to liquidate debt securities, the Company classifies such short-term investment securities within current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses reported as a separate component of Stockholders Equity under the caption Accumulated other comprehensive income. The amortized cost basis of debt securities is periodically adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included as a component of interest income. The amortized cost basis of securities sold is based on the specific identification method and all such realized gains and losses are recorded net as a component within Gain (loss) on the sale of short-term investments in the statement of operations.

Management reviews the carrying values of the Company s investments and writes down such investments to estimated fair value by a charge to operations when in management s determination, the decline in value of an investment is considered to be other than temporary.

Fair Value of Financial Instruments

The carrying amounts of the Company s cash and cash equivalents, receivables and accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these balances. Our marketable securities available-for-sale are carried at fair value based on quoted market prices. The carrying amounts of the Company s short-term and long-term debt obligations approximate fair value as the rates of interest for these instruments approximate market rates of interest currently available to the Company for similar instruments.

Receivables

Receivables 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.

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Restricted Cash

The Company has restricted cash representing long-term certificates of deposit pledged under a security agreement in lieu of cash deposit, on facilities subject to an operating lease and is reflected as restricted cash in the accompanying consolidated balance sheet and had a balance of approximately $1.4 million and $14,000 at December 31, 2004 and 2003, respectively.

Inventories

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

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets using the straight-line method. Amortization of leasehold improvements is computed on the straight-line method over the shorter of the lease term or the estimated useful lives of the assets. Maintenance and repairs are charged to operations as incurred. When assets are sold, or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and any gain or loss is included in operations.

Acquired Technology Rights

Acquired technology rights are recorded at cost and include identifiable intangible assets acquired in business combinations. Once commercialization of a technology begins, the related cost of the acquired technology rights are amortized into cost of sales over the estimated useful life, generally three to ten years.

Intangible Assets and Goodwill

In accordance with SFAS No. 142, Goodwill and Other Intangible Assets, the Company does not amortize goodwill and intangible assets with indefinite useful lives. The Company amortizes identifiable intangible assets over the estimated useful lives of the assets. Goodwill associated with the acquisitions of SynX and Epoch represents the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets when accounted for using the purchase method of accounting. Goodwill is not amortized, but rather subject to periodic review for impairment. SFAS No. 142 requires that these assets be reviewed for impairment at least annually and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. The Company performs its annual goodwill impairment tests during the fourth quarter of its fiscal year and more frequently if an event or circumstance indicates that impairment has occurred. If the assets were considered to be impaired, the impairment charge would be the amount by which the carrying value of the assets exceeds the fair value of the assets.

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 (excluding goodwill and indefinite 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, as of December 31, 2004, the Company believes the future cash flows to be received from the long-lived assets will exceed the assets carrying value. The Company s evaluations for impairment during the years ended December 31, 2004 and 2002 determined that no impairment of long-lived assets existed. During the year ended December 31, 2003, the Company recognized impairment losses related to acquired technology licenses totaling $1.0 million.

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Common Stock Warrant Liability

As a result of our acquisition of Epoch, the Company assumed certain warrants representing 381,317 shares of our common stock with an exercise price of $8.32 per share and an expiration in early 2009. These warrants contain a provision whereby, under certain circumstances pertaining to a change of control of the Company, the warrant holders have the right to redeem their warrant for cash equal to the estimated fair value of the warrant at such time using the Black Scholes method to calculate the fair value. The volatility factor to be used in this calculation, is limited to the lesser of 50% or the Company s actual historical volatility. As a result, and in accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock, the fair value of the cash redemption portion of the warrants, measured in accordance with the terms of the warrant agreements, is recorded as a current liability on our balance sheet. The increase in the market price of our common stock and other changes in the valuation assumptions from the closing of the acquisition on December 16, 2004 to December 31, 2004 resulted in an increase in the value of the warrants between these dates of $74,000. Therefore, the Company reported an other expense of $74,000 as a warrant valuation adjustment in our statement of operations for the year ended December 31, 2004.

The assumptions used in the Black-Scholes pricing model were:

	December 31, 2004
Expected term	4.2 years
Interest rate	3.6%
Volatility	50%
Dividends	

Until the warrants are exercised or expire, the valuation of the warrants and the corresponding liability will be re-measured quarterly and the financial statements will reflect a non-cash valuation adjustment based on the change in the fair value of the warrants during each reporting period.

Revenue Recognition

Product revenue is generated by the sale of commercial products and services under various sales programs to the end user and through distribution channels. Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 101, superseded in part by SAB 104, provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB No. 101 establishes the SEC s view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller s price to the buyer is fixed or determinable; collectibility is reasonably assured, and requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. The Emerging Issues Task Force (EITF) issued Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables addressing the determination of whether an arrangement involving more than one deliverable contains more than one unit of accounting and how arrangement consideration should be measured and allocated to the separate units of accounting. The Company believes that our revenue recognition policies are in compliance with SAB 101, SAB 104 and EITF Issue No. 00-21.

Product sales

The Company sells NanoChip Molecular Biology Workstations (NanoChip Systems) and related consumables (NanoChip Cartridges, also known as Analyte-Specific Reagents or ASRs), real time PCR reagent products, real time ASRs and point-of-care diagnostic tests (diagnostic tests) to end users and distributors in the research and clinical diagnostic fields.

Revenue from product sales that require no ongoing obligations are recognized as revenue when shipped to the customer (f.o.b. shipping point in the United States or Delivery Duty Paid at the customer s site in Europe), title

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has passed and collection is reasonably assured. 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. As of December 31, 2004, the Company has not entered into sales transactions where rights-of return exist.

The Company sells NanoChip Systems under various commercial programs such as; (i) direct sales, and (ii) reagent rental/cost per test agreements.

(i) Direct sales

Revenue from the direct sales of NanoChip Systems and related consumables to an end user or a distributor are recognized following receipt of a purchase order, shipment of the product, and title has passed. 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 cost of sales related to the consumables is recorded in the period is which the corresponding revenue from the consumable is recognized.

NanoChip Systems are sold with a warranty. The fair value of the warranty is recorded as deferred revenue. The revenue is recognized ratably over the warranty period. The fair value of the warranty is determined by the renewal price for a maintenance contract on similar equipment and is consistent for all customers.

Workstations sold to distributors are sold outright with title transferring at point of shipment (f.o.b. shipping point in the United States or Delivery Duty Paid at the customer s site in Europe).

(ii) Reagent rental/cost per test agreements

Revenue from fee per test agreements results when a NanoChip System is provided to a customer in return for the customer paying a premium for consumable products over a contractual number of years, and include minimum consumable purchases. Revenue is recognized when the consumable products are shipped. When the fee per test agreement is consummated, the value of the NanoChip® System is reclassified from inventory to fixed assets, and the system is amortized to the cost of sales over the period of the arrangement. The cost of sales related to the consumables is recorded in the period is which the corresponding revenue from the consumable is recognized.

License and royalty fees

The Company recognizes royalty revenue when the amounts are earned and determinable, which is generally when the cash payment is received. The Company is able to recognize minimum required payments on an accrual basis, as they are determinable under contract. However, since the Company is not able to forecast product sales by licensees, royalty payments that are based on product sales by the licensees are not determinable until the licensee has completed their computation of the royalties due and/or remitted their cash payment. Should information on licensee product sales become available so as to enable us to recognize royalty revenue on an accrual basis, materially different revenues and results of operations could occur.

Sponsored research, contract and grant revenue

The Company earns revenue for performing tasks under research agreements with both commercial enterprises and governmental agencies. Sponsored research and contract and grant revenue are generally recorded as the costs and expenses to perform the research are incurred. Milestone payments are recognized as revenue upon meeting the following criteria: i) the achievement of specified milestones when the Company has earned the milestone payment, ii.) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, iii.) the fees are non-refundable, and iv.) collection of the payment is reasonably assured. 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

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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. Any amounts received prior to satisfying the Company s revenue recognition criteria are recorded as deferred revenue in the balance sheet.

Comprehensive Income (Loss)

SFAS No. 130, Reporting Comprehensive Income (SFAS 130) requires all components of comprehensive income (loss), including net income (loss), be reported in the financial statements in the period in which they are recognized. Comprehensive income (loss) is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, including foreign currency translations adjustments and unrealized gains and losses on marketable securities. The Company presents other comprehensive loss in its consolidated statements of stockholders equity.

Net Loss Per Share

The Company computes net loss per share in accordance with SFAS No. 128, Earnings Per Share. Basic per share data is computed by dividing income (loss) available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income (loss) available to the common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common share equivalents that would have been outstanding if potential common shares had been issued using the treasury stock method. 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.

The Company has excluded all potentially dilutive securities from the calculation of diluted loss per share attributable to common stockholders during the years ended December 31, 2004, 2003 and 2002, 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,		
	2004	2003	2002
Stock options	6,188,672	4,861,366	4,459,428
Warrants outstanding	1,558,328	2,747,293	365,863
	7,747,000	7,608,659	4,825,291

Stock-Based Compensation

The Company applies the intrinsic value-based method of accounting as prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations including Financial Accounting Standards Board (FASB) Interpretation

No. 44, Accounting for Certain Transactions involving Stock Compensation an interpretation of APB Opinion No. 25 to account for its stock option plans. Under the intrinsic value method, compensation expense is measured on the date of grant only if the then current market price of the underlying stock exceeded the exercise price and is recorded on a straight-line basis over the applicable vesting period. Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, the Company has elected to continue to apply the intrinsic value-based method of accounting described above, and has adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure.

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The pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated at the date of grant using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. Black-Scholes does not consider the employment, transfer or vesting restrictions that are inherent in the Company s employee options. Use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each option grant. Because the Company s employee stock options have characteristics significantly different from those of freely traded options, and because the assumptions underlying the Black-Scholes model involve substantial judgment, the Company s estimate of the fair value of its awarded stock options may differ materially from the ultimate value realized by the recipient employee.

The weighted average estimated fair values of stock options granted and stock issued under the employee stock purchase plan during the year ended December 31, 2004, 2003 and 2002 was $3.95, $2.37 and $1.77 per share, respectively. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	Stock Options		
	For the years ended December 31,		
	2004	2003	2002
Expected term	5 years	5 years	5 years
Interest rate	3.6%	3.2%	3.0%
Volatility	93%	110%	83%
Dividends			

	Employee Stock Purchase Plan		
	For the years ended December 31,		
	2004	2003	2002
Expected term	6 months	6 months	6 months
Interest rate	3.6%	3.2%	3.0%
Volatility	93%	110%	83%
Dividends			

Had compensation expense for our 2004, 2003 and 2002 grants under stock-based compensation plans, including costs related to prior years grants, been recorded based on SFAS 123, our pro forma net loss, and pro forma loss per share would have been as follows:

For the years ended December 31,

	2004	2003	2002
	(In thousands, except per share data)		
Net income (loss):			
As reported	$ (38,907)	$ (30,596)	$ (22,246)
Add: Stock based employee compensation expense included in reported net income (loss), net of related tax effects			
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(4,482)	(4,723)	(6,126)
Pro forma	$ (43,389)	$ (35,319)	$ (28,372)
Basic loss per share:			
Basic loss per common share:			
As reported	$ (1.21)	$ (1.38)	$ (1.02)
Pro forma	$ (1.35)	$ (1.59)	$ (1.31)

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The pro forma compensation expense may not be representative of such expense in 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.

Warranty

The Company provides product warranty coverage under direct sale and fee per test transactions related to NanoChip® Molecular Biology Workstations. Warranty periods are generally for one year under direct sales, and over the period of the contract for a cost per test agreement transaction. Instruments sold to distributors typically are sold without warranty coverage.

Historically, warranty service was performed by Hitachi, the instrument manufacturer, under a service agreement. In March 2004, Hitachi exercised its right to terminate the service agreement. Hitachi continued to service existing field units through the end of 2004, at which time the responsibility for servicing units transferred to the Company. The Company has developed an in-house service function to handle this responsibility. Expenses under the in-house service functions are expensed as warranty costs in the period incurred.

Changes in the Company s warranty liability were as follows (in thousands):

	Balance at January 1,	Warranty Additions (charges to expense)	Payment for warranty service	Balance at December 31,
2004:				
Warranty reserve	$ 159	$ 147	$ (289)	$ 17
2003:				
Warranty reserve	$ 190	$ 431	$ (462)	$ 159

Foreign Currency

The functional currency for our Canadian and Netherlands subsidiaries is the U.S. dollar. The functional currency for our majority owned German subsidiary is the euro. 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.

The Company has 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 2004, 2003 and 2002, foreign currency transaction losses were not material.

Segment Information

SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information , establishes standards for reporting information on operating segments in interim and annual financial statements. The Company operates in one segment, which is the business of development, manufacturing and commercialization of advanced diagnostic products. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

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Recent Accounting Pronouncements

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), Share-Based Payment , which is a revision of SFAS No. 123, Accounting for Stock-Based Compensation (SFAS 123R). SFAS 123R supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees, and amends SFAS 95, Statement of Cash Flows. Generally, the approach in SFAS 123R is similar to the approach described in SFAS 123. However, SFAS 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. SFAS 123R must be adopted no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt SFAS 123R on July 1, 2005.

As permitted by SFAS 123, the Company currently accounts for share-based payments to employees using Opinion 25 s intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123R s fair value method will have a significant impact on our result of operations, although it will have no impact on our overall financial position. The impact of adoption of SFAS 123R cannot be predicted at this time because it will depend on levels of share-based payments granted in the future and the assumptions for the variables which impact the computation. However, had the Company adopted SFAS 123R in prior periods, the impact of that standard would have approximated the impact of SFAS 123 as described in the disclosure of pro forma net income and earnings per share elsewhere in Note 2 to our consolidated financial statements. The Company cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options).

In November 2004, the FASB issued SFAS No. 151, Inventory Costs, an amendment of ARB No. 43, Chapter 4. This statement amends the guidance in ARB No. 43 Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB No. 43, Chapter 4, previously stated that . . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and rehandling costs may be so abnormal to require treatment as a current period charges . . . This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this statement requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement will be effective for inventory costs during the fiscal years beginning after June 15, 2005. The Company does not believe that the adoption of this statement will have a material impact on its financial condition or results of operations.

In March 2004, the FASB issued EITF Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments which provides new guidance for assessing impairment losses on debt and equity investments. Additionally, EITF Issue No. 03-1 includes new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB delayed the accounting provisions of EITF Issue No. 03-1; however, the disclosure requirements remain effective and have been adopted for our year ended December 31, 2004. The Company will evaluate the effect, if any, of EITF 03-1 when final guidance is released.

3. Financial Statement Details

Short-term Investments

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

	Amortized Cost	Unrealized gain	Unrealized loss	Market Value
2004				
Obligations of U.S. government agencies	$ 6,000	$	$ (28)	$ 5,972
Corporate debt securities	15,456		(73)	15,383
Asset backed securities	461		(6)	455
U.S. Treasuries	5,499		(23)	5,476
Auction Rate securities	7,300			7,300
Certificate of deposit	2,000		(24)	1,976
	$ 36,716	$	$ (154)	$ 36,562

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	Amortized Cost	Unrealized gain	Unrealized loss	Market Value
2003				
Obligations of U.S. government agencies	$ 5,007	$ 9	$	$ 5,016
Corporate debt securities	2,313	2		2,315
Asset backed securities	7,180	22	(12)	7,190
U.S Treasuries	6,040	3		6,043
	$ 20,540	$ 36	$ (12)	$ 20,564

The following table shows the gross unrealized losses and fair values of the Company s investments in individual securities that have been in a unrealized loss position believed to be temporary, aggregated by investment category, at December 31, 2004:

	Less than 12 month of temporary impairment		
	Number of investments	Market Value	Unrealized loss
2004			
Obligations of U.S. government agencies	1	$ 5,972	$ (28)
Corporate debt securities	7	14,064	(73)
Asset backed securities	2	455	(6)
U.S. Treasuries	2	5,476	(23)
Certificate of deposit	1	1,976	(24)
		$ 27,943	$ (154)

Temporarily impaired securities were mainly purchased during 2004.

The Company believes that the decline in value is temporary and related to the change in market interest rates since purchase. The decline is not related to any company or industry specific event, and all portfolio investments are rated A1 or P1 or better by various rating agencies. The Company anticipates full recovery of amortized cost with respect to these securities at maturity or sooner in the event of a change in the market interest rate environment.

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

	2004		2003	
	Amortized Cost	Market Value	Amortized Cost	Market Value
Due in one year or less	$ 34,227	$ 34,094	$ 12,060	$ 12,072
Due between one and two years	2,489	2,468	6,416	6,439

Due between three and five years			2,064	2,053
	$ 36,716	$ 36,562	$ 20,540	$ 20,564

Net realized loss from the sale of securities total $47,000 for the year ended December 31, 2004. During year ended December 31, 2003, a realized loss of approximately $1.9 million from the sale of short-term investments related to the sale of Combimatrix shares received as part of a settlement agreement as discussed in Note 5. Realized gains from sale of securities totaled $197,000, for the year ended December 31, 2002.

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Receivables

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

	December 31,	
	2004	2003
Product	$ 721	$ 1,341
License fees	1,375	38
Contract and grant	103	141
	2,199	1,520
Allowance for doubtful accounts	(176)	(105)
	$ 2,023	$ 1,415

Inventories

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

	December 31,	
	2004	2003
Raw materials	$ 1,924	$ 1,469
Work in process	2,398	1,745
Finished goods	3,282	4,043
	7,604	7,257
Reserve for excess and obsolescence	(5,860)	(2,483)
	$ 1,744	$ 4,774

Finished goods includes $969,000 and $1.7 million of NanoChip® Systems at December 31, 2004 and 2003, 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:

	Estimated Useful Life (in-year)	December 31, 2004	December 31, 2003
Scientific equipment	5	$ 9,338	$ 7,479
Office furniture and equipment	3 5	4,061	3,436
Manufacturing equipment	5	1,858	921
Leasehold improvements	(lesser of lease term or life of improvements)	7,247	4,425
		22,504	16,261
Less accumulated depreciation and amortization		(14,004)	(11,985)
		$ 8,500	$ 4,276

For the years ended December 31, 2004, 2003, and 2002, depreciation and amortization expense related to property and equipment totaled $3.1 million, $2.3 million, and $2.4 million, respectively.

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Acquired Technology Rights

Acquired technology rights consist of the following (in thousands) as of:

		December 31, 2004		December 31, 2003	
	Life	Gross Carrying Amount	Accumulated amortization	Gross Carrying Amount	Accumulated amortization
In-licensed technology rights	3 10 years	$ 6,111	$ (4,897)	$ 6,137	$ (3,629)
Customer contracts acquired	7 years	1,210			
Completed technology acquired	3 10 year	9,395			
Total acquired technology rights		$ 16,716	$ (4,897)	$ 6,137	$ (3,629)
Intangible assets not subject to amortization:					
Trademarks & trade names		$ 294		$	

The amortization expense of intangibles for the years ended December 31, 2004 and 2003 was $1.3 million and $1.0 million, respectively.

Estimated amortization of intangibles (in thousands) for the years ended:

2005	$ 2,136
2006	1,761
2007	1,737
2008	1,538
2009	1,488
Thereafter	3,159
	$ 11,819

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following (in thousands) as of:

	December 31,

	2004	2003
Accounts payable	$ 918	$ 290
Accrued compensation and benefits	2,443	1,534
Accrued legal fees	944	673
Accrued acquisition costs	2,329	
Accrued warrant rescission	598	
Other	2,691	2,312
	$ 9,923	$ 4,809

4. Business Combinations

The Company completed the following acquisitions during the year ended December 31, 2004 that were accounted for under the purchase method of accounting:

SynX Pharma Inc.

On April 21, 2004, the Company acquired all the outstanding common stock of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests.

As a result of the merger, SynX stockholders received 0.123 (the exchange ratio) of a share the Company s common stock for each share of SynX common stock. Each holder of SynX debentures received the Company s

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common stock based upon (i) the aggregate principal amount plus accrued and unpaid interest owed on the debenture (ii) the currency exchange rate on April 21, 2004, and (iii) the average best bid and best ask price for the Company s stock on April 21, 2004. In addition, the Company assumed all SynX options and warrants outstanding at the effective time of the merger, and each such option or warrant is now exercisable for 0.123 of the Company s common stock and exercise prices were adjusted accordingly. SynX shareholders received an aggregate of 1.6 million shares of the Company s common stock. In addition, 270,000 shares of the Company s common stock are issuable upon exercise of the assumed options and warrants.

The fair value of SynX s options and warrants assumed were determined using the Black-Scholes option pricing model using the stock price of $7.63 which is the value ascribed to SynX s share in determining the purchase price with the following assumptions:

	Options	Warrants
Expected term	2 years	2 years
Interest rate	1.47%	1.47%
Volatility	90%	90%
Dividends		

The results of operations of SynX have been included in the accompanying consolidated financial statements from the date of acquisition. The valuation of the common stock exchanged was based on $7.60 per share, which represents the market value as of April 21, 2004, the date of acquisition. The total cost of the acquisition has been recorded as follows (in thousands):

Nanogen common stock exchanged	$ 12,493
Fair value of options and warrants assumed	1,237
Direct transaction costs	2,279
Total purchase price	$ 16,009

The allocation of the above purchase price is as follows (in thousands):

Fair value of tangible assets acquired	$ 5,818
Fair value of intangible assets acquired	4,052
Goodwill	10,452
Total assets acquired	20,322
Liabilities assumed	(4,313)
Net assets acquired	$ 16,009

Purchased intangibles include $3.8 million in-process research and development and $294,000 in an indefinite lived asset related to acquired trade names. The amount assigned to acquired in-process research and development was recorded as an expense in the statement of operations for the year ended December 31, 2004. Operations in a market niche that is complimentary and operational and technological synergies were among the factors that contributed to a purchase price resulting in the recognition of goodwill. In addition, as part of the acquisition, the Company acquired certain real estate commitments approximating current market lease rates for comparable properties of SynX averaging

$917,000 per year for a total of approximately $6.6 million on a building lease through 2012.

Epoch Biosciences, Inc.

On December 16, 2004, the Company acquired all the outstanding common stock of Epoch Biosciences, Inc. (Epoch). Based in Bothell, Washington, Epoch develops and sells proprietary products and technologies with commercial applications in the genomics and molecular diagnostics fields.

As a result of the acquisition, Epoch s stockholders received 0.4673 (the exchange ratio) of a share of the Company s common stock for each share of Epoch common stock. In addition, the Company assumed all Epoch

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options and warrants outstanding at the effective time of the merger, and each such option or warrant is now exercisable for 0.4673 of the Company s common stock and exercise prices were adjusted accordingly. Epoch s shareholders received 13.4 million shares of the Company s common stock. In addition, 1.7 million shares of the Company s common stock are issuable upon exercise of the assumed options and warrants.

The fair value of the Company s shares used in determining the purchase price was $7.06 per share, which represents the market value of the Company s common stock on the date of closing, December 16, 2004. The actual number of shares issued was calculated based on the average closing price of the Company s shares for the 20 days ending on and including the third trading day prior to the closing on December 16, 2004. The fair value of Epoch s options and warrants was determined using the Black-Scholes option pricing model using the stock price of $7.06 which is the value ascribed to Epoch s share in determining the purchase price with the following assumptions:

	Options	Warrants
Expected term	5 years	4.2 years
Interest rate	3.53%	3.53%
Volatility	94%	94%
Dividends		

The results of operations of Epoch have been included in the accompanying consolidated financial statements from the date of acquisition. The total cost of the acquisition has been recorded as follows (in thousands):

Nanogen common stock exchanged	$ 94,787
Fair value of options and warrants assumed	5,895
Direct transaction costs	3,980
Total purchase price	$ 104,662

The allocation of the above price is preliminary (pending receipt of such items as a final asset appraisal and final transaction related invoices) and estimated as follows (in thousands):

Fair value of tangible assets acquired	$ 12,726
Fair value of intangible assets acquired	10,605
Goodwill	85,620
Total assets acquired	108,951
Liabilities assumed	(4,289)
Net assets acquired	$ 104,662

Purchased intangibles include $9.4 million in completed technology and $1.2 million in contractually based customer relationships. Operations in a market niche that is complimentary and operational and technological synergies were among the factors that contributed to a purchase price resulting in the recognition of goodwill. In addition, as part of the acquisition, the Company acquired certain real estate commitments approximating current market lease rates for comparable properties of Epoch averaging $806,000 per year for a total of $6.5 million, on a building lease through 2012.

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Pro Forma Information

The results of operations of SynX and Epoch have been included in the Company s consolidated statements of operations since the completion of the acquisitions on April 21, 2004 and December 16, 2004, respectively. The following unaudited pro forma information presents a summary of the results of operations of the Company assuming the acquisitions of SnyX and Epoch occurred on January 1, 2004 and 2003 (in thousands, except per share data):

	For the year ended December 31,	
	2004	2003
	(unaudited)	
Revenues	$ 13,904	$ 20,041
Net loss (1)	(44,031)	(40,813)
Loss per share (basic and diluted)	$ (0.97)	$ (1.09)

(1) Includes $3.8 million for the write-off of in-process research and development costs in year ended December 31, 2004.

5. Commitments and Contingencies

Hitachi, Ltd. Purchase Commitment

The Company s has a manufacturing agreement with Hitachi, Ltd. (Hitachi) that requires certain minimum purchase commitments for the second generation of NanoChip® systems from Hitachi. As of December 31, 2004, the Company had commitments to purchase approximately $590,000 in second generation NanoChip® systems through February 28, 2005. At December 31, 2004, the inventory under our purchase commitment with Hitachi is within our expected usage levels based upon current and estimated future demands.

Leases

The Company leases its facilities and certain equipment under operating lease agreements that expire at various dates through 2012.

At December 31, 2004, minimum annual obligations for operating leases were as follows (in thousands):

	Operating Leases
2005	$ 2,658

2006	2,799
2007	2,892
2008	2,967
2009	3,038
Thereafter	4,882
Total minimum lease payments	$ 19,236

Rent expense was $1.3 million, $843,000 and $927,000 in for the years ended December 31, 2004, 2003 and 2002, respectively. As of December 31, 2004, the Company had $592,000 in deferred rent recorded as a long term liability in the balance sheet.

The Company has entered into various debt obligations to provide financing for equipment purchases. In connection with the agreements, the Company originally issued eight promissory notes to its lender under the agreement for a total of approximately $2.1 million. The interest rates on these notes range from 8.9% to 12.4% per annum with principal and interest due in monthly payments of approximately $57,000 maturing in 1 to 3 years and are secured by equipment.

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Upon acquisition of Epoch, the Company acquired obligations relating to financing of equipment purchases. In connection with the agreements, the Company acquired six promissory notes for a total of approximately $585,000. The interest rates on these notes is prime rate plus 0.5% (5.25% at December 31, 2004) per annum with principal and interest due in monthly payments of approximately $45,000 maturing over 3 years and are secured by equipment.

Principal payments on the debt obligations are as follows for the years ended December 31 (in thousands):

	Debt obligations
2005	$ 1,051
2006	465
2007	194
Total minimum debt obligations payments	1,710
Less amount representing interest	(112)
Present value of future minimum debt obligations	1,598
Less amounts due in one year	(988)
Long term portion of debt obligations	$ 610

Litigation

CombiMatrix Corp.

In 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, the Company 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 that were assigned by Dr. Montgomery, an ex-employee of the Company, 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 and issue 4,016,346 shares of CombiMatrix tracking common stock that as of December 18, 2002 became publicly tradable on the NASDAQ National Market to the Company. This stock was initially valued upon receipt at $10.8 million and represented 17.5% of CombiMatrix s outstanding common stock. In 2003, the Company sold 3,583,600 shares of the common stock for net proceeds totaling $8.9 million and recognized a loss of approximately $1.9 million. In addition to the issuance of the stock, CombiMatrix is required to make royalty payments of 12.5% on sales of products that incorporate the patented technology to the Company, subject to certain quarterly minimums. Also, as part of the settlement agreement, CombiMatrix and Dr. Montgomery agreed to drop their counterclaims against the Company and CombiMatrix retained sole ownership of the patented technology.

Oxford Gene Technologies, Inc.

In 2002, Oxford Gene Technologies (OGT) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that the Company infringes U.S. Patent No. 6,054,270 (the 270 Patent) entitled Analyzing Polynucleotide Sequences. In 2003, the Company filed an answer to the complaint that denies that it infringes the 270 Patent. In October, 2003, the Company and OGT entered into a settlement agreement which was not material to the Company s financial statements pursuant to which the lawsuit was dismissed by OGT without prejudice.

Litigation

The Company is subject to other potential liabilities under various claims and legal actions that may be asserted. These matters have arisen in the ordinary course and conduct of the Company s business, as well as through acquisitions, and some maybe to be covered, at least partly, by insurance. Claim estimates that are

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probable and can be reasonably estimated are reflected as liabilities of the Company. The ultimate resolution of these matters is subject to many uncertainties. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to the Company. Although the amount of liability at December 31, 2004, with respect to these matters cannot be ascertained, the Company believes that any resulting liability should not materially affect the Company s consolidated financial statements.

6. Related Party Transactions

Graviton, Inc.

The Company s Chief Executive of Officer and Chairman of the Board, Mr. Birndorf served as a director and investor in Graviton Inc. (Graviton). In the year ended December 31, 2002, 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. The Company s Board of Directors appointed a committee of disinterested members of the Board of Directors to evaluate and approve 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 a Collaboration License Agreement on December 15, 1999.

In 2002, the Company entered into an agreement with Graviton to terminate and release the Company and Graviton (the July 2002 Release) of their obligations under a Collaboration and License Agreement dated December 15, 1999. The Company received 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 as compensation for termination of this arrangement. The Company determined these securities fair value to be immaterial as Graviton was privately-held and did not maintain a market for its stock.

In September 2002, Graviton commenced a recapitalization and a new round of financing. In exchange for the Company s consent for the recapitalization and new round of financing, Graviton issued the Company 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. For the year ended December 31, 2002, the Company recorded a loss of approximately $452,000 for the remaining carrying value of acquired technology rights as result of the termination of the collaboration agreement.

During 2003, the Company was notified that Graviton was dissolved.

Separation agreements

In 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 2003, to settle all outstanding obligations between the two parties, including indebtedness to the Company amounting to approximately $167,000.

Also in 2002, the Company s then President, resigned effective in January 2003. In connection with the resignation, the Company made a net severance payment of approximately $384,000 in 2003, to settle all outstanding obligations between the two parties, including indebtedness to the Company amounting to approximately $300,000.

In 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 the Company sold the Chief Financial Officer 20,000 shares of unrestricted Company common stock at par value ($0.001) and accelerated the vesting on his existing stock options. The Company recorded a severance expense of approximately $82,000 related to the sale of common stock and acceleration of stock options.

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In 2004, the Company entered into a separation agreement with its then Senior Vice President of Global Operations and Business Development. Under the terms of the agreement the Company made severance payments totaling approximately $110,000.

In 2004, the Company entered into a separation agreement with its then President and Chief Operation Officer. Under the terms of this agreement, the terms of the vested options that the then President and Chief Operation Officer was entitled to were modified to extend the exercise period for the vested options from 90 days to 180 days. This stock option modification resulted in a $470,000 non-cash stock compensation expense following his separation. In addition he agreed to a consulting fee equal to $1,200 per day and his services have not been used.

Leased aircraft

The Company s Chief Executive Officer (Mr. Birndorf) owns an aircraft which was leased by a charter aircraft company. For the years ended December 31, 2004, 2003 and 2002, the Company paid approximately $13,000, $82,000, and $175,000, respectively, to the local charter aircraft company for Mr. Birndorf s aircraft for business related travel. In 2004, 2003 and 2002, Mr. Birndorf received approximately $1,500 per hour of usage when his aircraft was leased to outside parties. As a result of the Company s use of Mr. Birndorf s aircraft, Mr. Birndorf received approximately $5,000, $44,000, and $82,000 for the years ended December 31, 2004, 2003 and 2002, respectively. 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.

7. 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 matching contributions. The Compensation Committee of the Board of Directors (Compensation Committee) did not approve a match for the years ended December 31, 2003 and 2002. The Compensation Committee approved a Company match in the form of Company stock equal to 25% of employee contributions or approximately $159,000 for the year ended December 31, 2004.

Equity Incentive Plans

The Company has several stock option plans, including several option plans that were assumed through acquisitions. The stock option plans include: Nanogen s 1993 Stock Option Plan, 1995 Stock Option/Stock Issuance Plan, and 1997 Stock Incentive Plan; SynX s 2001 Stock Option Plan; and Epoch s 1991 Incentive Stock Option, Nonqualified Stock Option And Restricted Stock Purchase Plan, 1993 Incentive Stock Option, Nonqualified Stock Option And Restricted Stock Purchase Plan, and 2003 Stock Incentive Plan. Of these plans, only two have shares available for future grant: Nanogen s 1997 Stock Incentive Plan (1997 plan), and Epoch s 2003 Stock Incentive Plan (2003 plan).

As of December 31, 2004, the cumulative amount of shares initially reserved, or subsequently approved by stockholders, for all option plans totaled approximately 12.4 million. Of this amount, outstanding stock options totaled approximately 6.2 million, and approximately 1.0 million were available for future grants.

Active Equity Incentive Plans (Containing Shares Available for Grant)

In August 1997, the Board of Directors adopted the 1997 Plan, under which 1,641,341 shares of common stock were reserved for issuance. The 1997 plan was subsequently amended and as of December 31, 2004 8,516,341 shares were reserved for issuance.

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On December 16, 2004, the date of our acquisition of Epoch, the Company assumed Epoch s 2003 Plan, under which approximately 563,000 shares of common stock were initially reserved for issuance of new stock options granted by the Company and approximately 1.2 million shares were reserved for issuance for outstanding grants assumed as part of the acquisition. Epoch s 2003 Plan contains an evergreen provision assumed by the Company which provides for annual increases in the number of shares available for issuance on the first day of each year. The annual increase is based on a percentage of fully diluted outstanding shares, however, it is limited to a maximum annual increase of approximately 350,500 shares. Based on this evergreen provision, in January 2005, approximately 350,500 shares became issuable under Epoch s 2003 Plan.

Stock Option Grants

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 25% after one year and the remainder ratably over the remaining three years. Options granted have a term of up to ten years.

As of December 31, 2004, 1,038,456 shares are available for future grant under the various stock option plans. The following table summarizes stock option activity in all plans through December 31, 2004:

	Number of Shares	Price Per Share	Weighted Average Exercise Price Per Share
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	1.00 to 45.81	6.12
Granted	2,212,263	3.00 to 12.90	5.55
Assumed in purchase transaction	1,410,463	1.00 to 46.34	8.31
Exercised	(1,301,618)	1.07 to 9.99	4.56
Cancelled	(993,802)	1.16 to 45.81	12.65
Outstanding at December 31, 2004	6,188,672	$ 1.00 to $46.34	$ 5.70

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The following table summarizes information about options outstanding at December 31, 2004:

	Options Outstanding			Options Exercisable	
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
$ 1.00 $ 1.90	706,399	7.96	$ 1.75	590,458	$ 1.78
$ 1.92 $ 3.34	322,538	8.27	2.58	214,851	2.52
$ 3.39 $ 3.45	889,621	8.55	3.45	641,757	3.45
$ 3.47 $ 4.17	655,773	9.50	3.91	381,507	3.94
$ 4.18 $ 4.50	268,480	9.05	4.28	109,813	4.35
$ 4.59 $ 4.70	975,060	9.57	4.70	34,378	4.69
$ 4.74 $ 5.87	725,121	8.38	5.47	316,533	5.17
$ 5.93 $ 6.97	648,520	8.61	6.54	345,840	6.50
$ 7.00 $11.94	700,100	7.92	9.33	441,223	10.05
$11.99 $46.34	297,060	5.02	23.96	295,379	24.02
	6,188,672	8.50	$ 5.70	3,371,739	$ 6.34

Employee Stock Purchase Plan

In 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. In both 2004 and 2001, an additional 150,000 shares were reserved for issuance under the Purchase Plan. The Purchase Plan permits eligible employees of the Company to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the participant s base salary subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the stock at either the beginning of the applicable offering period or the last day of the accumulation period. Each offering period is 24 months, with new offering periods commencing every six months, and an accumulation period is six months in duration. During the years ended December 31, 2004, 2003 and 2002, there were 100,226, 79,250 and 75,009 shares, respectively, issued under the Purchase Plan.

Stock Bonus Plan

In 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. This plan provides for the payment of some or a portion of annual bonuses in the form of restricted shares. Amount of payout is based on Board approval. 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 were no shares issued as an annual bonus for either of the years ended December 31, 2004 or 2003. There are 178,390 shares available for grant as of December 31, 2004.

Shares Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at December 31, 2004:

Stock options outstanding	6,188,672
Stock options available for grant	1,038,456
Stock bonus plan	178,390
Employee stock purchase plan	137,414
Warrants outstanding	1,558,328
	9,101,260

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Shares reserved for future issuances related to warrants outstanding include: 639,713 shares related to a joint venture agreement (Note 1) expiring at various dates in 2006 and 2008; 71,004 shares related to the SynX Pharma assumed warrants at an exercise price of $4.97 expiring in July 2005, 423,368 shares related to the Epoch Biosciences assumed warrants at a range of exercise price of $5.41 to $21.81, the majority of which expire in 2009, and 424,243 shares at an exercise price of $4.75 which expire in 2008 related to a private financing that closed in September 2003.

8. Stockholder Rights Plan

In 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.

In 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.

9. Stock Repurchase Plan

In 2002, the Board of Directors authorized a limited stock repurchase program under which the Company may purchase up to an aggregate of 10% of its outstanding Common Stock from time to time. Any purchases under the Company s 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 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, 2004, the Company held a total of 500,189 treasury shares at a cost of $922,000.

10. Income Taxes

Due to the Company s net loss position for the years ended December 31, 2004, 2003 and 2002 as the Company recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal or state income tax provision for the years ended December 31, 2004, 2003 and 2002.

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The tax effects of temporary differences that gave rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2004 and 2003 are as follows (in thousands):

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 92,013	$ 58,144
Research and development credits	10,840	8,126
Capitalized research expenses	15,259	2,494
Accrued expenses	632	354
Basis difference in intangibles	1,519	1,306
Basis difference in assets	566	
Other, net	6,387	2,120
Total deferred tax assets	127,216	72,544
Valuation allowance for deferred tax assets	(123,531)	(72,351)
Net deferred tax assets	3,685	193
Deferred tax liabilities:		
Basis difference in intangibles	(3,685)	
Depreciation		(193)
Net deferred tax assets	$	$

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. Management periodically evaluates the recoverability of the deferred tax asset. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a valuation allowance of $123.5 million as of December 31, 2004 to reflect the estimated amount of deferred tax assets that may not be realized. The Company increased its valuation allowance by approximately $16.4 million for the year ended December 31, 2004. This increase does not include the valuation allowance attributable to SynX and Epoch Biosciences prior to the date of acquisition.

Included in the valuation allowance is $34.7 million attributable to deferred tax assets of Epoch and SynX, entities acquired during the year ended December 31, 2004. The subsequent recognition of the tax benefit related to these assets will be allocated to reduce goodwill or other non-current intangible assets of the acquired entity when realized.

At December 31, 2004, the Company has federal, state and foreign net tax operating loss carryforwards of approximately $231.3 million, $70.1 million and $26.2 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 prior years limitation on state loss carryforwards applicable to tax years ending before December 31, 2004. The federal tax loss carryforwards will begin expiring in 2005 unless previously utilized. The state tax loss carryforwards will continue to expire in 2005, unless previously utilized. The foreign tax loss carryforwards will begin expiring in 2005 unless previously utilized. The Company also has federal and state research tax credit carryforwards of approximately $8.0 million and $4.4 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 result in $2.4 million allocated to additional paid-in capital.

Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of the Company s net operating losses and credit carryforwards may be limited due to cumulative changes in ownership of more than 50% over a 3-year period. The Company may be subject to similar limitations on its Canadian losses acquired from SynX. The Company has not performed a formal analysis to quantify the amount of possible limitations. Currently the net operating losses reflected above have not been reduced by potential limitations, however, a full valuation allowance has been placed on all deferred tax assets and, therefore, there is no material impact on the financial statements of the Company.

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

Hitachi, Ltd. has a non-exclusive right to distribute NanoChip® Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip® Systems sold by Hitachi, Ltd. in Japan. The Company retains the right to distribute, directly or through others, NanoChip® Systems 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 the NanoChip 400, the second generation NanoChip System. Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the NanoChip 400 exclusively for the Company for worldwide distribution.

Pursuant to our manufacturing agreements with Hitachi, the Company is required to provide annual purchase commitments to Hitachi for NanoChip® Systems. As of December 31, 2004, the Company had a commitment to purchase approximately $590,000 in NanoChip® Systems from Hitachi through February 28, 2005.

Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. Research agreement

In 2000, the Company executed a research agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute potential products based on the parties proprietary technologies. Pursuant to the terms of the agreement, Hitachi and the Company each may contribute, toward the research and development efforts of the Company, cash over the period of the agreement. The Company is liable to repay to Hitachi 50% 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.

In accordance with Statement of Financial Accounting Standards No. 68 Research and Development Arrangements , the Company recorded sponsored research revenue under this arrangement as expenses were incurred, in amounts not exceeding scheduled payments under the agreement. Sponsored research revenue recognized under this agreement totaled $500,000, $1.5 million and $1.4 million for the years ended December 31, 2004, 2003 and 2002, respectively. Upon receipt of the funds, the Company records a long-term liability for 50% of the amount in Other long-term liabilities in the accompanying balance sheet, which amounted to approximately $4.9 million and $4.3 million for the year ended December 31, 2004 and 2003, respectively. The Company has classified the entire balance of this liability as long-term due to the immaterial amount of current payments due under this obligation, as calculated under the agreement as percentage of gross NanoChip® Cartridge revenue.

In 2003, in accordance with the terms of the agreement, Hitachi exercised its right to terminate the collaborative research agreement. The termination of this agreement did not accelerate the repayment due Hitachi for the 50% of the funding. Based on discussions, the Company and Hitachi determined to focus their efforts on the development and manufacture of the NanoChip 400 instrument. Hitachi is responsible for world-wide manufacturing of the NanoChip® system. The Company is responsible for development of assays and for marketing and sales.

Princeton BioMeditech Corporation

As a result of the SynX acquisition, the Company gained access to a development and manufacturing agreement with Princeton BioMeditech Corporation (PBM), which SynX entered into in 2001 and 2002. PBM

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has the right to perform development, production and distribution functions for SynX s point-of-care product line, including the right to be SynX s exclusive producer of certain rapid assay diagnostic point-of-care products. Payment for PBM s services will be based on a defined percentage of the net sales price to customers of such products. In 2002, SynX and PBM signed an exclusive agreement for Canadian distribution rights for PBM s LifeSign® brand point-of-care diagnostic products. In addition, this agreement allowed SynX to distributes certain LifeSign® brand products in Europe.

Nanogen Recognomics GmbH

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. Based in Frankfurt, Germany, Nanogen Recognomics is 60% owned by the Company and 40% owned by Aventis. 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. In addition, Nanogen Recognomics owns several patent applications filed jointly by the Company and Aventis and the Company has licensed certain aspects of its NanoChip® technology to Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics.

In 2004, the shareholders of Nanogen Recognomics decided to reorganize into a non-operating holding company and discontinue all the business activities. Pursuant to the joint venture agreement the Company is required to assume reorganization costs. In addition, 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 Nanogen Recognomics are consolidated in the Company s financial statements. Nanogen Recognomics incurred approximately $1.3 million, $2.5 million and $2.3 million in operating expenses in the years ended December 31, 2004, 2003 and 2002, respectively. Approximately $946,000 of the total expenses during the year ended December 31, 2004, related to reorganization costs and expenses. These reorganization costs and expenses are reflected as research and development costs in the statement of operations. The Company will expense future reorganization costs as incurred. Such costs are not expected to be material. No minority interest was recorded for the years ended December 31, 2004 and 2003, respectively.

In accordance with Statement of Financial Accounting Standards No. 52, Foreign Currency Translation and its related interpretations, the functional currency of Nanogen Recognomics is the Euro. As a result of the increasing value of the Euro versus the U.S. Dollar during the period from inception of Nanogen Recognomics through the reorganization, the Company recorded cumulative unrealized gains on foreign currency translation of approximately $1.2 million. The Company realized approximately $1.2 million in previously unrealized foreign currency translation gains during in the year ended December 31, 2004 upon discontinuance of its business activity.

12. Licensed Technology

Licensing

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 2003, the Company recognized $1.0 million in impairment related to two previously acquired licenses as a result of a decision to restructure or terminate the agreements. It was determined that minimum future royalty

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payments on such licenses significantly limit the financial viability of bringing the licensed technology to market. As a result, an impairment loss was recorded for the carrying amount of the technology acquired under the two licenses. There has been no similar acquired technology impairment determinations in the year ended December 31, 2004.

Roche Diagnostics, Inc.

As a result of the SynX acquisition, the Company gained access to a cross-licensing agreement between Roche Diagnostics, Inc. (Roche) and SynX entered into in 2003. The Company has a non-exclusive world-wide license relating to the development, manufacture and marketing in the field of point-of-care diagnostics of immunoassays that detect the congestive heart failure marker NT-proBNP. As part of the cross-license agreement, the Company granted Roche a non-exclusive world-wide license on the technology relating to the development, manufacture and marketing of immunoassays that detect the congestive heart failure marker NT-proBNP. The value of the license was included as a component of acquired in-process research and development.

13. Contract and Grant Revenue

U.S. Army Medical Research Acquisition Activity

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 the Company s funds. Revenue is recognized under these agreements as expenses are incurred and totaled $466,000, $1,093,000, and $688,000 for the years ended December 31, 2004, 2003, and 2002, respectively. The first and second agreements were completed in the years ended December 31, 2003 and 2004, respectively.

The National Institute of Justice

In April 1997, The National Institute of Justice, U.S. Department of Justice, provided funding for the development of a chip based genetic detector for rapid DNA-based identification of individuals in an amount totaling approximately $4.4 million over a 9-year period. Revenue is recognized under these agreements as expenses are incurred and totaled $747,000, $979,000, and $232,000, for the years ended December 31, 2004, 2003, and 2002, respectively.

National Institutes of Health (NIH)

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 biological warfare

agent (BWA) analyzer. In May and September 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 BWA detection. The total awards of these grants totaled approximately $1.0 million to the Company over a 4-year period. Revenue is recognized under these grants as expenses are incurred and totaled $415,000, $188,000 and $25,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

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14. 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, (in thousands):

	2004	2003	2002
Customer Location:			
United States	$ 2,058	$ 1,500	$ 12,554
Europe	896	1,329	1,664
Mexico/Canada	226	17	10
Total	$ 3,180	$ 2,846	$ 14,228

Revenue from customers representing 10% or more of total revenue during years ended December 31 is as follows:

	2004	2003	2002
Sponsored research:			
Customer A	%	22%	%
License fees:			
Customer B	%	%	63%
Contract and grants:			
National Institutes of Health	14%	%	%

15. Stock transactions

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 net proceeds of approximately $31.7 million.

In April 2004, the Company sold 900,000 shares of its common stock to institutional investors at a price of $8.60 per share, for net proceeds of approximately $7.7 million.

16. Quarterly Financial Data (unaudited)

Summarized quarterly financial data for fiscal 2004 and 2003 are as follows (in thousands, except per share data):

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Fiscal 2004				
Revenues	$ 2,159	$ 1,118	$ 1,082	$ 1,015
Costs and expenses (2)	8,837	13,972	10,623	12,317
Loss from operations	(6,678)	(12,854)	(9,541)	(11,302)
Net loss	(5,375)	(12,889)	(9,442)	(11,201)
Net loss per share basic and diluted (1)	$ (0.20)	$ (0.39)	$ (0.28)	$ (0.31)
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)	(5,944)
Net loss per share basic and diluted (1)	$ (0.50)	$ (0.32)	$ (0.33)	$ (0.25)

(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 just cost of sales.

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17. Subsequent Events

In December 2004, certain warrant holders related to our acquisition of SynX exercised their warrants resulting in cash proceeds to the Company of $598,000. Subsequent to December 31, 2004, these stockholders requested to rescind their exercise and return their restricted common shares. The Company agreed to the request. The Company has reflected the proceeds received in current liabilities at December 31, 2004, as the proceeds from the warrant holders were returned in February 2005.