

NANOGEN INC
Form 10-K
March 16, 2006
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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, 2005

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

(State or other jurisdiction of
incorporation or organization)

10398 Pacific Center Court, San Diego, CA

(Address of principal executive offices)

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

33-0489621

(I.R.S. Employer
Identification No.)

92121

(Zip code)

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

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Preferred Stock Purchase Rights

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 NO

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES 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, 2005 (the last day of the registrant's most recently completed second fiscal quarter), as reported on the Nasdaq National Market was approximately \$176,644,416. For purposes hereof, directors, executive officers and 10% or greater shareholders have been deemed 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 56,332,888 as of February 28, 2006.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its annual meeting of stockholders to be held in 2006 are incorporated by reference in Part III of this Form 10-K.

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Trademarks and trade names

NANOGEN®, Nanochip®, NGEN™ Reagents, MGB Alert™ Reagents, MGB Eclipse®, DrugMET™, Assay Blueprint™, MGB Eclipse® Probes, Nexus D_x™ and Status First™ our other logos and trademarks are the property of Nanogen Incorporated. All other brand names or

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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.

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PART I

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 are 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, intends, estimates, could, should, would, continue, seeks, pro forma or anticipates, or other similar words (including their use in the negative), or by discussions of future matters such as the development of new product, integration of acquisitions, 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 1A. 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

Our company is based on the vision of providing a higher quality of healthcare through advanced diagnostic products. Our business strategy is to assemble the companies, products and knowledge base to become a leading supplier of the technologies and products that will help drive a new era of personalized medicine. We were early to recognize that the adoption of personalized medicine is dependent on the advancement of diagnostic technologies. The commercialization of our products and technologies will help bridge the gap between early-stage scientific research and actual clinical practice. We are developing several product lines that are directly targeting specific markets within the advanced diagnostics field that have significant potential for revenue growth. We see recent successes and a growing capability in the clinical laboratories ability to perform accurate advanced diagnostic testing as a strong validation of our strategy. In addition, the U.S. Food and Drug Administration (the FDA) has recently released guidance encouraging the generation of more pharmacogenomics data and molecular diagnostic testing during drug development and clinical trials, and before the use of medications. We believe these applications of advanced diagnostics will help build demand for our products and technologies.

In the last twelve months we have introduced several new products and believe they present significant opportunities for Nanogen to increase its revenues in 2006 and beyond. These new products represent important milestones for our company and the implementation of a sustainable, multi-product business model that over time will demonstrate improved financial performance. We released our second generation advanced diagnostic instrument, the NanoChip[®] 400, late in the third quarter of 2005. With its ability to target a large number of

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specific genes for testing at once, we believe the NanoChip[®] 400 is a prime example of the technologies we are commercializing that are bridging the gap between early-stage scientific research and actual clinical practice. We also released several Analyte Specific Reagents (ASRs) for the identification of a series of specific respiratory viruses, Factor V/II, HSV 1 and 2 viruses. In addition, in 2006 we plan to supply clinical laboratories with ASRs for the detection of the 23 most common genetic mutations related to Cystic Fibrosis and also for certain pharmacogenomic applications.

Our 2005 annual revenues of \$12.5 million more than doubled as compared to 2004. In 2005, we used \$34.6 million of cash in operating activities and our multi-product commercialization strategy continues to require a significant investment. We believe we will continue to use cash and have net losses until revenues from our product offerings climb substantially. To continue to fund our commercialization strategy we raised a combined \$62.6 million in capital in 2005 and 2004. In our most recent offering, in September 2005, we received approximately \$20.0 million, or \$18.8 million, net of expenses, by issuing to institutional investors a combination of approximately 6.8 million shares of common stock and warrants to purchase approximately one million shares of common stock at an exercise price of \$4.00 per share for five years. In March 2006, we received approximately \$15 million by issuing to an investor 5,660,377 shares of common stock at \$2.65 per share. These offerings were conducted under a shelf registration statement filed with the Securities and Exchange Commission in June 2005 that covers the sale of up to \$60.0 million of our securities. We have an additional \$20.9 million under this shelf registration statement. We believe that we will have the ability to sell a sufficient amount of securities to investors to continue our strategy of expanding our product pipelines by acquiring companies or assets and supporting our on-going internal product development.

As a part of our on-going long-term strategy, we actively and selectively seek to acquire companies with complementary products and strong intellectual property positions. We also specifically target companies with existing product lines that complement and add depth to our product portfolio that are or can be turned into cash flow positive entities when integrated into our company. In addition, we are developing an internal infrastructure that allows us to rapidly integrate acquired businesses or product lines into our existing sales, distribution and administrative functions. We have recently acquired or invested in the following companies:

On February 6, 2006, we acquired the revenue generating rapid cardiac immunoassay point-of-care test business of Spectral Diagnostics Inc. (Spectral). This acquisition expanded our menu of products available for point-of-care customers. The acquired products include rapid tests for levels of CKMB, Myoglobin and Troponin, all of which are frequently used in cardiac care. In addition, we acquired an ability to manufacture these and other point-of-care products. On February 6, 2006, we completed the acquisition of this business and the related assets. The total purchase price was approximately \$7.8 million that was comprised of \$4.9 million in cash and 975,193 shares of our common stock valued at \$2.9 million on the date of acquisition. The results of this business operations will be consolidated within our financial statements beginning February 6, 2006.

On July 5, 2005, we purchased \$350,000 in common stock of Pharmacogenetics Diagnostic Laboratory, LLC (PGx) a development stage research and development company, which will provide us access to services and certain know-how related to pharmacogenetics. In November 2005, we purchased an additional \$50,000 in common stock based on PGx obtaining certain milestones.

On July 20, 2005, we made an equity investment of approximately \$1.5 million in Jurilab LTD (Jurilab), a Finnish company that has assembled a large database of genetic markers by studying the genetic patterns of a founder population in East Finland. Our minority investment in Jurilab is an example of our goal to add proprietary content on top of our advanced diagnostic tools and thereby create unique solutions to evaluate and diagnose diseases.

In 2004, we identified SynX Pharma Inc. (SynX) and Epoch Biosciences, Inc. (Epoch) as businesses operating in market niches that were complementary to our existing business. In addition, they provided us the opportunity to broaden our product lines in the point-of-care and real-time polymerase chain reaction (PCR) diagnostic markets. We acquired SynX and Epoch in all stock transactions on April 21, 2004 and December 14, 2004, respectively.

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In 2004, we recognized \$96.1 million in goodwill assets that were created using the purchase method of accounting for our acquisitions of SynX and Epoch. A goodwill asset represents the difference between the acquisition price and the fair value of the identifiable tangible and intangible assets in an acquired business. In the fourth quarter of 2005, we reviewed our goodwill assets for potential impairments. We determined that the implied fair value of the goodwill asset associated with our real-time PCR reporting unit was impaired and we incurred a \$59 million non-cash accounting charge. However, we believe this reporting unit will continue to significantly contribute to our ongoing business strategy.

We are 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 reports 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 and Customers

Technology

Our diagnostic technologies focus on the identification of the nucleic acid sequences, gene variations and gene expressions associated with both genetic conditions and infectious diseases. We believe that our research will contribute to a new healthcare paradigm where disease is diagnosed and understood at the molecular level. We believe that this will lead to the introduction of new therapies, 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. Our tests will provide doctors with the information they require to tailor specific therapies to the individual patient. Therefore, we have developed a variety of diagnostic tools for both the relatively simple and complex testing required to render disease specific molecular information accessible to researchers and clinicians.

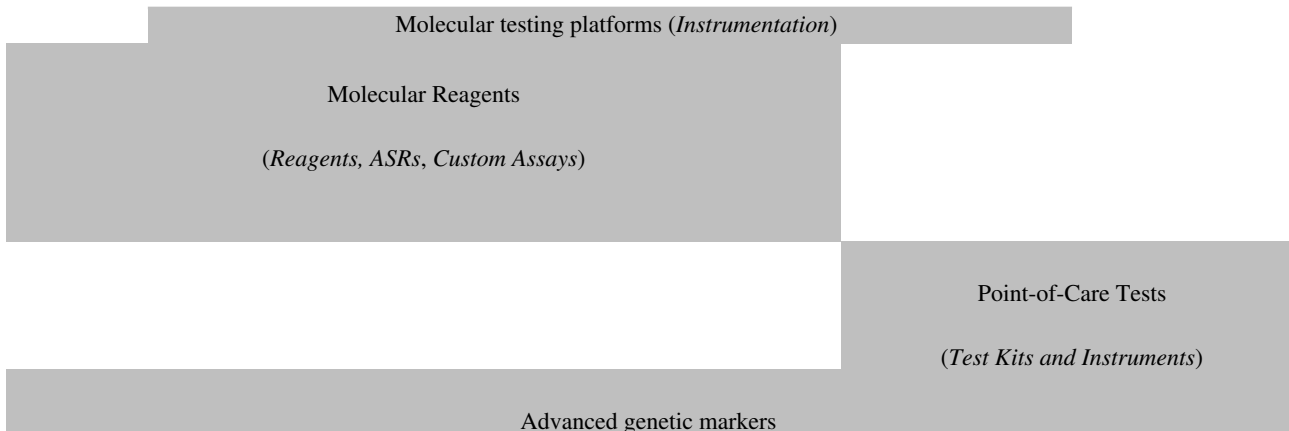
Below illustrates how our platform technologies address our customer s requirements for advanced molecular diagnostic tools:

Potential customers addressed Richard Davidson by our technologies:

Advanced Research
(Universities, research facilities, etc.)

Clinical Laboratory (CLIA certified central laboratories and clinical research laboratories)

Point-of-care (Emergency room or urgent care settings)



As illustrated above we have four categories of advanced diagnostic technologies: 1) molecular testing platforms 2), molecular reagents 3) point-of-care tests and 4) advanced genetic markers.

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1) Molecular Testing Platforms (Instrumentation)

For our customers that need to develop or perform more complex testing than is available with real-time instruments, we have developed the second generation NanoChip®400 system and the Molecular Biology Workstation. These systems are based on our proprietary lab on a chip detection technology that allows testing for multiple gene markers or mutations on one test site. Using our open system architecture, researchers and clinical laboratories can readily develop assays to test multiple genetic mutations for multiple patient samples and to perform them on an automated system.

2) Molecular Reagents (ROU Reagents, ASRs, Custom Assays)

Molecular reagents encompass real-time PCR products and molecular reagents. The real-time products include both custom designed products for the research market and ASRs which are sold to laboratories certified under the Clinical Laboratory Improvement Amendments of 1998 (CLIA) to develop, optimize and validate tests for clinical uses. These products are advanced molecular probes that amplify disease specific genetic sequences for analysis or identification in a simple test with rapid turn around. An advantage of our real-time PCR products is its platform independence providing us a broader market and customer base. In addition, we believe these products provide us name recognition and compliment our current sales and marketing efforts with a wider array of solutions for our customers. The customers for this product line are primarily advanced research and clinical laboratories that test for single markers or mutations in genes. We also offer reagents for more complex testing. These reagents provide capability for laboratories to test a patient sample against multiple targets. We currently offer reagents for the testing of respiratory viruses (RVA) and blood clotting (Factor V/II).

3) Point-of-Care (Test Kits)

Our point-of-care tests consist of highly specific tests for identifying proteins that play a role in specific diseases. By identifying the level of specific proteins present in a patient sample, doctors can more accurately diagnose and monitor the progress of specific diseases. Our researchers are developing diagnostic products that focus on congestive heart failure, stroke and traumatic brain injury. We believe our technologies will help to move many of these tests from the clinical reference lab to the point-of-care settings such as the emergency room. On February 6, 2006, with our acquisition of Spectral's point-of-care assets, we acquired several revenue generating rapid cardiac immunoassay tests that broadened our menu of products available for point-of-care customers. The acquired products include rapid tests for levels of CKMB, Myoglobin and Troponin, all of which are frequently used in cardiac care. In addition, we acquired the ability to manufacture these and other point-of-care products.

In March 2006, we received FDA clearance to begin marketing our plasma based NT-proBNP congestive heart failure product for use on human plasma that may be marketed for use in clinical laboratories. For the larger point of care market, our NT-proBNP congestive heart failure product for use on human whole blood remains under development.

4) Advanced Genetic Markers

With our investment in Jurilab, in 2005, we gained access to a large database of advanced genetic markers created by studying the genetic patterns of a founder population in East Finland. This database provides insights to the correlation of genetic patterns as prognostic indicators of disease. We expect this collaboration to enhance the development and commercialization of our technology platforms by adding proprietary solutions to evaluate and diagnose disease. In addition, we expect to pursue license and royalty opportunities related to technologies that we do not wish to commercialize.

Customers

The customers for our instrumentation, ASRs, reagents and custom assays are university and private 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

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laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988, known as CLIA. All products sold in Europe require CE marking. Our customers in Europe are currently serviced through a distributor network.

Customers for our diagnostics technology and products therefore include:

Advanced research customers (Universities, research facilities, etc.) These customers develop and create tests to detect various single nucleotide polymorphisms (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.

Clinical Laboratories (CLIA certified central laboratories and research 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 and develop and validate their own tests. Ease of use and throughput is important to these customers.

The customers of our point-of-care products are primarily in near patient settings in hospital laboratories and/or emergency rooms. To market and sell to these customers we are required to receive the approval of the FDA through a pre-market application. The point-of-care products we acquired from Spectral, in February 2006, have received FDA clearance and are CE marked for distribution in Europe. Our other point-of-care products currently in development, such as the congestive heart failure product, will require FDA clearance before we distribute the product in the United States and CE marking prior to distribution in Europe.

Products

We generate our product sales revenue with our advanced diagnostic product lines that we categorize as: 1) instrumentation, 2) reagents, 3) custom assays, and 4) test kits.

Instrumentation

Despite recent advances in technology, many molecular testing methodologies are too specialized or inflexible to be used for the varied needs of the diagnostic and research laboratories. 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. We have developed the NanoChip® System to address the needs of the molecular diagnostics customer with an objective to become the preferred platform for development of applications for complex detection of genetic mutations by the clinical or clinical research laboratory. We believe our design is unique in the industry as it offers flexibility to the clinical laboratories to match their testing requirements. For example, our instrumentation systems allow the clinical laboratory customer to determine if it is more commercially effective for them to test for multiple genetic mutations on an individual set of genes, or a specific genetic mutation on multiple sets of individual genes or some combination of both. 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 embedded 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.

Molecular Biology Workstation Introduced in 2000, the Molecular Biology Workstation (MBW) is a semi-automated solution for developing molecular assays in basic and clinical research labs. MBW

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users have created over 200 molecular assays using the blank electronic microarray. This system uses our 100 site NanoChip cartridge.

NanoChip® 400 System Released in 2005 and designed with the clinician in mind, the NanoChip 400 System is a general laboratory automated platform for molecular testing. At the heart of the system is the NanoChip 400 cartridge (400-site cartridge) which provides the multisample and multianalyte reporting capabilities when creating homebrew, clinical tests. This system uses our 400 site NanoChip cartridge.

LifeSign DXpress™ Reader The LifeSign DXpress Reader is a multi-functional portable tabletop camera-based instrument that will be used to read results of in vitro immunodiagnostic assays. This system will be available for sale in connection with the launch of the quantitative CHF test.

iLynx Reader The iLynx reader is a portable system used in conjunction with the tests acquired in connection with the Spectral asset purchase. This system is a qualitative reader with the ability to record useful information relating to the conduct of the tests. In connection with the development of our quantitative CHF test, we will offer the LifeSign DXpress Reader. This product is a multi-functional portable tabletop camera-based instrument that will be used to read results of in vitro immunodiagnostic assays.

Reagents:

We offer the following reagent products to customers for the conduct of molecular tests:

NGEN™ Reagents are reagents designed for use in detecting nucleic acid sequences for specific organisms or genetic mutations. These reagents can be used in connection with PCR amplified patient samples and hybridization detection utilizing fluorescently-labeled probes.

MGB Alert™ Reagents are clinical reagents used for detecting nucleic acid sequences for specific organisms or genetic mutations associated with diseases in a real-time PCR format.

MGB Eclipse® Probe Systems are reagents used in the development of diagnostics or other research applications in a real-time PCR format.

In 2006, we expect to offer DrugMEt™ Reagents, which are a pharmacogenetic test, to be offered through a partnership with Jurilab. These tests are for genotyping Cytochrome P450 and phase II enzymes involved in drug metabolism.

Custom Assays:

Our applications scientists develop products to meet our customers' application needs through two programs:

Assay BlueprintSM is a custom assay development service for laboratory customers that want to quickly and confidently expand multiplexed based applications. Our customers simply provide the samples and the target SNP sequence, and we provide a protocol and a field applications specialist to transfer the optimized test.

MGB Eclipse Online Design is an easy to use on-line service that enables the design and ordering of custom MGB Eclipse® Probes.

Test Kits:

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We are developing a pipeline of potential diagnostic products based on detecting specific proteins that play a role in assisting the diagnosis and monitoring of specific diseases. Our technology is designed to move these

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tests from the clinical reference lab to near patient settings such as the hospital laboratory or emergency room. These tests include:

Cardiac STATus® and Decision Point™ (Spectral point of care products) On February 6, 2006 we acquired several FDA cleared point-of-care products from Spectral that include rapid qualitative tests for CKMB, Myoglobin and Troponin, in individual, tandem and in an all-in-one testing format used in cardiac care.

Nexus D_x (in development) we are developing an immunassay product line useful in the early assessment of acquired brain injuries (stroke, non-inflicted trauma) and inflicted trauma such as Shaken Baby Syndrome.

Nexus DX™ ELISA Test Kits (in development) we are developing research use ELISA test kits for central nervous system diseases such as the early assessment of brain injury.

StatusFirst™ CHF NT-proBNP (in development) is intended for use with the LifeSign DXpress Reader to provide quantitative determination of NT-proBNP levels in human plasma and whole blood. This potential congestive heart failure test allows for efficient triaging of congestive heart failure patients, while providing accurate diagnostic test results. This product will be manufactured by Princeton BioMeditech (PBM).

Our Growth Strategy

We plan to grow our business through both the development and launch of new products as well as through the acquisition of products. The new products we introduced late in 2005 are expected to contribute to revenue during 2006. These products include the second generation NanoChip® 400, ASRs for infectious disease and several real-time ASRs. We are currently in the final stages of developing ASRs to detect the mutations commonly associated with Cystic Fibrosis, expected to be introduced in 2006, and our point-of-care congestive heart failure product. In addition, we will continue to invest in the internal development of new diagnostic products as well as acquire complementary entities or product lines that address large and growing markets.

Molecular Testing Platform

With the development of our second generation molecular testing platform, the NanoChip®400 system, 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. This molecular testing platform was designed with an open architecture to facilitate development of molecular tests by our customers and collaborators, driving the growth in assay development far beyond our internal capacities. We believe the NanoChip®400 System could transform molecular diagnostics by delivering speed, efficiency and accuracy on a robust platform. We seek 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. With each placement of the NanoChip® System, we create a potential source of on-going revenue streams through the sale of our consumables such as the NanoChip® Cartridges, ASRs and other products.

Reagents and Custom Assays

We believe we will increase our revenues by developing proprietary reagents that do not necessarily require our instrumentation. We believe by developing products for both the multiplexed based and real-time formats we will not limit our potential revenue growth to a particular form of technology. In addition, we will continue to supply our research reagents and our customized assay services in support of customer requests.

Test Kits:

FDA-cleared and CE marked test kits are an important component of our growth plans. Our acquisition of the Cardiac STATus® and Decision Point products will provide a basis for growth in point of care testing.

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Emergency rooms and urgent care units represent a significant market for rapid point-of-care testing for cardiovascular and neurological conditions. We are in development of a congestive heart failure test utilizing the NT-proBNP protein, that once fully developed and cleared/approved by the FDA, European and Canadian regulatory authorities will add to our point-of-care product line. We also plan to develop FDA cleared and CE marked kits for multiplex molecular assays. These products will enable us to expand our addressable market beyond the complex CLIA certified laboratories that can use ASRs in testing applications.

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.

Instrumentation:

In 2006, we see a two track approach to the development of our instrumentation platforms. The first approach is to focus on the user interface of our molecular testing platform technology to enable us, in the near future, to submit 510(k) applications for the detection of mutation genes. An example of one of these potential 510(k) applications is for the detection of the Cystic fibrosis Transmembrane Conductance Regulator gene (CFTR). The second approach is to continue focusing on the open format version of the NanoChip400[®] system that allows our customers to tailor its use to their particular requirements. From the open format version of the NanoChip400[®] system we are continually learning new and novel uses of our equipment from our customers and collaborators. In addition, we supply general purpose reagents that allow our customers to develop their own multiplexed assays for genetic or infectious disease detection. This allows us to quickly focus our research and development on providing specific enhancements to our NanoChip400[®] operating system and components in a cost effective manner. We believe that this allows us to meet our customers requirements beyond our original vision of the NanoChip400[®] s capabilities. Also, we continue to work to miniaturize our electronic array technology with the support of several government and privately funded grants.

Identification of genetic and infectious disease

We are also working to increase our menu of advanced molecular reagents that amplify or detect target specific genetic sequences. These advanced molecular reagents consist of our proprietary real time PCR technologies and are sold as ASRs to CLIA certified laboratories for their internal development of highly sensitive assays. We intend to make available reagents for various infectious diseases such as Epstein Barr Virus, Bordetella pertussis, Bordetella parapertussis, and Varicella Zoster Virus. We are working with our customers to develop research applications for gene expression of cancers, genetic diseases and and microRNAs.

Point-of-care

We are currently developing 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 StatusFirst CHF NT-proBNP test in conjunction with a reader will aid physicians in diagnosing patients presenting with CHF symptoms according to class I through IV (NYHA guidelines) and differentiating 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 result in approximately 15 minutes.

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.

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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.

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). Individuals metabolize drugs differently based on the individuals' genetic make up. Certain variations in these genes can result in an inability to process specific categories of drugs, leading 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 differences 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.

Research and Development

As of December 31, 2005, we had 86 full-time employees in research and development. Our research and development expenses were \$22 million in 2005, \$18 million in 2004 and \$18 million in 2003. These research and development expenses have been directed toward developing products in areas where there is a significant opportunity for a return on investment. Most of our research and development has been conducted at our facilities in San Diego California; Bothell Washington; or Toronto, Canada or in collaboration with various partners.

Sales and Marketing

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.

We sell our molecular diagnostic products including our molecular testing platforms, ASRs, and custom assays in the United States through our own direct sales force. As of December 31, 2005, our staff included approximately 52 sales, marketing and technical support representatives. These representatives principally focus on complex 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.

All sales to customers outside the United States are made through distributors or agents. We currently have distributors addressing the European and middle-east markets. In the future, we plan to add additional

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distributors to address the major Asian markets. To support our commercial efforts in Europe, in 2000 we established Nanogen Europe B.V., a limited liability company, in The Netherlands. This wholly-owned subsidiary operates as our primary European sales, marketing and technical support office.

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 catalog probe systems as part of its QuantiTect™ Gene Expression Assays product line.

We have built our own internal services organization. This field service organization provides initial installation of the NanoChip® system, on-going technical support and warranty and maintenance work as needed.

All sales to customers for point-of-care products are made through distributors or agents. We currently have distributors addressing North American, European and Middle East countries. We support the efforts of our distributor in the United States with a direct sales force that calls on hospitals and urgent care facilities. In the future, we plan to add distributors to address the major Asian markets. In North America, initial distribution of the CHF product will be managed by our partner, Princeton BioMeditech or PBM, who will develop a 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 entering 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:

Jurilab

In July 2005, we made an equity investment of approximately \$1.5 million in Jurilab LTD (Jurilab), a Finnish company that has assembled a large database of genetic markers by studying the genetic patterns of a founder population in East Finland. This unique database was constructed over the last twenty years providing novel insights to the correlation of genetic patterns as a prognosticator of disease. Our investment in Jurilab is an example of our desire to add proprietary content on top of our advanced diagnostic tools and thereby create unique solutions to evaluate and diagnose disease. We expect to make another equity investment of approximately \$1.5 million during 2006. The investment agreement provides us with an option to purchase the entire company over the next several years at certain not-to-exceed prices.

Applied Biosystems

Our license agreement with Applied Biosystems Inc. (Applied Biosystems), with the underlying patents expiring at various dates between 2010 and 2015, provided us approximately \$5.6 million in revenues in 2005. After October 1, 2005 our contractual quarterly minimum royalty payments expired and royalties became based on actual sales. In December 2005, we renegotiated our contract with Applied Biosystems to include a royalty agreement with quarterly minimums, additional rights to certain intellectual property and a modification to our manufacturing and know-how transfer agreement.

Although we expect this relationship to continue into the foreseeable future this contract can be terminated with a 180-day notice.

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FasTraQ Inc.

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of a certain future product. In October and December 2005 we amended this letter of agreement. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. Mr. Birndorf abstained from all the discussions and votes regarding FasTraQ at the meetings of our Board of Directors. As a result of these agreements and related amendments we made an initial non-refundable payment of \$500,000 in 2005 to begin the initial development of this product and we will provide FasTraQ an additional \$500,000 in funding through April 2006. In addition, in 2005, we paid \$25,000 to purchase a certain product from them. As of December 31, 2005, \$525,000 had been expensed.

We are also obligated to supply materials at no cost to be used in the development of this technology and pay FasTraQ up to \$500,000 based on meeting certain research milestones.

Princeton BioMeditech (PBM)

Through our SynX acquisition, we were a party to a 2001 development and manufacturing agreement between SynX and PBM to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. As of January 2006, we terminated all of our previous agreements with PBM and replaced them with renegotiated contracts. These new agreements include a manufacturing and distribution agreement and a development agreement. There were no payments between us and PBM associated with entering into these agreements and there were no minimum purchase requirements between the parties.

We agreed to continue the joint development of a point-of-care product that incorporates PBM's proprietary technology, our proprietary reagents and an exclusive license between us and Roche Diagnostics GmbH. PBM is responsible for the development of a reasonably priced instrument and for manufacturing of a CHF test that uses our reagents to determine the amount of target NT-proBNP present in a patient. We will fund 50% of the development cost of the instrument, up to an agreed upon maximum amount. In addition, we are required to develop and manufacture the reagents used in the instrument and supply them to PBM. We are also responsible to conduct the testing of our reagents required to obtain regulatory approval to market them. The parties will share revenues associated with this point-of-care instrument and test with the majority of revenues being allocated to the party responsible for selling, marketing and distributing the instrument and test within a specific geographic territory. Each party will be responsible for its own manufacturing, sales and marketing expenses and both parties are required to provide each other a forecast of expected demand for each others product (reagents or instruments).

We provided PBM with an option to purchase or to receive a nonexclusive license for certain biological markers for the incorporation into a future point-of-care instrument related to congestive heart failure, stroke or traumatic brain injury. We have agreed to negotiate in good faith commercially reasonable terms for such a license or supply arrangement. However, if we are unable to agree upon such terms PBM will pay Nanogen a certain royalty for the use of these markers.

In the year ended December 31, 2005, we ordered and paid approximately \$265,000 for instruments from PBM.

Pharmacogenetics Diagnostic Laboratory

On July 5, 2005, we invested \$400,000 in Pharmacogenetics Diagnostic Laboratory, LLC (PGx) a development stage research and development company. We believe our ownership interest in PGx will provide us with access to technology related to pharmacogenetics. We may increase our aggregate equity investment up to approximately \$500,000 if PGx reaches certain agreed upon milestones.

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Prodesse

In September 2003, we entered into a collaboration agreement with Prodesse, Inc. to develop automated, highly sensitive molecular testing 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, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. Research agreement

In 2000, we 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 we each may contribute, toward our research and development efforts, cash over the period of the agreement. We are 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 our gross NanoChip® Cartridge sales until the liability is paid in full.

In accordance with Statements of Financial Accounting Standards (SFAS) No. 68 *Research and Development Arrangements*, we 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 for the years ended December 31, 2004 and 2003, respectively. We had no revenue under this agreement in the year ended December 31, 2005. Upon receipt of the funds, we recorded 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 for the year ended December 31, 2005 and 2004, respectively. We have 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, we determined to focus our efforts on the development and manufacture of the NanoChip® 400 instrument. Hitachi is responsible for world-wide manufacturing of the NanoChip® system. We are responsible for development of assays and for marketing and sales.

Government Grants

National Institutes of Health (NIH)

The National Institute of Allergy and Infectious Diseases for the 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 March of 2005 we began phase two of this grant and were awarded an additional \$529,000 over a two year period. In May and September 2003, Nanogen was awarded a second and third grant. The second grant is for the development of a dielectrophoretic (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 \$1.5 million over a 4-year period. In July 2005, we were awarded a fourth grant for the diagnosis of Sepsis and community acquired pneumonia for a total of \$2.5 million over five years. Revenue is recognized under these grants as expenses are incurred and totaled \$650,000, \$415,000 and \$188,000 for the years ended December 31, 2005, 2004 and 2003, respectively.

Bill and Melinda Gates Foundation grant

In July 2005, the University of Washington was awarded a \$15.4 million grant from the Bill and Melinda Gates Foundation as lead partner of a consortium to develop a prototype portable device that healthcare workers

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could pack into remote regions to quickly and easily make life-saving diagnoses on such diseases as malaria. Our share over 5 years is expected to be \$3.2 million. This consortium, which includes us, will concentrate of filling the need for an affordable portable device to do point-of-care testing and provide rapid results. Revenue under this grant is recognized as expenses are incurred and totaled \$429,000 in the year ended December 31, 2005.

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 \$154,000 \$747,000 and \$979,000 for the years ended December 31, 2005, 2004, and 2003, respectively. The funding for this grant was completed in the year ended December 31, 2005.

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

Patents and Proprietary Technology Rights

We consider the protection of our proprietary technologies and products to be an important element in the success of our business strategy. In 2005, we were granted 26 U.S. patents bringing our current total to 137 issued U.S. patents and numerous foreign patents expiring at varying dates. In addition, we have a number of pending patent applications filed in the U.S. and abroad. When it is appropriate we pay for rights to third-party intellectual property. In 2005, under our agreements with Applied Biosystems, we have received \$5.6 million and will receive \$1.5 million through the first quarter of 2008. We are evaluating our intellectual property position and may choose to license portions of our patent portfolio in the future, if we believe the terms and conditions are acceptable in relationship to our future product pipeline.

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 new products can be commercialized, our related patents 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

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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 in November 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 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.

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, TM Biosciences 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 the point of care market, there are numerous competitors that offer rapid cardiac tests. In particular, Biosite currently has FDA-cleared tests and a large installed base of customers for cardiac rapid tests including CHF. 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.

Government Regulation

In the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD 's concerns that the NanoChip® systems and certain related ASRs might be construed as a closed system and therefore a medical

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device that requires a pre-market application. We have submitted a written response to the FDA in which we have clarified that these products are not intended to be linked together. We also stated in our written response that we will revise certain of our marketing materials to address the FDA's concerns regarding the labeling and representations of intended use of our products. We have also requested and had a meeting with the FDA to discuss the matter. We believe we had an open and productive discussion with the FDA representatives as to the appropriateness of the labeling of our various products in this highly regulated area. If there is an unfavorable decision in this matter it could delay sales of our NanoChip[®]400 to clinical laboratories in the United States. During 2006, we plan to submit a 510(k) for the NanoChip[®]400 with one or more assays to the FDA for clearance.

For our initial commercial markets, biomedical research market and high complexity CLIA certified laboratories, we believe FDA clearance for our NanoChip[®] System and ASRs are not required prior to marketing. The FDA has recently communicated, however, that certain multiplexed 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 multiplexed device 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 ASR products. We anticipate, however, that the distribution of some or all of the diagnostic products we may develop and seek to commercialize in the future will be subject to regulation in the U.S. and in other countries. In addition to clinical diagnostic markets, we also may pursue forensic, agricultural, environmental, laboratory and industrial applications for our products which may be subject to different government regulation. Aspects of our manufacturing and marketing activities may also be subject to federal, state and local regulation by various governmental authorities.

In the U.S., the FDA regulates, as medical devices, most diagnostic tests and *in vitro* reagents that are marketed as finished test kits and equipment. Pursuant to the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated thereunder, the FDA regulates the preclinical and clinical testing, design, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of our new medical devices that require pre-market authorization until we receive clearance or approval from the FDA, which can be a lengthy, expensive, and uncertain process. Noncompliance with applicable requirements can result in, among other things, warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant premarket clearance (510(k)) or premarket approval (PMA) for devices, withdrawal of marketing clearances or approvals, or criminal prosecution.

In the U.S., medical devices are generally classified into one of three classes (i.e., Class I, II or III) on the basis of the controls deemed necessary by the FDA to reasonably ensure the safety and effectiveness of the product. Class I devices are subject to general controls (e.g., labeling, postmarket controls, Medical Device Reporting and adherence to Quality System Regulations, or QSR). Class II devices are subject to general and special controls (e.g., performance standards, premarket notification and postmarket surveillance). 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

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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 PMA application process is more expensive, burdensome, and lengthy than the 510(k) clearance process. A PMA must establish the performance of the device which typically requires extensive data from clinical trials 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. 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 (RUO) or investigational use only (IUO), 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. Also as a part of the PMA review and approval process which can take up to one year or longer, 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.

After a 510(k) or a PMA is accepted for filing, the FDA begins its review of the submitted information. During this review period, the FDA may 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 the 510(k) clearance or PMA approval.

Manufacturers of medical devices marketed in the U.S. are required to adhere to the QSR requirements (formerly known as 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.

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.

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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 NanoChip400® 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 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 regulatory bodies 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, 2005, we had 235 employees of whom 39 hold Ph.D. degrees and 23 hold other advanced degrees. Approximately 86 are involved in research and development, 60 in operations, manufacturing and quality assurance, 52 in sales and marketing, and 37 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.

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Item 1A. Risk Factors

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, 2005, total approximately \$311.7 million. Moreover, our negative cash flow and losses from operations will continue for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, which could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the molecular testing platform 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, goodwill or other impairment charges, non-cash stock option expenses, 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 new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements various government and private 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.

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, significant 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 amount of revenue we are able to generate;

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;

acquisition(s) or investment(s) into other businesses;

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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 will be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

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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, 2005, we had only a limited product offering that includes real-time PCR products (both custom and proprietary tests), molecular testing platforms (NanoChip® system), ASRs and the point-of-care diagnostic tests for myocardial infarction and drugs of abuse. Our congestive heart failure point of care test remains in development. Our second generation molecular testing platform, the NanoChip® 400, began shipping in October 2005. Most of our ASRs are under development. Our molecular testing platforms, ASRs 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 molecular testing systems at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. These reagent rentals and cost-per-test agreements result in us investing current capital in the cost of an instrument, while revenues recognized and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer.

Lack of market acceptance of our products and technology would harm us.

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.

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 twelve months ended December 31, 2005, we did not incur any charge to reduce our inventory to its net realizable value; however, in the years ended December 31, 2004, 2003, and 2002, we took accounting charges of approximately \$3.7 million, \$908,000 and \$424,000, 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.

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Performance issues with our products may also harm market acceptance of our products and reduce our revenues. During the year ended December 31, 2004, certain clinical laboratories experienced performance issues with our cystic fibrosis analyte specific reagent, CFTR ASR, which negatively impacted our revenue. We are not currently offering our CFTR ASRs for sale in the United States. Although we are developing new reagents for the CFTR ASRs, some of which we expect to launch in 2006, we may not be able to address product issues to the satisfaction of our customers and they may decide to adopt alternative products or may not resume purchases of our CFTR ASRs.

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, licensors, licensees and others. Our success depends in part upon the performance by these collaboration partners and potential collaboration partners of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect, and we may not derive any revenue or other benefits from these arrangements. We do not know whether our collaborations will successfully develop and market any products under our respective agreements. Moreover, some of our collaborators are also researching competing technologies targeted by our collaborative programs.

Our molecular testing systems platforms, including Molecular Biology Workstation and the second-generation NanoChip[®] 400, are manufactured by Hitachi. As such our success in the molecular testing based diagnostics market is largely dependent upon Hitachi's ability to perform under our manufacturing agreement

Through SynX we were a party to a 2001 development and manufacturing agreement between SynX and Princeton BioMeditech Corporation (PBM) to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. As of January 2006, we terminated all of our previous agreements with PBM and superseded them with renegotiated contracts. These contracts include a manufacturing and distribution agreement and a development agreement. We agreed to continue the joint development of a point-of-care instrument that incorporates PBM's proprietary technology, our proprietary reagents and an exclusive license between us and Roche Diagnostics GmbH. PBM is responsible for the development of an instrument that uses our reagents to determine the amount of target NT-proBNP present in a patient. We are required to develop and manufacture the reagents used in the instrument and supply them to PBM who manufacture the test device. We also have to conduct the testing of our reagents required to obtain regulatory approval to market and sell them. As a result, our success in the point-of-care market is dependent in part upon PBM's ability to perform under these agreements.

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.

The transition to new products subjects us to risks and uncertainties including undetected defects or unexpected technical or operational problems which could adversely affect our business.

In October 2005, we announced the release of our second-generation instrument system, the NanoChip[®] 400. Risks inherent in the transition to our second-generation system and other new products we may release in the future include the following:

potential delays in initial shipments of new products;

undetected defects or unexpected technical or operational problems with the new products;

the possibility that new products may erode demand for our current products, including those under reagent rental agreements;

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a decline in sales of our molecular testing instrumentation and as a result a build-up of 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; and

additional costs related to providing customer support and service for both first generation and second generation systems.

The occurrence of any one of the foregoing factors could negatively impact our financial results, delay market acceptance of our products, divert our development resources, or otherwise have an adverse effect on our business.

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, which could result in future non-cash impairment charges such as the \$59 million non-cash goodwill impairment charge recorded in the fourth quarter of 2005;

Difficulties in integration of the operations, technologies, and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;

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

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

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. Further, any additional equity financing, debt financing, or credit facility used for such acquisition may not be on satisfactory terms, and any such financing or facility may place restrictions on our business. 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 the rapid cardiac immunoassay test business of Spectral Diagnostics, of Epoch Biosciences, Inc. or of SynX Pharma Inc. or other acquisitions due to integration and other challenges.

On February 6, 2006, we completed the acquisition of the rapid cardiac immunoassay test business of Spectral Diagnostics (Spectral). In 2004, we completed two significant acquisitions: the acquisition of SynX Pharma, Inc. (SynX) in April 2004 and Epoch Biosciences, Inc. (Epoch) in December 2004. We expect that the Spectral and SynX product lines will accelerate our entry into the point-of-care market. However, we cannot be certain that we will achieve these and other benefits which we currently expect from these acquisitions. The

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process of integrating these and other 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 with those of acquired companies 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, Spectral and SynX are located in Canada and Epoch is located in the state of Washington, and because our facilities in San Diego, California are or may be physically separated from facilities of other companies we acquire, 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 the following:

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;

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, Epoch or Spectral 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.

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

The Financial Accounting Standards Board (FASB) recently issued a revised standard that requires that we record compensation expense in the statement of operations for employee stock options using a fair value method. The adoption of the new standard will have a significant adverse effect on our results of operations, 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 fair value of stock options. As a result, the adoption of the new standard in the first quarter of fiscal 2006 could negatively affect our stock price.

Competing technologies may adversely affect us.

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

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

diagnostic and pharmaceutical companies;

companies developing drug discovery technologies;

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,

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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 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, maintaining and enforcing 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. Budgetary concerns may cause us to not file, or continue, litigation against known infringers of our patent rights, or may cause us not to file for, or pursue, patent protection for all of our inventive technologies in jurisdictions where they may have value.

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 confidentiality 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. In the past, we and the companies we have acquired have received, and may in the future receive, notices claiming infringement from third parties as well as invitations to take licenses under third-party patents which have, in some instances, resulted in litigation, settlement of litigation and our licensing of third party intellectual property rights. In particular, the receipt of infringement notices by us may subject us to costly litigation, divert management resources and result in the invalidation of our intellectual property rights. These claims may require us to pay significant damages, cease production of infringing products, terminate our use of infringing technologies or develop non-infringing technologies. Further, any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-

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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. These actions may also subject us to liability for damages. Although in the past we and the companies we have acquired have succeeded in settling some third party claims concerning alleged infringement of intellectual property rights, which settlements have involved the payment of royalties by us or such companies we have acquired, there can be no assurance that in the future we would be successful in settling such claims. In addition, there can be no assurance that, even if such settlements are achieved, that they would be on commercially reasonable terms or would not otherwise have a material adverse impact on the company's business. We or our collaborative partners may not prevail in an action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

There are many U.S. and foreign patents and patent applications held by third parties in our areas of interest, and we believe that there may be significant other litigation in the industry regarding patent and other intellectual property rights. Additional litigation could result in substantial costs and the diversion of management's efforts regardless of the result of the litigation. Additionally, the defense and prosecution of interference proceedings before the U.S. Patent and Trademark Office, or USPTO, and related administrative proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may in the future become subject to 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 have opposed one allowed European patent granted to Oxford Gene Technology that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. We opposed the grant of that European patent, and Oxford Gene Technology subsequently narrowed its claims. However, we are still opposing such narrower claims before the European Patent Office's Opposition Division. Even if Oxford Gene Technology successfully defends its current, narrower claims, and even if a patent is subsequently granted for such claims, we do not believe that our product will infringe upon such claims. Nonetheless, Oxford Gene Technology may still later assert that some of our products infringe upon its patents that Oxford Gene Technology may obtain from time to time. 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 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 tolling agreement with Oxford Gene pursuant to which the lawsuit was dismissed by Oxford Gene without prejudice. Under the tolling agreement, we are obligated to give Oxford Gene notice if we determine that we desire to commercialize DNA arrays for use in certain assay formats. If that notice is given, we and Oxford Gene are obliged to discuss in good faith for 30 days whether we wish to acquire, and whether Oxford Gene is willing to grant a license under the patent involved in the litigation. If we and Oxford Gene are unable to enter into such a license or other agreement within such 30 days, Oxford is free to re-initiate the litigation.

On June 30, 2005, we gave Oxford Gene notice that we desired to commercialize DNA arrays for use in such assay formats. Oxford Gene is now free to re-initiate the litigation against us under the tolling agreement. 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 clearances and approvals required to manufacture, market and sell our products are uncertain, and our failure to comply with such clearances and approvals could have a material adverse effect on our company.

Unless otherwise exempt, medical devices require FDA approval or clearance prior to marketing in the United States. We believe our currently marketed products, including general laboratory instruments and analyte specific reagents as well as certain of those products we intend to market in the future, other than our CHF test in development and assets we acquired in our Spectral acquisition, are not subject to 510(k) clearance or premarket approval requirements. As a result, to date we have not applied for FDA or any other regulatory approvals or clearances with respect to any of our products other than with respect to our CHF test. Obtaining 510(k) clearance and premarket approval may be time-consuming, expensive and uncertain. The regulatory approval or clearance process required to manufacture, market and sell our existing and future products is currently uncertain. If the FDA or other regulatory authorities assert that our products are subject to 510(k) clearance and premarket approval requirements or other similar procedures, our business may experience incremental costs, increased regulatory risks and production delays. In addition, we could be subject to:

the recall or seizure of our products;

total or partial suspension of the production of our products;

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

substantial delay in the manufacture or sale of our current or future products;

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

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

We received an untitled letter from the FDA on August 12, 2005, regarding the NanoChip[®] Molecular Biology Workstation, the NanoChip[®] Microarray, and certain of our ASRs in which the FDA stated that the Workstation, Microarray, and ASRs appear to be promoted to work together as an integrated system and that there are inconsistencies with the labeling and the representations of the intended use of our products. The FDA further stated that these products as labeled are considered medical devices and subject to the requirements of the premarket approval or clearance process. The FDA requested that we respond within 30 days and indicated that we could request a meeting with the FDA to discuss the matter. We have submitted a written response to the FDA in which we have clarified that these products are not intended to be linked together. We also stated in our written response that we will revise certain of our marketing materials to address the FDA's concerns regarding the labeling and representations of intended use of our products. We have also requested and had a meeting with the FDA to discuss the matter. We believe we had an open and productive discussion with the FDA representatives as to the appropriateness of the labeling of our various products in this highly regulated area.

There can be no assurance that the FDA will agree with our position that with these revisions our products are not subject to 510(k) clearance or the premarket approval process. The FDA may ultimately require, or we may determine it appropriate, to submit our existing or future products to the premarket approval process or the 510(k) clearance process, either of which may be time-consuming, expensive and uncertain. In addition, if we submit our current products to the premarket approval process or the 510(k) clearance process, it is unclear what the impact would be on our products that have been or are being sold without such approvals. We may be allowed to continue to market our current products pending the outcome of the clearance or approval process for each product, but there can be no assurance that the FDA would not require us to withdraw one or more of our products from the marketplace pending receipt of such approvals or clearances.

Furthermore, the FDA could determine that other products we manufacture or sell or intend to manufacture or sell, including the second-generation NanoChip[®] 400, also are subject to the premarket approval process or the

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510(k) clearance process. If the FDA makes any such determination or otherwise disagrees with our position, the FDA could preclude us from manufacturing or shipping the NanoChip® 400 until we have received FDA marketing authorization. The FDA could also revise its definition of analyte specific reagents in a manner that might cause our current or future analyte specific reagents to be subject to the 510(k) clearance process. In addition, the FDA could subject us to any of the penalties described above, including administrative or judicially imposed sanctions and the recall or seizure of our products. Any such result could substantially delay the release of our current and future products. Furthermore, any such result would have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

The regulatory approval process for our products may be expensive, time-consuming and uncertain.

To the extent that our products require FDA or other regulatory approval or clearance prior to marketing, such regulatory approval process may be expensive, time-consuming, uncertain and may prevent us from obtaining or maintaining required approvals for the commercialization of our products, which may have a significant impact on our business. It generally takes at least three to six months from the time of submission or more to obtain 510(k) clearance, but the process may take longer if the FDA requests more data or research. The premarket approval process takes between one and two years from the time of submission. Regulatory clearance or approval of any of our products may not be granted by the FDA or foreign regulatory authorities for several years, if at all. Our failure to obtain required approvals from regulatory authorities could have a material adverse effect on our business, results of operations and financial condition. In other countries, the manufacture or sale of our products may require approval by local government agencies with missions comparable to the FDA's. The process of obtaining any such approval may also be lengthy, expensive and uncertain.

We expect to submit some of our products in the future to the 510(k) clearance process or premarket approval process and, as such, expect to incur significant expenses in order to receive such clearances or approvals. We also cannot predict the likelihood of obtaining such clearances or approvals. The failure to obtain such clearances or approvals could prevent the successful development, introduction and marketing of certain of our products, and could cause the market price for our stock to decline.

In addition, whether or not our products are subject to 510(k) clearance or premarket approval, we are subject to certain FDA regulations covering, among other things, manufacturing, promotions and medical device reporting. For instance, manufacturing facilities are required to adhere to the FDA's current Quality System Regulations, including extensive record keeping and reporting and periodic inspections of our manufacturing facilities. Similar requirements are imposed by foreign governmental agencies. Compliance with these regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full compliance. Failure to comply with such regulations at one of our manufacturing facilities could result in an enforcement action brought by the FDA, which could include withholding the approval of products manufactured at that facility.

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; PBM will manufacture certain of our point-of-care products; and we manufacture our NanoChip® Cartridges, our ASRs, the cardiac product line acquired from Spectral, and most of our other 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.

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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.

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 or PBM'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.

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 NanoChip® 400 as well as our Workstation and other hardware products, and we will rely on another manufacturer for our some of point-of-care products, and such reliance 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 by us. In addition, we have an

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exclusive manufacturing agreement with PBM for the manufacture of certain future point-of-care products, including CHF tests.

Because we are solely dependent on these other companies for the manufacture of these products, any disruption in either of these companies businesses or in our relationship with such companies may have a material adverse effect on our business. To the extent we have adverse developments in our relationship with Hitachi or PBM, or to the extent we develop contractual disputes, it may have an adverse impact on our business, our ability to implement existing products or launch new products. In particular, to the extent we seek to amend, modify or extend or otherwise change aspects of our contractual relationship with either of these parties, we may experience manufacturing delays associated with negotiating the terms of those arrangements and other related complications. If we determine to curtail or terminate our manufacturing relationship with either of these parties, 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. Furthermore, the manufacturing of certain point-of-care products, including CHF tests, depends on certain intellectual property owned by PBM and licensed by PBM from third parties, and we may not be able to manufacture or find an alternative manufacturer of the design of these products without this intellectual property, which would severely impact our point-of-care products.

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 Nanogen products.

As of December 31, 2005, we had 52 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;

political and economic instability, including the war on terrorism; and

difficulties in staffing and managing foreign offices.

In addition, we expect increased costs in 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;

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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 and marketing of our products. In addition, we began a targeted acquisition strategy during 2004, and our due diligence of acquired companies may fail to reveal material risks relating to product liabilities of such companies. 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. We may be required to pay substantial damages in connection with any product liability claims. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations. Further, we may not be able to maintain adequate levels of product liability insurance at reasonable cost or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

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 twelve months ended December 31, 2005, 2004 and 2003, we experienced turnover rates of 17%, 27% and 25%, respectively. Turnover at these rates may continue and, if they continue, may 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. Future layoffs could have an adverse effect on us.

Health care reform and restrictions on reimbursement may adversely affect our business.

In recent years, health care payors as well as federal and state governments have focused on containing or reducing health care costs. We cannot predict the effect that any of these initiatives may have on our business, and it is possible that they will adversely affect our business. Health care cost containment initiatives focused on genetic testing could cause the growth in the clinical market for diagnostic testing to be curtailed or slowed. In

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addition, health care cost containment initiatives could cause pharmaceutical companies to reduce research and development spending. In either case, our business and our operating results would be harmed. In addition, diagnostic testing in clinical settings is often billed to third-party payors, including private insurers and governmental organizations. If our current and future clinical products are not considered cost-effective by these payors, reimbursement may not be available to users of our products. In this event, potential customers would be much less likely to use our products, and our business and operating results could be seriously harmed.

In addition, sales of our future products may depend, in large part, on the availability of adequate reimbursement to users of those products from government insurance plans, managed care organizations and private insurance plans. Physicians' recommendations to use our products may be influenced by the availability of reimbursement by insurance companies and other third-party payors. There can be no assurance that insurance companies or third-party payors will provide coverage for our products or that reimbursement levels will be adequate for the reimbursement of the providers of our products. In addition, outside the United States, reimbursement systems vary from country to country and there can be no assurances that third-party reimbursement will be made available at an adequate level, if at all, for our products under any other reimbursement system. Lack of or inadequate reimbursement by government or other third-party payors for our products could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

asset impairment charges, including goodwill and other intangible assets;

adoption of new stock option expensing rules;

the announcement of issues involving our liquidity;

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that announcement of product development failures;

the announcement of financing or acquisitions that dilutes our equity;

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 molecular testing platforms, ASRs or our other products;

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

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

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purchases by Nanogen pursuant to our stock repurchase program;

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

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

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

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 SEC 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 and quarterly reports on Form 10-Q 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 as of the end of the fiscal year. How companies are maintaining their compliance with these requirements including internal control reforms, if any, to comply with the requirements of Section 404, and how independent auditors are applying these requirements and testing companies' internal controls, remain subject to uncertainty. We

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expect that our internal controls will continue to evolve as our business activities change. In addition, the acquisitions we made during 2004, the acquisition of the rapid cardiac immunoassay test business of Spectral in 2006, and any future acquisitions we make may impact our ability to maintain effective internal controls over financial reporting. Further, if, during any year, our independent auditors are not satisfied with our internal controls over financial reporting, including the internal controls over financial reporting of SynX and Epoch, 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 take some stockholder actions, including the amendment of any of the anti-takeover provisions contained in our certificate of incorporation or amendment of our bylaws.

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 the Nasdaq National Market, 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. Our efforts to comply with these new regulations have resulted in, and are likely to 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 2006 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, to provide for Epoch manufacturing the product for Applied Biosystems. In July 2002 this agreement was further amended to remove

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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. In January 2006, we renegotiated the contract with Applied Biosystems to maintain minimum quarterly payments through December 31, 2006 and convert to actual royalties thereafter. 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 license and royalty revenues in 2006 and future periods. Since the July 2002 and January 2006 amendments, 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.

Although we expect this relationship to continue into the foreseeable future this contract can be terminated with a 180 day 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.

Our relationship with Jurilab subjects us to numerous risk and uncertainties.

In July 2005, we acquired a minority equity interest in Jurilab of approximately 17% and we hold two of Jurilab's four board of director seats. Our relationship with Jurilab subjects us to numerous risk and uncertainties, including:

we have invested approximately \$1.5 million in Jurilab and anticipate investing a similar amount in 2006 and we may lose all of our investment;

we are required to consolidate Jurilab's financial statements with our own and as a result our operating results may be less predictable, subject to significant fluctuation beyond our control and adversely affected by the results of Jurilab;

our relationship with Jurilab may require our management to devote substantial time and resources to Jurilab's business, which may adversely affect our business;

we have the right to acquire Jurilab, and if we exercise this right, it would entail significant risks, which risks would be even more acute because Jurilab is an early stage company; and

in the event we were to acquire Jurilab, we would likely be required to seek additional financing that may not be available to us on acceptable terms, or at all.

Terrorist attacks, war, natural disasters and other catastrophic events may negatively impact aspects of our operations, revenue, costs and stock price.

Threats of terrorist attacks in the United States of America, as well as future events occurring in response to or in connection with them, including, without limitation, future terrorist attacks or threats against United States of America targets, rumors or threats of war, actual conflicts involving the United States of America or its allies, including the on-going U.S. conflicts in Iraq and Afghanistan, further conflicts in the Middle East and in other developing countries, or military or trade disruptions affecting our domestic or foreign suppliers of merchandise, may impact our operations. Our operations also may be affected by natural disasters or other similar events, including floods, hurricanes, earthquakes or fires. Our California and Washington facilities, including our corporate offices and principal product development facilities, are located near major earthquake faults. The potential impact of any of these events to our operations includes, among other things, delays or losses in the delivery of products by us and decreased sales of such products. Additionally, any of these events could result in increased volatility in the United States of America and worldwide financial markets and economies. Also, any of these events could result in economic recession in the United States of America or abroad. Any of these occurrences could have a significant impact on our operating results, revenue and costs and may result in the volatility of the future market price of our common stock.

Table of Contents**Item 1B. Unresolved Staff Comments**

None.

Item 2. Properties

At December 31, 2005, 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	Bothell, Washington	30,000	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 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

We currently are not a party to any material legal proceedings and are not aware of any pending or threatened litigation that would have a material adverse effect on us or our business.

Item 4. Submission of Matters to a vote of Security Holders

No matters were submitted to a vote of security holders during the quarter ended December 31, 2005.

Table of Contents**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, 2005	High	Low
1 st Quarter	\$ 6.98	\$ 3.48
2 nd Quarter	\$ 4.08	\$ 2.66
3 rd Quarter	\$ 4.65	\$ 2.98
4 th Quarter	\$ 3.21	\$ 2.58
Year ended December 31, 2004		
1 st Quarter	\$ 13.20	\$ 6.60
2 nd Quarter	\$ 9.54	\$ 5.39
3 rd Quarter	\$ 7.25	\$ 3.18
4 th Quarter	\$ 7.86	\$ 3.82

As of February 2, 2006 there were approximately 328 stockholders of record of our common stock. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future.

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The selected financial data set forth below has been derived from our audited financial statements. This data should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and notes included in this Annual Report on Form 10-K on pages F-1 through F-40 in this document:

	Years Ended December 31,				
	2005 ⁽¹⁾	2004 ⁽²⁾	2003	2002	2001
	(in thousands, except per share amounts)				
Consolidated Statement of Operations Data:					
Revenues:					
Product sales	\$ 4,544	\$ 2,690	\$ 2,762	\$ 3,384	\$ 2,245
License fees	6,530	490	84	10,844	
Sponsored research		500	1,500	1,355	7,457
Contract and grant	1,470	1,694	2,367	1,596	1,467
Total revenues	12,544	5,374	6,713	17,179	11,169
Costs and expenses:					
Cost of product sales	4,518	5,642	3,176	2,466	1,606
Research and development	22,033	18,117	18,014	21,020	18,597
Selling, general and administrative	23,578	18,232	15,319	20,375	28,932
Impairment charge on goodwill	59,000				
Charge for acquired in-process research and development		3,758			
Impairment of acquired in-process technology rights	167		1,024		
Amortization of purchased intangible assets	1,571				
Total costs and expenses	110,867	45,749	37,533	43,861	49,135
Loss from operations	(98,323)	(40,375)	(30,820)	(26,682)	(37,966)
Interest income, net	864	517	489	2,119	4,390
Other income (loss)	(78)	(221)	(141)	(15)	30
Warrant valuation adjustment	1,026	(74)			
Gain (loss) on sale of investments		(47)	(1,925)	197	116
Gain (loss) on foreign currency transactions	17	1,293	(16)	(21)	22
Minority interest in loss of consolidated subsidiary			1,817	2,156	907
Net loss	\$ (96,494)	\$ (38,907)	\$ (30,596)	\$ (22,246)	\$ (32,501)
Net loss per share - basic and diluted	\$ (1.95)	\$ (1.21)	\$ (1.38)	\$ (1.02)	\$ (1.54)
Number of shares used in computing net loss per share - basic and diluted	49,585	32,203	22,244	21,722	21,091
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 32,379	\$ 51,934	\$ 29,114	\$ 52,729	\$ 67,524
Working capital	30,651	44,999	30,872	53,050	71,516
Total assets	98,081	176,024	43,849	71,360	90,091
Other long-term liabilities and debt obligations, less current portion	14,536	6,065	5,005	4,219	3,430
Accumulated deficit	(311,656)	(215,162)	(176,255)	(145,659)	(123,413)
Total stockholders' equity	\$ 74,495	\$ 157,516	\$ 32,823	\$ 57,393	\$ 74,929

(1) 2005 includes the results of operations of Jurilab since of July 20, 2005, the date of consolidation, which affects comparability of the Selected Financial Data.

(2) 2004 includes the results of operations of SynX and Epoch since 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 in Item 1A. Risk Factors. 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, 2005, 2004 and 2003 in this Annual Report on Form 10-K.

Overview

We were founded on the vision of providing a higher quality of healthcare through advanced diagnostic products. We are strategically anticipating the transformation of medical care as it shifts from reactive to proactive personalized medicine. With this vision, we have focused on developing multiple products that target specific needs within the advanced diagnostic continuum. Our products are bridging the gap between early-stage scientific research and actual clinical practice. We have organized our products into four broad categories based on their particular technologies:

Molecular testing platforms We are a supplier of leading edge proprietary molecular testing platforms that can target a large number of specific genes at once. These instrument platforms are for research and clinical customers dealing with more complex genetic diseases or conditions than can be adequately addressed with traditional real-time PCR molecular testing. These systems, that include the first and second generation NanoChip® systems, are based on our proprietary lab on a chip testing technology. The advantage of these systems is that they allow researchers and clinics to test for diseases or conditions that would require multiple tests using real-time PCR molecular testing into a single test. An example of this is our potential cystic fibrosis test which requires specifically targeting 23 genes sequences into a single test.

Real-time PCR molecular testing We are a supplier of real-time PCR and Analyte Specific Reagents (ASRs) used in research and clinical laboratories. These products are advanced molecular probes that focus on single genetic sequences or mutations in genes that are used as indicators of specific diseases or conditions.

Point-of-care pipeline To fulfill the need of doctors to accurately diagnose specific diseases in the urgent/critical care area, we are developing easy to use tests for identifying protein markers that play a role in diseases. Our researchers are developing products that focus on the diagnoses of congestive heart failure, of stroke and traumatic brain injury. On February 6, 2006, with our acquisition of Spectral's point-of-care assets, we acquired several revenue generating rapid cardiac immunoassay tests that broadened our menu of products available for point-of-care customers. The acquired products include rapid tests for levels of CKMB, Myoglobin and Troponin, all of which are frequently used in cardiac care. In addition we acquired the ability to manufacture these and other point-of-care products.

Advanced genetic markers With our investment in Jurilab in 2005 we gained access to a large database of advanced genetic markers created by studying the genetic patterns of a founder population in East Finland. This database may provide insights to the correlation of genetic patterns as a prognosticator of disease. We expect this technology to feed the development and commercialization of our real-time PCR or molecular testing platforms by adding proprietary solutions to evaluate and diagnose disease. In addition, we expect to pursue license and royalty opportunities related to technologies that we do not wish to commercialize.

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We believe through our technology and product lines we are in a unique position for growth and leadership in a rapidly emerging market. We see a growing capability in the clinical laboratories ability to perform accurate advanced diagnostic testing as a strong validation of our strategy of investing in advanced diagnostic technologies. In addition, the FDA has recently released guidance encouraging the generation of more pharmacogenomics data and molecular diagnostic testing during drug development and clinical trials that should drive demand for our products and technologies.

We are working to achieve a definable path to profitability by focusing on the development of multiple product lines by leveraging organic and acquisitive growth, as well as licensing agreements and partnerships. Each of these product lines targets key areas of the advanced diagnostic market for their revenue and growth potential. We are able to strategically target our product offerings in each market to determine the most profitable approach to revenue generation. In some cases, we seek to capture vertical markets by leveraging our portfolio of genetic markers to create proprietary diagnostic reagents for a specific disease indication and own the instrumentation that uses the reagents. This business model often called the *razor/razor blade* where the sale of the instrument delivers strong aftermarket consumables flow. In other markets we may out-license genetic markers or reagents for *platform independent* instrumentation or diagnostic equipment.

Liquidity: Developments

From commencement of operations in 1993 through 2003 we applied the majority of our resources toward the development of our molecular technology instrumentation (e.g. NanoChip[®] Systems). Beginning in 2004, in addition to our internal research and development, we commenced a targeted acquisitions strategy to acquire product lines through strategic investments or the acquisition of businesses. In 2004, we acquired both our real-time PCR reagents and point-of-care businesses. In 2005, we invested in Jurilab, LTD and in February 2006 we acquired the cardiac test business of Spectral. We will continue to consume cash and have quarterly net losses during the next several years as we manage our products life cycles from the cash consuming early stages to the mature stages where they provide a return on investment.

We have incurred negative cash flows from operations since inception and have an accumulated deficit of \$311.7 million. We believe it is beneficial to maintain a significant amount of cash and short-term investments to ensure we can fund our operations and provide us sufficient leverage to make financing deals that are beneficial to our current stockholders. In addition, we believe that our existing working capital, and our access to financing combined with our current revenues will be sufficient to support our current and planned operations through at least the next twelve months. To continue to have access to financing, in June 2005, we filed a shelf registration statement with the Securities and Exchange Commission that permitted us to raise up to \$60.0 million in registered equity transactions.

In September 2005, under our shelf registration, we issued to institutional investors a combination of approximately 6.8 million shares of common stock and warrants to purchase up to approximately one million shares of common stock exercise price of \$4.00 per share for five years and received gross proceeds of approximately \$20.0 million, or \$18.8 million, net of expenses. In addition, in March 2006, we received approximately \$15 million by issuing to an investor 5,660,377 shares of common stock at \$2.65 per share. Subsequent to this filing, we have an additional \$20.9 million available under the shelf registration statement that could be used to issue some combination of common stock, preferred stock, debt securities or warrants. We assume that we will have the ability to sell a sufficient amount of securities to investors to continue our strategy of expanding our product pipeline by acquiring companies or assets and supporting our on-going internal product development. Without access to financing, on terms acceptable to us, we will have to cease or curtail operations and product development that may materially alter our current business strategy.

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 these sales.

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Product sales: Developments

With our goal of becoming one of the leading suppliers of molecular testing products in the advanced diagnostic market, we have focused on meeting the technology requirements of a large and underserved range of customers in the advance research, clinical laboratory and point-of-care settings. We provide our customers the technology to identify specific molecules (proteins, genes, etc.) role in a disease. In 2005, our real-time PCR reagents and molecular testing product lines were primarily responsible for our product sales revenue. To broaden our market for the NanoChip® system we have strategically developed and released in 2005 a second generation of this instrument, the NanoChip®400 system, to broaden our access to the larger clinical laboratory market and potentially, with regulatory clearance, the point-of-care market.

We have significant product development occurring in all four of our technology areas:

Molecular testing platform pipeline we are focusing on the development of ASRs for our second generation molecular testing system to drive demand for the system. These consumable tests include a variety of tests from identifying specific respiratory viruses to identifying the genes commonly associated with cystic fibrosis.

Molecular Reagents (Reagents, ASRs, custom assays) pipeline we are making significant progress expanding our library of real-time PCR and ASR reagents with broad markets. We will have released several reagents related to herpes simplex viruses 1 & 2 and are finalizing reagents for the pertussis, parapertussis, BK viruses and the VZV virus which is principally for chicken pox or shingles.

Point-of-care pipeline to broaden our menu of point-of-care products on the market, in February 2006, we purchased a point-of-care product line for cardiac testing. One of the FDA approved products we acquired is a point-of-care three-in-one test that tests for levels of CKMB, MI, and a Troponin I which is frequently administered to determine cardiac health. In addition, we acquired an ability to manufacture both the three-in-one test and future point-of-care products. We also have a point-of-care product in development for congestive heart failure test that will detect levels of the protein NT-proBNP. We are uncertain as to the timing of its release as we are required to complete additional testing.

In March 2006, we received FDA clearance to begin marketing our plasma based NT-proBNP congestive heart failure product for use on human plasma which may be marketed for use in clinical laboratories. For the larger point-of care market, our NT-proBNP congestive heart failure product for use on human whole blood remains under development.

Advanced genetic markers We continue to study the database of advanced genetic markers for potential commercialization. In 2005, we also gained access to a large database of advance genetic markers with our investment in Jurilab LTD. This may feed the development of our real-time PCRs or molecular instrument's consumable test suites by adding proprietary solutions to evaluate and diagnose disease.

License fee and royalty income: Developments

Our agreement with Applied Biosystems Inc. (Applied Biosystems) with the underlining patents expiring at various dates between 2010 and 2015 provided us approximately \$5.6 million in revenues in 2005. After October 1, 2005 our contractual quarterly minimum royalty payments expired and became based on actual sales. In January 2006, we renegotiated our contract with Applied Biosystems to maintain quarterly payments through December 31, 2006 and actual royalties thereafter.

Although we expect this relationship to continue into the foreseeable future this contract can be terminated with a 180 day notice.

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In addition, with our growing intellectual property profile of U.S. patents and with our relationship with Jurilab, LTD, we are continuing to evaluate royalty and licensing opportunities and we may choose to license our technology in the future, if we believe the terms and conditions are acceptable.

Contracts and grants: Developments

We fund some of our research and development efforts through contracts and grants awarded by various federal, state and private 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 will offset some of our research and development costs.

The National Institute of Allergy and Infectious Diseases for the National Institutes of Health (NIH) provided us additional funding this year for several grants. In March 2005, we received a grant for a total of \$529,000 over a two-year period to start the second phase of the development of a central micro fluidics based pathogen analyzer. In July 2005, we received a grant for a total of \$1.2 million over four years for the diagnosis of Sepsis and community acquired pneumonia.

In July 2005, the University of Washington received a grant from the Bill and Melinda Gates Foundation as the lead partner of a consortium to develop a portable device that healthcare workers could pack into remote regions to make life-saving diagnoses. Our portion of this grant is anticipated to be approximately \$3.6 million. This consortium, which included us, will concentrate on the development of an affordable portable device to conduct point-of-care testing and provide rapid results. Our portion of the revenue under this grant totaled \$429,000 in the year ended December 31, 2005.

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. At a minimum, we were required to match the Hitachi contribution to our research and development on an annual basis over a ten-year period. In addition, we are required to repay 50% of Hitachi's contributions to research and development with no interest over an indefinite period of time. From the inception of the collaboration agreement with Hitachi through the termination of the agreement in August 2003, we received a total of \$9.8 million in sponsored research funding. Half of this funding was recorded as revenue and the remaining half is 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. At December 31, 2005 we owe approximately \$4.9 million to Hitachi and the repayment amount is determined as 2% of our gross sales of ASRs used on molecular testing platforms.

Acquisitions, investments and goodwill: Developments

We actively and selectively seek to acquire or invest in companies with complementary products and strong intellectual property positions to allow us to penetrate emerging markets. We anticipate using a combination of cash and common stock to purchase future companies or assets.

Spectral Diagnostics Inc. asset purchase

On February 6, 2006 we acquired the rapid cardiac immunoassay point-of-care test business of Spectral Diagnostics Inc. (Spectral). The total purchase price was approximately \$7.8 million that was comprised of \$4.9 million in cash and 975,193 shares of our common stock valued at approximately \$2.9 million on the date of acquisition. In addition, we are required to use our best efforts to register the shares issued in this transaction with the Securities and Exchange Commission within fifteen days of closing of the acquisition. We did not register these shares by this date and there is a cash settlement provision in the asset purchase agreement related to the difference between the closing price of \$3.01 a share and the future closing price of the shares when they

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are registered. If the share price has fallen more than 25% from the February 6, 2006 closing price or \$2.26 a share on the date of registration we maybe required to pay Spectral in cash for the difference. The maximum liability is 837,500 in Canadian dollars. Conversely, if our share price increases more than 25% above the closing price or \$3.76 under certain circumstances Spectral maybe required to refund us cash for the difference between the closing price and the increase in price. The maximum refund is 837,500 Canadian dollars. We have not recorded the value of this cash settlement option on our books as of December 31, 2005 as the purchase price and results of this business's operations will be consolidated within our financial statements beginning February 6, 2006. We will account for this acquisition under the purchase method of accounting and, as of the date of this report, we have not allocated the purchase price to this business's assets.

Jurilab, LTD investment

In July 2005, we invested approximately \$1.5 million in cash into Jurilab LTD (Jurilab) to acquire 16.7% of the outstanding stock and obtain effective control of the board of directors. We anticipate making a second equity investment in Jurilab in 2006. In addition, we have the option to purchase the entire company (in cash or stock) at not-to-exceed prices through December 31, 2007. We believe that this investment strategy is an effective use of our cash, because it provides us approximately two years to evaluate Jurilab's technology for potential commercialization and integration into our product lines before we commit to purchasing the entity.

Based on our analysis of the Jurilab investment agreement we are considered the primary beneficiary under FIN 46R *Consolidation of Variable Interest Entities*. We are the primary beneficiary because Jurilab's equity investment at risk is not sufficient to permit Jurilab to finance its activities without additional support, we have the direct ability through the Board of Directors to make decisions about their activities, and our equity interest is not proportional to the losses we will take from the research and development expenses. In addition, substantially all of Jurilab's activities are conducted on our behalf despite our disproportionate ownership percentage. Therefore, we have consolidated Jurilab's operations into our financial results; however, their creditors have no recourse against us and our maximum exposure to loss is the \$1.5 million we have invested in the entity. Conversely, assets recognized as a result of consolidating do not represent additional assets that could be used to satisfy claims against our general assets.

Included in our consolidated balance sheet at December 31, 2005 were the net liabilities (in thousands) of Jurilab:

	December 31, 2005 (Unaudited)
Cash	\$ 77
Restricted cash	355
Other assets	719
Debt obligations	(7,245)
Other long-term liabilities	(1,018)
Net liabilities	\$ (7,112)

Consolidation of Jurilab's results of operations included the following:

	From July 5, 2005 to December 31, 2005 (Unaudited)
Net sales	\$ 142
Cost of product sales	(100)
Research and development expense	(1,882)
Other income	(80)
Net loss	\$ (1,920)

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Pharmacogenetics Diagnostic Laboratory, LLC

In July 2005, we invested \$400,000 in Pharmacogenetics Diagnostic Laboratory, LLC (PGx), a development stage research and development company, to provide us access to certain technology related to pharmacogenetics. We may increase our investment to an aggregate amount of approximately \$500,000 if PGx reaches certain agreed upon milestones. We conducted a sensitivity analysis that considered both the qualitative and quantitative factors of our initial and potential additional investments in PGx to consider if we should consolidate PGx as a VIE under FIN 46. We did not consider PGx a VIE because we believe it is likely PGx will obtain additional and operating funding from other third parties. Moreover, even if PGx were a VIE, its creditors have no recourse against us and our maximum exposure to PGx's losses is the extent of our investment. Therefore, we will expense PGx's net losses to research and development. Once our investment, which is carried as other long-term assets, is reduced to zero, we will stop recording the results of operations of PGx in our financials. We believe this appropriately reflects the substance of this transaction, which is to fund research and development. For the year ended December 31, 2005 we have expensed \$125,000 of PGx's net losses into research and development.

FasTraQ, Inc.

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of a certain future product. In October and December 2005 we amended this letter of agreement. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. Mr. Birndorf abstained from all the discussions and votes regarding FasTraQ at the meetings of our Board of Directors. As a result of these agreements and related amendments we made an initial non-refundable payment of \$500,000 in 2005 to begin the initial development of this product and we will provide FasTraQ an additional \$500,000 in funding through April 2006. In addition, in 2005, we paid \$25,000 to purchase a certain product from them. As of December 31, 2005, \$525,000 had been expensed.

We are also obligated to supply materials at no cost to be used in the development of this technology and pay FasTraQ up to \$100,000 based on meeting certain research milestones.

Acquisition of SynX Pharma Inc. and Epoch Biosciences, Inc.

As a part of our long-term strategy to build a stronger company with products to serve the advanced diagnostic marketplace, in 2004, we identified SynX Pharma Inc. (SynX) and Epoch Biosciences, Inc. (Epoch) as businesses operating in market niches that were complementary to our existing business. In addition, they provided us the opportunity to broaden our product lines in the proteomics technology pipeline (e.g. point-of-care) and real-time PCR diagnostic markets. Therefore, we acquired SynX and Epoch in all stock transactions on April 21, 2004 and December 14, 2004, respectively.

In these acquisitions we recognized \$96.1 million in goodwill. A factor that led to this goodwill valuation was our belief that we would increase our sales revenue by selling their current and future products with our existing sales and marketing infrastructure. In addition, we believed there were numerous redundant operational and administrative functions, which could be combined within the consolidated company at a cost savings.

We utilized a third party to perform a valuation analysis related to the intangible assets of SynX and Epoch as of their respective acquisition dates. We reviewed the assumptions, calculations and conclusions of this valuation analysis for accuracy and reasonableness. We recognized identified intangible assets in our acquisitions if we could identify an asset from contractual or other legal rights or if the asset is separable from the business. We considered an asset separable if it (a) was capable of being sold, transferred, licensed, rented or exchanged or (b) can be transferred in combination with a related asset or liability. We then identified the intangible assets in SynX and Epoch in the following areas: marketing, customer relationships, artistic creation, contracts and technologies. For technologies acquired, we used the prescribed methodology set forth in SFAS No. 2

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Accounting for Research and Development Expense and FASB Interpretation No. 4 *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method* (Collectively SFAS No. 2) to determine whether a technology was to be classified as completed or as in-process research and development (IPR&D). Pursuant to the above guidelines, we assessed the value and future applications of technology assets to be used in IPR&D projects. We expensed technologies determined to have no alternative future use. Completed technologies were recorded at their fair value and will be amortized over its estimated remaining useful life.

In-process research and development: Developments

We used the prescribed methodology set forth in SFAS No. 2 to determine the technology required to be classified as IPR&D in our SynX and Epoch acquisitions. We determined that we had no IPR&D in our Epoch acquisition. In our SynX acquisition we had IPR&D related to congestive heart failure (CHF), traumatic brain injury (TBI) and diabetes diagnostic products as these applications were determined to be unique to our research and development efforts at the time of the acquisition. To determine the value assigned to the acquired IPR&D we used a third party valuation specialist and we reviewed their calculations and conclusions for reasonableness and accuracy. We began by estimating the expenses required to develop the acquired IPR&D into commercially viable products, estimating the resulting cash flows from the products and discounting the net cash flows to their present values and to reflect the risks associated with the development of the products. The discount rates used ranged from 30% to 40% reflecting the inherent risks involved in launching complex diagnostic products. In addition, these calculations were adjusted to reflect the creation efforts which were made prior to the close of the acquisition. At the time of the acquisition, the CHF product was the closest to completion, and expected to be launched in 2006. The TBI and diabetes products are still in the early stages of the development cycle. Therefore we allocated \$2.7 million in fair value to CHF, \$504,000 in fair value to TBI and \$577,000 in fair value for diabetes diagnostics and as prescribed by FIN 4 the \$3.8 million in IPR&D assets were expensed at the date of acquisition.

The development of medical diagnostic devices is subject to a number of risks, including development, regulatory and marketing risks. There can be no assurance our development stage products will overcome these hurdles and become commercially viable products or gain commercial acceptance. We did not have accurate estimates as to the resources required to launch these products at the time of the acquisition. We fund the development of these products with our working capital. As of December 31, 2005, none of these products has been commercialized.

Goodwill impairment analysis: Developments

In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill and intangible assets with indefinite useful lives. In 2004, using the purchase method of accounting we recorded goodwill with our acquisitions of SynX and Epoch that represented the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets. This goodwill was subject to our quarterly reviews for indicators of impairment.

During our first three quarterly reviews in 2005 there were no material events or changes in circumstances to indicate that the carrying amount of our goodwill might not be recoverable. Therefore, we performed our required annual goodwill impairment testing during the fourth quarter of our fiscal year. We allocated our goodwill assets to our Epoch and SynX reporting units and performed our goodwill testing to determine if the reporting units carrying amount including goodwill was greater than its fair value. To determine the estimated fair value of the reporting units we used a third party to perform a valuation analysis of our reporting units, while we reviewed their assumptions, calculations and conclusions for reasonableness and accuracy. We determined that the carrying amount of the reporting unit that included Epoch was in excess of its fair value. The fair value was based on a combination of the income approach, which estimates the fair value based on the future discounted cash flows, and the market approach, which estimates the fair value based on comparable market

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prices. Under the income approach, we assumed a cash flow period through 2010 with terminal values thereafter, long-term annual revenue growth rates of 5% to 43%, a discount rate of 20% and terminal value growth rates of 5%. We determined that the fair value of the reporting unit related to Epoch was approximately \$26.6 million. Therefore, we incurred a non-cash impairment charge to our goodwill of \$59.0 million, which did not affect our liquidity.

We believe we have taken an appropriate valuation approach to determine the fair value of this goodwill asset; however, because there is no exact method to derive the value of a goodwill asset we had to make significant assumptions as to the ratio of market approach versus a income approach. Had we changed the following assumptions our goodwill asset and related impairment charge would have changed by the following amounts:

Assumption	Market approach	Income approach	Goodwill Valuation	Resulting Goodwill Impairment Charge
Our valuation approach	33%	67%	\$ 26,620,000	\$ 59,000,000
Pure income approach	0%	100%	\$ 15,884,000	\$ 69,776,000
Pure market approach	100%	0%	\$ 49,600,000	\$ 36,000,000

Development and manufacturing agreement with Princeton BioMeditech Corporation (PBM): Developments

Through SynX we were a party to a 2001 development and manufacturing agreement between SynX and Princeton BioMeditech Corporation (PBM) to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. As of January 2006, we terminated all of our previous agreements with PBM and superseded them with renegotiated contracts. These agreements include a manufacturing and distribution agreement and a development agreement. There were no payments between us and PBM associated with entering into these revised agreements and there were no minimum purchase requirements between the parties.

We agreed to continue the joint development of a point-of-care instrument that incorporates PBM s proprietary technology, our proprietary reagents and an exclusive license between us and Roche Diagnostics GmbH. PBM is responsible for the development of a reasonably priced instrument that uses our reagents to determine the amount of target NT-proBNP present in a patient. In addition, PBM is required to obtain the regulatory approval of the instrument and will own these approvals. We will fund a portion of the development cost of the instrument, up to an agreed upon maximum amount. In addition, we are required to develop and manufacture the reagents used in the instrument and supply them to PBM. We also have to conduct the testing of our reagents required to obtain regulatory approval to market and sell them. We will own these regulatory approvals. Further, we will share revenues associated with this point-of-care instrument with the majority of revenues being allocated to the party responsible for selling, marketing and distributing the instrument within a specific geographic territory. Each party will be responsible for its own manufacturing, sales and marketing expenses and both parties are required to provide each other a forecast of expected demand for each others product (reagents or instruments).

We provided PBM with an option to purchase or to receive a nonexclusive license for certain biological markers for the incorporation into a future point-of-care instrument related to congestive heart failure, stroke or traumatic brain injury. We have agreed to negotiate in good faith commercially reasonable terms for such a license or supply arrangement. However, if we are unable to agree upon such terms PBM will pay Nanogen a certain royalty for use of these markers.

In July 2005 we ordered and paid approximately \$265,000 for instruments from PBM.

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FDA regulations: Developments

The FDA requires that many of our micro-array instrumentation ASR consumable test suites and real-time PCR products are to be used only for research purposes or by CLIA-certified laboratories when developing and validating their own diagnostic tests. When we begin to distribute and manufacture products for non-CLIA laboratories and point-of-care customers, we are subject to additional FDA requirements such as pre-market applications. Additionally, some of these same sites and products are intended to comply with certain voluntary quality programs such as ISO 9001 or ISO 13485:2003.

In March 2006, we received FDA clearance to begin marketing our plasma based NT-proBNP congestive heart failure product for use on human plasma which may be marketed for use in clinical laboratories. For the larger point-of-care market, our NT-proBNP congestive heart failure product for use on human whole blood remains under development.

In the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD's concerns that the microarray NanoChip® systems and certain related ASRs might be construed as a closed system and therefore a medical device that requires a pre-market application. We believe that our microarray NanoChip® systems and the related ASRs are independent and are not marketed or intended as a closed system. If there is an unfavorable decision in this matter it could delay sales of our NanoChip®400 to clinical laboratories in the United States. During 2006, we plan to submit the NanoChip®400 with one or more assays to the FDA for clearance.

Other:

Manufacturing:

Except for our custom real time PCR products and specialized manufacturing production businesses, which are make-to-order businesses, we principally manufacture products for inventory and ship products shortly after the receipt of orders, and anticipate that we will continue to do so in the future. We do not currently have a significant backlog and do not anticipate we will develop a material backlog in the near future. In addition, we rely on third-party manufacturers to supply many of our raw materials, product components, and in some cases, entire products.

Hitachi manufactures our NanoChip® systems and we manufacture the majority of our consumable products in our manufacturing facilities in San Diego, California and Bothell, Washington.

In February 2006, we purchased a point-of-care product line from Spectral Diagnostics, Inc. and acquired the ability to manufacture the associated future point-of-care products in our facilities in Toronto, Canada.

Fluctuations:

We anticipate that our results of operations will fluctuate on a quarterly and annual basis and will be difficult to predict. The timing and degree of fluctuations will depend upon several factors, including those discussed under Item 1A-Risk Factors. In addition, the timing of orders from distributors and the mix of sales between our product lines could affect our results of operations. We cannot assure you that we will be able to achieve revenue growth on a quarterly or annual basis.

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 judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of

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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 consider an accounting estimate and policy to be critical if: 1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and 2) changes in the estimate that are reasonably likely to occur from period to period, or the use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. We believe that the following critical accounting policies and assumptions may involve a higher degree of judgment and complexity than others.

Liquidity

We expect that our access to financing, including the March 2006 sale of our common stock at \$2.65 per share for net proceeds of approximately \$14.9 million, combined with our existing capital resources, anticipated product revenues, license fees and contract and grant funding will be sufficient to support our planned operations, at least through the next twelve months. As we continue to consume cash and have quarterly net losses we are required to make significant assumptions about our operating cash requirements and our ability to continue to raise capital to finance our on-going operations. We assume that we will have the ability to sell a sufficient amount of securities to investors to continue our strategy of expanding our product pipeline by acquiring companies or assets and supporting our on-going internal product development. Without access to this financing, on terms acceptable to us, we will have to cease or curtail operations and product development that may materially alter our current business strategy.

Valuation of Goodwill, Intangible Assets and Investments

We have recorded as assets \$37.2 million of goodwill and other intangibles in our December 31, 2005 consolidated financial statements. We used significant estimates and assumptions to determine the value of these assets. In many cases we use a third party to perform a valuation analysis on these assets, while we review their assumptions, calculations and conclusions for reasonableness and accuracy.

We test goodwill for possible impairment on an annual basis. This testing requires that we make judgments to identify our reporting units and significantly effects our valuation analysis. In addition, we test goodwill for possible impairment if events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable. We assess potential impairments to these intangible assets when there is evidence that events or circumstances indicate that the recorded value of an asset (the carrying amount) may not be recovered. These assessments are based on judgments and estimates of the materiality of various on-going events and circumstances related to the asset. Indicators of impairment may include the inability to meet prior revenue estimates, inconsistent operational performance, lack of future potential, or other factors. The estimates and assumptions we use are consistent with our internal planning and there are inherent uncertainties in this assessment process as it is difficult to model all possible future events. 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 or intangible assets. Any resulting impairment loss could have an adverse impact on our results of operations.

Revenue Recognition

We recognize revenue principally from real-time PCR products (both custom and proprietary tests), molecular testing platforms (the NanoChip[®] systems), ASRs, sponsored research, contract and grant agreements and from license and royalty fees for intellectual property. Each element of revenue recognition requires a certain

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amount of judgment to determine if the following criteria have been met: i) persuasive evidence of an arrangement exists; ii) delivery has occurred or services have been rendered; iii) the seller's price to the buyer is fixed or determinable; iv) collectibility is reasonably assured, and v) both title and the risks and rewards of ownership are transferred to the buyer. We are required to make more significant estimates involving our recognition of revenue from license and royalty fees, than from revenue generated from our products sales and contracts and grant agreements. Our license and royalty fees revenue estimates depend upon on our interpretation of the specific terms of each individual arrangement and our judgment to determine if the arrangement has more than one deliverable and how each of these deliverables should be measured and allocated to revenue. In addition, we have to make significant estimates about the useful life of the technology transferred to determine when the risk and rewards of ownership have transferred to the buyer to decide the period of time to recognize revenue. In certain circumstances we are required to make judgments about the reliability of third party sales information and recognition of royalty revenue before actual cash payments for these royalties have been received.

Inventory and related reserves

We have a history of writing down the value of our inventory due to lack of market demand. We have approximately \$3.6 million of finished goods inventory as of December 31, 2005. Given the inherent unpredictability of demand for new product lines, we were required to make significant estimates about the future demand for this inventory. Our estimates of realizable value are based upon our analysis and assumptions including, but not limited to, forecasted sales levels by product, expected product lifecycle, product development plans and future demand requirements. If actual market conditions are less favorable than our forecasts or actual demand from our customers is lower than our estimates, we may be required to record additional inventory write downs. If actual market conditions are more favorable than anticipated, inventory previously written down may be sold, resulting in lower cost of sales and higher income from operations than expected in that period.

Variable Interest Entities

We provide various forms of funding into other entities for business purposes. Examples of these include our investments into Jurilab, FasTraq and PGx. FIN46R *Consolidation of Variable Interest Entities* requires that we make significant assumptions about these entities ability to generate unrelated additional capital funding and/or revenues. In addition, we are required to make assumptions about the intentions of unrelated parties' initial and potential future investments to determine if we are required to consolidate or de-consolidate these entities. If any of these facts, circumstances or assumptions change in the future we maybe required to consolidate or de-consolidate these entities operations.

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, 2005, our valuation allowance was \$135.6 million.

Table of Contents**Results of Operations***Years ended December 31, 2005, 2004 and 2003*Revenues

The following table summarizes our revenues for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Product sales	\$ 4,544	\$ 2,690	\$ 1,854	\$ 2,690	\$ 2,762	\$ (72)
License fee and royalty income	6,530	490	6,040	490	84	406
Sponsored research		500	(500)	500	1,500	(1,000)
Contracts and grants	1,470	1,694	(224)	1,694	2,367	(673)
Total	\$ 12,544	\$ 5,374	\$ 7,170	\$ 5,374	\$ 6,713	\$ (1,339)

Product sales revenue is primarily generated from real-time PCR products (both custom and proprietary tests), molecular testing platforms (NanoChip[®] systems) and ASRs. Product sales revenue grew in 2005 as compared to 2004 and 2003 due to additional revenue generated from real-time PCR products acquired through the acquisition of Epoch in December 2004. Revenue from our first generation molecular testing platform and related consumables fell in 2005 and 2004 by approximately 47% and 14% when compared to 2003 revenue. This was primarily due to price reductions of the first generation molecular testing system in 2005 and 2004 to clear excess inventory. We released the second generation of our molecular testing system, the NanoChip[®]400, in the fourth quarter of 2005. However, we did not generate enough revenue from the new system to offset the prior years price reduction of the first generation system.

The future: The downward trend in sales revenue for the first generation molecular testing platform was primarily due to a lack of a broad menu of ASRs that may be used on the system to drive demand for the system beyond the limited market for the research customer. In 2003, we began to address the much larger clinical diagnostic laboratory market by starting the development of our second-generation molecular testing system, the NanoChip[®]400, which was designed specifically to meet the needs of the clinical diagnostic user. In the fourth quarter of 2005, we released the NanoChip[®]400. Therefore we expect a modest increase in revenue in 2006. Demand for this system will be driven primarily by our future development and commercial acceptance of a menu of reagents that may be run on the NanoChip[®]400. In 2006, we expect a modest increase in revenue from ASRs used to detect genetic sequence of respiratory viruses and cystic fibrosis which should drive demand for the NanoChip[®]400 from the clinical diagnostic laboratory market. However, before we gain commercial acceptance of our ASRs from the clinical diagnostic customer we may require regulatory clearance from the FDA to market the device as a closed system.

We expect growth in revenues from our custom and real-time PCR products as we are making significant progress expanding our library of real-time PCR and ASR reagents with broad markets. In 2006, we plan to release several reagents related to herpes simplex viruses 1 & 2 and are finalizing reagents for the pertussis, parapertussis, BK viruses and the VZV virus which is principally for chicken pox or shingles.

To broaden our menu of point-of-care products on the market, in February 2006, we purchased a point-of-care product line for cardiac testing. These products are now on the market and we should see revenue from these products in the first quarter of 2006. The point-of-care product in development that is closest to commercialization is our congestive heart failure test that will detect levels of the protein NT-proBNP. Although we believe we are currently in the final stages of the development of this product, we are uncertain as to the timing of its release as we are required to receive final FDA clearance for distribution.

License fees include nonrefundable fees generated from the licensing of our technology with third parties. License fees and royalty income increased in 2005 as compared to 2004 and 2003 due to the

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royalty bearing licensing agreement with Applied Biosystems for the TaqMan[®] 5 -nuclease real-time PCR assays. License fees increased in 2004 from 2003 primarily due to contractual minimum royalties from CombiMatrix as a result of a litigation settlement in 2002.

The future: After October 1, 2005 our contractual quarterly minimum royalty payments with Applied Biosystems expired and became based on actual sales. In January 2006, we renegotiated the contract with Applied Biosystems to maintain minimum quarterly payments through December 31, 2006 and actual royalties thereafter. Although we expect this relationship to continue into the foreseeable future this contract can be terminated with a 180 day notice. In addition, with our growing intellectual property profile of 137 U.S. patents and with our relationship with Jurilab, LTD, we are continuing to evaluate royalty and licensing opportunities and we may choose to license our technology in the future, if we believe the terms and conditions are acceptable.

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, state and private 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 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 2005 as compared to 2004 primarily related to revenue generated in 2005 from a Bill and Melinda Gates Foundation grant and two new NIH grants not offsetting the winding down of several contracts entered into in previous years. The decrease in contract and grant revenue in 2004 as compared to 2003 was 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 (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Cost of product sales	\$ 4,518	\$ 5,642	\$ (1,124)	\$ 5,642	\$ 3,176	\$ 2,466

Cost of product sales includes the material, manufacturing labor, overhead costs and inventory impairment charges (inventory reserves) related to our products. In 2005, the cost of product sales primarily included the cost of manufacturing real-time PCR products (both custom and proprietary tests) along with the second generation molecular testing platforms (NanoChip[®] systems) and ASR test suites. In 2005, all sales of our first generation system were excluded from our cost of sales due to the reserves we had taken in 2004. In 2004 and 2003 the cost of product sales primarily related to the first generation

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molecular testing systems and various ASRs. In addition, in 2004 and 2003 we incurred significant inventory reserve expenses of \$3.7 million and \$908,000, respectively, that related to underutilized capacity, excess instrumentation inventory and obsolete components. The increase in reserve expense in 2004 as compared to 2003, related to purchase commitments from Hitachi that lead to a large inventory build up of our first generation molecular testing systems.

The decrease in cost of product sales in 2005 as compared to 2004 related to a \$3.7 million inventory reserve expense in 2004. Without this inventory reserve expense the cost of product sales would have increased in 2005 as compared to 2004. This increase related to incurring a full year of manufacturing cost for real-time ASRs that were acquired in our December 2004 Epoch acquisition. The increase in cost of product sales in 2004 as compared to 2003 related to the \$3.7 million inventory reserve incurred in 2004 as compared to a \$908,000 inventory reserve incurred in 2003. Without these inventory reserves the cost of product sales decreased in 2004 as compared to 2003. This was primarily caused by a lower number of first generation molecular testing system units and ASR sold in 2004.

As of December 31, 2005, 2004 and 2003 we had inventory reserves of \$5.1 million, \$5.9 million and \$2.5 million that primarily related to our first generation molecular testing system. This inventory reserve was accumulated throughout 2004 and 2003 during our quarterly evaluations of anticipated sales for the next twelve months. After our announcement of a second generation molecular testing system in October 2004 and evaluating actual sales during the year, we reserved (expensed) the net remaining carrying value of all first generation molecular testing systems without customer purchase orders as of December 31, 2004. In the year ended December 31, 2005, we sold approximately \$223,000 of first generation molecular testing systems that had been fully reserved. Going forward, future sales of our first generation system are highly uncertain in light of our release of a second generation system in October of 2005. Future sales of the first generation NanoChip® systems, if any, will have a minimal cost of product sales.

The future. We are still in the early stages of the commercialization of our real-time PCR products (both custom and proprietary tests) along with the second generation molecular testing system and ASRs. We are working to build in efficiencies into our manufacturing processes, however we anticipate the second generation molecular testing system will have a lower selling price per unit; therefore, our gross margins will depend on the number of units sold or rented to absorb our fixed capacity costs. We expect to continue to incur significant costs associated with excess production capacity within our manufacturing facilities in 2006 as we work to build demand for our second generation molecular testing system and ASRs.

Research and development expenses (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Research and development	\$ 22,033	\$ 18,117	\$ 3,916	\$ 18,117	\$ 18,014	\$ (103)

Research and development expenses include the costs associated with the development of our technology. In 2005, through our on-going acquisition and development strategy, we have broadened our research and development efforts from focusing solely on the molecular testing platforms, ASRs and real-time PCR products (both custom and proprietary tests), highly specific point-of-care tests for identifying protein markers and advanced genetic markers that are prognosticators of diseases. While these research and development efforts are focused on distinct technology platforms, the knowledge gained researching this technology provides us an advantage developing our suite of advanced medical diagnostic products across all our product lines.

The increase in research and development costs in 2005 as compared to 2004 related to incurring an additional \$3.2 million for a full year of research and development costs associated with our real-time PCR products that we acquired in our Epoch acquisition in December 2004. In addition, we incurred approximately \$1.9 million of research and development costs associated with the September 2005 investment and subsequent consolidation of Jurilab LTD (a variable interest entity). The slight increase in

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research and development costs in 2004 as compared to 2003 was primarily due to cost reductions in 2004 related to the first generation molecular testing system that offset the additional \$3.6 million in costs associated with the development of point-of-care product lines.

The future. As we are in the early stages of our product development life cycles, we expect our research and development expenditures to increase modestly from 2005 levels. We expect to shift our focus from the development of our second generation molecular testing system to developing ASRs to drive demand for the system. In addition, we continue to focus on developing a broader product line of both custom and proprietary tests for our real-time PCR product lines. Also, we will continue to focus on seeking regulatory approval and the commercialization of our point-of-care tests.

Selling, general and administrative expenses (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Selling, general and administrative	\$ 23,578	\$ 18,232	\$ 5,346	\$ 18,232	\$ 15,319	\$ 2,913

Selling, general and administrative expenses include sales and marketing personnel, tradeshow, promotional activities and materials, administrative personnel, legal, other professional expenses and general corporate expenses. The upward trend in selling, general and administrative expenses each year was due to our acquisition strategy where we incurred the incremental costs of managing a broader portfolio of product lines.

The increase in 2005 selling, general and administrative expenses as compared to 2004 primarily related to \$3.9 million in additional expenses due to incurring a full year of SynX and Epoch's selling and administrative costs. In addition, we incurred an additional \$1.2 million for selling and marketing expenses as compared to 2004 that was primarily related to the release of our second generation molecular testing system and the anticipated release of several new products. The increase in expenses in 2004 as compared to 2003 primarily relates to \$1.8 million in additional expenditures related to our acquisition of SynX and the subsequent incremental operating expenses. In addition, we incurred approximately \$450,000 in expenses 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 our then President and Chief Operating Officer.

The future. We expect that our selling, general and administrative expenditures on a percentage basis will trend lower than the increases in our revenue. On a consolidated basis, 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 2006. Expenses may also be further impacted by potential future business combinations or corporate development transactions.

Charges for goodwill, acquired in-process research and development & impairment for acquired technology (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Impairment charge on goodwill	\$ 59,000	\$	\$ 59,000	\$	\$	\$
Charge for acquired in-process research and development	\$	\$ 3,758	\$ (3,758)	\$ 3,758	\$	\$ 3,758
Impairment for acquired technology rights	\$ 167	\$	\$ 167	\$	\$ 1,024	\$ (1,024)

Goodwill is created using the purchase method of accounting for acquisitions and it represents the difference between the acquisition price and the fair value of the identifiable tangible and intangible assets. In 2004, we recognized \$85.6 million and \$10.5 million in goodwill assets related to our

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purchases of Epoch and SynX, respectively. Under the first step of the SFAS 142 analysis we determined our reporting units. We allocated our goodwill assets to our Epoch and SynX reporting units and performed our goodwill testing to determine if the reporting units carrying amount including goodwill was greater than its fair value. To determine the estimated fair value of the reporting units we used a third party to perform a valuation analysis of our reporting units, while we reviewed their assumptions, calculations and conclusions for reasonableness and accuracy. We determined that the carrying amount of the reporting unit that included Epoch was in excess of its fair value. Therefore, we were required to proceed to the second step of the SFAS 142 analysis for the Epoch reporting unit and use the methodology described in SFAS No. 141 *Business Combinations* to determine the fair value of the reporting unit as if we purchased the reporting unit on October 1, 2005. The fair value was based on a combination of the income approach, which estimates the fair value based on the future discounted cash flows, and the market approach, which estimates the fair value based on comparable market prices. Under the income approach, we assumed a cash flow period through 2010 with terminal values thereafter, long-term annual revenue growth rates of 5% to 43%, a discount rate of 20% and terminal value growth rates of 5%. We determined that the fair value of the reporting unit related to Epoch was approximately \$26.6 million. Therefore, we incurred a non-cash impairment charge to our goodwill of \$59.0 million, which did not affect our liquidity.

The future. Annually, we assess potential impairments to goodwill when there is evidence that events or circumstances indicate that the recorded value of an asset (the carrying amount) may not be recovered. These assessments are based on estimates of the materiality of various on-going events and circumstances related to the goodwill asset. Indicators of impairment maybe the assets inability to meet prior revenue estimates, inconsistent operational performance, lack of future potential, or other factors. As of December 31, 2005 we believe we have recorded the fair value of our goodwill on our balance sheet and do not expect any material future charges. However, it is difficult to model all possible future events and 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 remaining goodwill.

We incurred a non-cash charge of \$3.8 million related to the expensing of acquired in-process research and development (IPR&D), related to the SynX acquisition in 2004. The IPR&D asset was expensed at the date of acquisition in accordance with FASB Interpretation No. 4 *Applicability of FASB Statement No.2 to Business Combinations Accounted for by the Purchase Method*. The estimated fair value of \$3.8 million in IPR&D expense was related to \$2.7 million for congestive heart failure (CHF), \$504,000 for traumatic brain injury (TBI) and \$577,000 for diabetes diagnostic products. These products as of the acquisition date in April 2004, had not reached technological feasibility and had no alternative future uses.

The future. The development of these diagnostic products is subject to a number of risks, including development, regulatory and marketing risks. As of December 31, 2005 none of these products has been commercialized; however, our CHF product is closest to commercialization. We do not currently have a schedule for the commercialization of the TBI or diabetes diagnostic products. The primary risk associated with not completing this technology, as anticipated, is the delay in recovery or non-recovery of our investment in this area of research and development. We do not expect to incur any additional charges for acquired IPR&D related to the SynX or Epoch acquisitions. However, if we acquire other companies in the future, we may incur additional material IPR&D expenses. Additional costs associated with the completion of IPR&D projects are recorded as research and development expenses in the period incurred.

The impairment of acquired technology rights relates to the difference of our license agreements assets carrying values and their estimated fair values. In 2005, we recognized \$167,000 of impairment charges related to our inability to utilize certain in-licensed technology rights. In 2003, we decided to restructure certain license agreements and it resulted in a \$1.0 million impairment expense.

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The future. As of December 31, 2005, we have approximately \$9.6 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.

Other income

The following table summarizes our other income for the years ended December 31, 2005, 2004 and 2003 (in thousands):

	Year ended December 31,			Year ended December 31,		
	2005	2004	Difference	2004	2003	Difference
Interest income, net	\$ 864	\$ 517	\$ 347	\$ 517	\$ 489	\$ 28
Other expense	(78)	(221)	143	(221)	(141)	(80)
Warrant valuation adjustment	1,026	(74)	1,100	(74)		(74)
Gain (loss) on sale of investments		(47)	47	(47)	(1,925)	1,878
Gain (loss) on foreign currency translation	17	1,293	(1,276)	1,293	(16)	1,309
Minority interest in loss of consolidated subsidiary					1,817	(1,817)
Total other income	\$ 1,829	\$ 1,468	\$ 361	\$ 1,468	\$ 224	\$ 1,244

Interest income, net

Interest income relates to the interest we receive on our cash, cash equivalents, and short-term investments. Our interest income trended upwards as a result of higher interest rate yields on our investment balances.

Warrant valuation adjustment

As a result of our December 2004 acquisition of Epoch, we assumed warrants for 381,317 shares of our common stock. The warrants have an exercise price of \$8.32 per share and expire in early 2009. If there is a change of control of Nanogen, under certain circumstances the warrants have a provision that allows them to be redeemed for cash based on the Black-Scholes formula. However, the volatility variable in the Black-Scholes formula is limited to the lesser of 50% or our actual historical volatility. Using the methodology prescribed in EITF 00-19, *Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock*, we recorded a current liability for the fair value of the cash redemption portion of the warrants. The liability was measured and recorded in accordance with the terms of the warrant agreements. The valuation of the warrants and the corresponding liability are re-measured quarterly until the warrants are exercised or expire.

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

	December 31, 2005	December 31, 2004
Expected term	3.2 years	4.2 years
Interest rate	4.5%	3.6%
Volatility	50%	50%
Dividends		
Calculated cash redemption value of the warrants	\$ 86,000	\$ 1,039,000

The decrease in the market price of our common stock and other changes in the Black-Scholes formula's variables from December 31, 2004 to December 31, 2005 resulted in a \$1.0 million decrease

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in the value of the warrants. Therefore, we reported \$1.0 million as a warrant valuation adjustment in our statement of operations for the year ended December 31, 2005.

Gain (loss) on the sale of investments

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

Gain on Foreign Currency Translation

In accordance with SFAS No. 52, *Foreign Currency Translation* we recognized a one time gain of \$1.2 million of previously unrealized foreign currency translation gains in 2004. This related to our decision to discontinue all material business activities of Nanogen Recognomics GmbH.

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 a \$5.0 million investment from a minority interest investor. Through 2003, we accounted for the minority interest in the subsidiary's expenditures in the cost and 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, the final minority interest investor's funds were expended.

Liquidity and capital resources*Short-term and long-term liquidity*

The following is a summary of our key liquidity measures as of December 31, 2005, 2004 and 2003 (in thousands):

	December 31, 2005	December 31, 2004	December 31, 2003
Cash and cash equivalents	\$ 6,194	\$ 15,372	\$ 8,550
Short-term investments, available for sale	26,185	36,562	20,564
Total cash and cash equivalents and short-term investment, available for sale	\$ 32,379	\$ 51,934	\$ 29,114
Current assets	\$ 39,701	\$ 57,442	\$ 36,893
Current liabilities	(9,050)	(12,443)	(6,021)
Working capital	\$ 30,651	\$ 44,999	\$ 30,872

Our cash and cash equivalents and short-term investments, available for sale and working capital decreased \$19.6 million and \$14.3 million, respectively, at December 31, 2005 as compared to December 31, 2004. These decreases were due to the early stages of our products' life cycle that requires us to expend cash as we bring our products to market and expand our product pipeline through acquisitions and product development. We believe we will continue to consume cash and have quarterly net losses during the next several years. We have incurred negative cash flows from operations since inception and do not expect to generate positive cash flows to fund our operations until we generate

significant revenues from our product offerings and/or begin generating a return on our intellectual property.

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In June 2005, we filed a shelf registration statement with the Securities and Exchange Commission that allowed us to raise up to \$60.0 million in equity transactions. In September 2005, to continue to fund our commercialization strategy, we received approximately \$18.8 million in cash by issuing to institutional investors a combination of 6.8 million shares of common stock at \$2.94 per share and a million warrants exercisable at \$4.00 per share for five years. We were subject to certain restrictions under the placement agency agreement in our September 2005 offering, which limited our ability to sell additional equity until December 31, 2005 unless it was in connection with merger and acquisition activity. After January 1, 2006 we may raise an additional \$36.0 million by selling some combination of common stock, preferred stock, debt securities or warrants. In March 2006, we received approximately \$15 million in cash by issuing to an investor 5,660,377 shares of common stock at \$2.65 per share. As a result of this transaction we now have available \$21.0 million under our shelf registration statement.

From inception to December 31, 2005, we have financed our operations primarily by:

Issuing our stock

Generating revenues

Obtained cash through our acquisition of Epoch

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 related 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.

Cash provided by (used in) operating, investing and financing activities of the years ended December 31, 2005, 2004 and 2003 is as follows (in thousands):

	December 31, 2005	December 31, 2004	December 31, 2003
Net cash used in operating activities	\$ (34,613)	\$ (29,495)	\$ (25,456)
Net cash provided by (used in) investing activities	\$ 5,404	\$ (13,791)	\$ 15,442
Net cash provided by financing activities	\$ 20,089	\$ 49,971	\$ 8,932

Operating activities

Net cash used in operating activities for the years ended December 31, 2005, 2004 and 2003 primarily related to our net losses and changes in working capital due to the product shipments and payments of liabilities. The net cash used was primarily related to the 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; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio. In addition, in the year ended December 31, 2005 our net loss increased by \$59.0 million that related to a reduction of the fair value of a goodwill asset. However, because this was a non-cash event it did not affect the cash used in operations, therefore we added back the \$59.0 million to our operating activities. The increasing amount of cash used in operations each year related to our acquisition activities and the resulting increase in operating costs that were not offset by increased revenues.

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Investing activities

Net cash provided by investing activities in 2005 and 2003 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.) 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. In 2005, we had approximately \$1.7 million in payments related to our December 2004 acquisition of Epoch. In addition, we paid approximately \$1.8 million of payments, net of cash consolidated related to our strategic investments in to Jurilab, FasTraq and PGx. 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 2005, 2004 and 2003 we used cash to purchase \$1.3 million, \$800,000 and \$1.2 million in property and equipment to support the development of our product lines.

Financing activities

Net cash provided by financing activities in 2005 related to the \$20.0 million gross cash proceeds or \$18.8 million net of expenses by issuing to institutional investors a combination of approximately 6.8 million shares of common stock and a million warrants exercisable at \$4.00 per share for five years. We received an additional \$564,000 from the exercise of employee stock options. Jurilab had approximately \$996,000 in net transactions related to 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 and \$1.3 million in 2004 and 2003, respectively. We received our last payment under this agreement in 2004.

In March 2005, we extended our \$2.0 million December 2003 equipment funding agreement to provide financing for equipment purchases through March 2006. We have approximately \$979,000 in financing available under this equipment funding agreement. In 2005 and 2004 we received \$828,000 and \$486,000, respectively, under this agreement.

Net cash provided by financing activities was offset by payments related to our debt obligations of \$1.0 million, \$846,000 and \$774,000 in 2005, 2004 and 2003, respectively, and the acquisition of treasury stock in 2003.

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).

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At December 31, 2005, our outstanding contractual obligations included (in thousands):

Contractual Obligations & Other Commitments	Total	Payments Due by Period			
		Less Than 1 year	1 to 2 years	2 to 3 years	3 years or more
Debt obligations ^(a)	\$ 1,344	\$ 701	\$ 643	\$	\$
Other long term liabilities ^(b)	4,853				4,853
Operating leases	16,566	2,788	2,892	8,126	2,760
Purchase commitments ^(c)	706	706			
Standby letters of credit ^(d)	1,794				1,794
Jurilab ^(e)	1,500	1,500			
Commitments to fund research and development ^(f)	600	600			
Spectral Diagnostics ^(g)	4,800	4,800			
Total contractual obligations & other commitments	\$ 32,163	\$ 11,095	\$ 3,535	\$ 8,126	\$ 9,407

- (a) We have recorded in our balance sheets debt related to the consolidation of Jurilab, a material VIE, of which we are the primary beneficiary. The liabilities recognized as a result of consolidating the VIE do not represent additional claims on our general assets; rather, they represent claims against the specific assets of the consolidated VIE. Therefore, we have only included debt obligations that represent claims on our general assets.
- (b) In July 2000, we executed a ten-year agreement with Hitachi to develop, manufacture and distribute potential products based on the parties proprietary technologies. At a minimum, we were required to match the Hitachi contribution to our research and development on an annual basis over a ten-year period. In addition, we are required to repay 50% of Hitachi's contributions to research and development with no interest over an indefinite period of time. From the inception of the collaboration agreement with Hitachi through the termination of the agreement in August 2003, we received a total of \$9.8 million in sponsored research funding. Half of this funding was recorded as revenue and the remaining half is 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. At December 31, 2005 we owe approximately \$4.9 million to Hitachi and the repayment amount is determined as 2% of our gross molecular testing system cartridge sales.
- (c) 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, 2005, we had commitments to purchase approximately \$706,000 of NanoChip[®] 400 workstations through April, 2006. Future purchase commitments will be determined based on product demand and inventory levels.
- (d) Payments are not required under the standby letters of credit and expire at various dates and therefore the table above does not reflect payment information over the five year period.
- (e) We may increase our equity investment in Jurilab by approximately \$1.5 million in 2006.
- (f) We entered in to material development agreements with FasTraq (a related party transaction) and PGx that commits us to \$500,000 and \$100,000, respectively, in funding with these entities reach certain contractually defined research and development milestones.

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- (g) On December 19, 2005, we entered into an asset purchase agreement with Spectral Diagnostics Inc. where we will acquire the assets related to its rapid cardiac immunoassay test business during the first quarter of 2006. In addition, we are required to use our best efforts to register the shares issued in this transaction with the Securities and Exchange Commission within two weeks of the transaction. We did not register these shares by this date and there is a cash settlement provision in the asset purchase agreement related to the difference between the closing price of \$3.01 a share and the future closing price of the shares when they are

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registered. If the share price has fallen more than 25% from the February 6, 2006 closing price or \$2.26 a share on the date of registration we maybe required to pay Spectral in cash for the difference. The maximum liability is 837,500 in Canadian dollars. Conversely, if our share price increases more than 25% above the closing price or \$3.76 under certain circumstances Spectral maybe required to refund us cash for the difference between the closing price and the increase in price. The maximum refund is 837,500 Canadian dollars. We have included the maximum liability in this outstanding contractual obligations table.

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

Future Accounting Requirements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for either equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. The statement eliminates the ability to account for share-based compensation transactions, as we do currently, using the intrinsic value method as prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires that such transactions be accounted for using a fair-value-based method and recognized as expenses in our consolidated statement of income. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options and are currently assessing which model we may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the consolidated statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, we will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include modified prospective and modified retroactive adoption options. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS No. 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of Release No. 33-8568, *Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Standard No. 123 (Revised 2004), Share-Based Payment*, that amends the effective date of FAS No. 123R. The effective date of the new standard under these new rules for our consolidated financial statements is January 1, 2006. Adoption of this statement will have a significant impact on our consolidated financial statements as we will be required to expense the fair value of our stock option grants and stock purchases under our employee stock purchase plan rather than disclose the impact on our consolidated net income within our footnotes, as is our current practice.

Net operating loss carryforwards

As of December 31, 2005, we had federal, state and foreign net operating loss, or NOL, carryforwards of approximately \$253.4 million, \$113.3 million and \$25.9 million, respectively, and \$8.7 million and \$5.6 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 continue expiring in 2006, unless utilized, and the

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state tax loss carryforwards will continue expiring in 2006, unless utilized. The federal and state R&D tax credit carryforwards will begin expiring in 2007 unless 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 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 of R&D tax credits to offset taxes payable. However, we do not believe 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.

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. 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 between the date of the transaction and the date of settlement. 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 material inter-company balances, was approximately \$5.2 million at December 31, 2005.

Item 8. *Financial Statements and Supplementary Data*

Our consolidated financial statements as of December 31, 2005 and 2004 and for the three years in the period ended December 31, 2005 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-40.

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

None.

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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, 2005 to ensure that information required to be disclosed 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 significant changes in our internal controls over financial reporting during the fourth quarter ended December 31, 2005 that could significantly affect our disclosure controls and procedures subsequent to the date of the previously mentioned evaluation.

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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, 2005. 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 consolidated variable interest entity, Jurilab LTD. We did not assess the effectiveness of internal control over financial reporting at this entity due to the immateriality of our investment in the entity and the consolidated financial statement amounts of the entity. However, we did assess controls over the recording of amounts related to our investment in Jurilab, LTD in our consolidated financial statements and determined those controls to be effective. Based on this evaluation we believe that, as of December 31, 2005, 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 62 of this Annual Report.

Date: March 16, 2006

/s/ HOWARD BIRNDORF
Howard Birndorf

Chairman and Chief Executive Officer

Date: March 16, 2006

/s/ ROBERT SALTMARSH
Robert Saltmarsh

Chief Financial Officer

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Report of Independent Registered Public Accounting Firm on Internal Control Over Financial Reporting

To The Board of Directors and Stockholders of Nanogen, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Nanogen, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Nanogen, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of 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 Management's Report on 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 Jurilab LTD (Jurilab), a recent investment made by Nanogen, Inc. which was considered a variable interest entity, that was consolidated with the 2005 consolidated financial statements of Nanogen, Inc., and constituted \$1.2 million of total assets and \$7.1 million of net capital deficit as of December 31, 2005 and \$142 thousand and \$1.9 million of revenues and net loss, respectively, for the period from the date of Nanogen, Inc.'s investment through December 31, 2005. Management did not assess the effectiveness of internal control over financial reporting at this entity due to the immateriality of their investment in the entity and the consolidated financial statement amounts. Our audit of internal control over financial reporting of Nanogen, Inc. also did not include an evaluation of the internal control over financial reporting of Jurilab.

In our opinion, management's assessment that Nanogen, Inc., maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, Nanogen, Inc., maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

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We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005 of Nanogen, Inc. and our report dated March 6, 2006, except for the second paragraph of Note 16 as to which the date is March 16, 2006, expressed an unqualified opinion thereon.

/s/ ERNST & YOUNG LLP

San Diego, California

March 6, 2006

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Item 9B. Other Information

Second Amended and Restated Collaboration, License and Supply Agreement

Effective as of December 31, 2005, we entered into an Amendment No. 2 to Second Amended and Restated Collaboration, License and Supply Agreement with Applied Biosystems. Pursuant to the terms of the amendment, Applied Biosystems is to continue minimum quarterly royalty payments through December 31, 2006. The amendment further provides Applied Biosystems with additional rights to intellectual property as well as manufacturing know-how associated with such intellectual property.

2006 Executive Officer Incentive Compensation Plan

On March 13, 2006, the Compensation Committee of our Board of Directors approved the 2006 Executive Officer Incentive Compensation Plan. Under the plan, participants are eligible for incentive compensation, to be paid, at the discretion of our Compensation Committee, in cash, stock or both, based on the achievement of corporate and personal performance goals. The plan establishes the 2006 incentive target compensation (stated as a percentage of base salary) of the participants. Some goals may carry a potential achievement of between 50% and 150% of the incentive target compensation, depending upon the actual performance versus the goal.

All of our executive officers (Howard Birndorf, David Ludvigson, Larry Repress, Rob Saltmarsh and Graham Lidgard) are participants in the plan. The plan establishes an incentive target of 60% and 50% of base salary for Mssrs. Birndorf and Ludvigson, respectively, and 37.5% of base salary for each of Mr. Reppess, Mr. Saltmarsh and Mr. Lidgard. Mssrs. Birndorf, Ludvigson, Repress and Saltmarsh are eligible for incentive compensation under the plan based exclusively on the achievement of the 2006 corporate goals, which consist of revenue targets, EBITDA targets and completion of designated strategic initiatives. Mr. Lidgard's incentive compensation is based in equal part on his achievement of the 2006 corporate goals and on personal goals directly related to his area of responsibility.

A copy of the 2006 Executive Officer Incentive Compensation Plan is filed with this report as Exhibit 10.59 and is incorporated herein by reference.

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 14, 2006 (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.

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Item 13. *Certain Relationships and Related Transactions*

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

Item 14. *Principal Accountant Fees and Services*

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

PART IV

Item 15. *Exhibits 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

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	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, 2005	\$ 176	\$	\$	\$ (106)	\$ 70
Year ended December 31, 2004	\$ 105	\$ 53	\$ 239	\$ (221)	\$ 176
Year ended December 31, 2003	\$ 41	\$	\$ 100	\$ (36)	\$ 105
Inventory reserve for obsolescence					
Year ended December 31, 2005	\$ 5,860	\$	\$	\$ (712)	\$ 5,148
Year ended December 31, 2004	\$ 2,483	\$	\$ 3,746	\$ (369)	\$ 5,860
Year ended December 31, 2003	\$ 2,258	\$	\$ 908	\$ (683)	\$ 2,483

(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.
2.3(29)	Asset Purchase Agreement among Registrant, SynX Pharma, Inc. and Spectral Diagnostics, Inc., dated December 19, 2005.
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 between Registrant and BankBoston, N.A., dated November 17, 1998.
4.3(8)	Amendment No. 1 to Rights Agreement between Registrant and FleetBoston, N.A., dated December 11, 2000.
10.1(21)(A)	Amended and Restated 1997 Stock Incentive Plan of Nanogen, Inc. (the 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.
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, Aventis Research and Technologies Verwaltungs GmbH, dated September 22, 2000. (10.9)

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Exhibit Number	Description of Document
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 Deutschland GmbH, dated June 6, 2003. (10.10)
10.11(5)(+)	Reader, Loader and Cassette Low Cost Engineering and Manufacturing Agreement between Registrant and Hitachi, Ltd., dated as of December 15, 1999.
10.12(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)
10.13(7)(+)	Collaboration Agreement among 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 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 June 3, 2001. (10.2)
10.23(15)(A)	Separation Agreement between Registrant and Kieran T. Gallahue, dated January 2, 2003.
10.24(15)(A)	Separation Agreement between Registrant and Dr. Vance R. White, dated 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 May 21, 2003. (10.30)

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Exhibit Number	Description of Document
10.31(22)(A)	