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

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

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

NONE

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

Common Stock $0.001 par value

Preferred Stock Purchase Rights

(Title of Class)

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

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 x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

YES x NO ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

Indicate by check mark whether the registrant is 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 x 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 x

The aggregate market value of the voting stock held by non-affiliates of the registrant based upon the closing sale price of the common stock on June 30, 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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NANOGEN, INC.

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FORM 10-K

For the Year Ended December 31, 2005

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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

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 s 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.

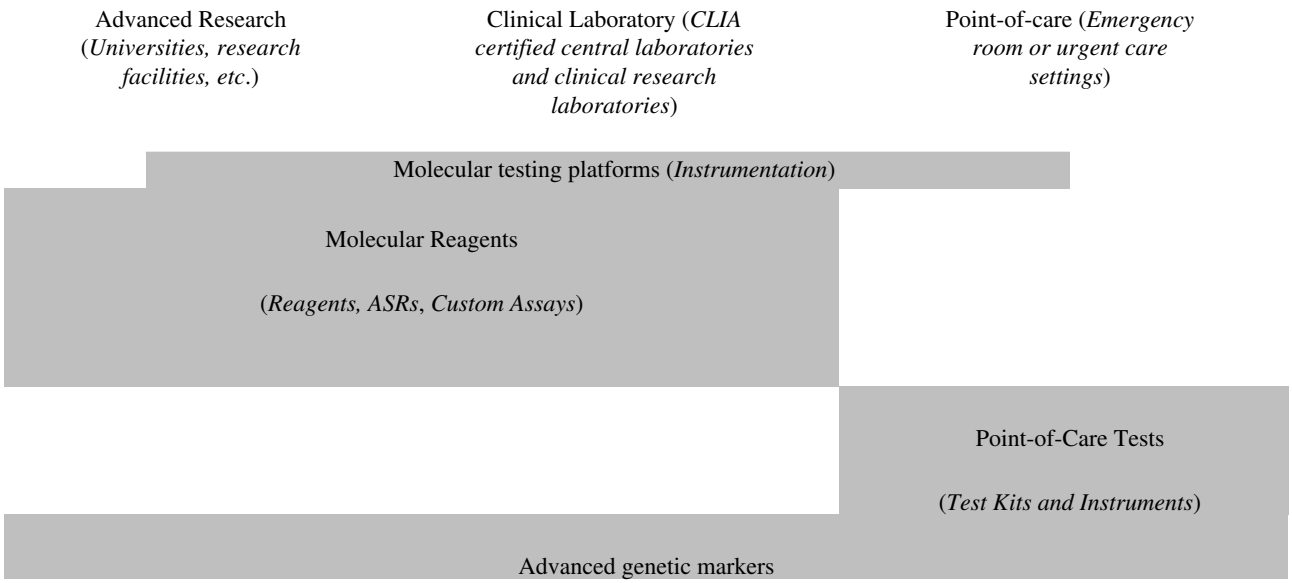
Technology and Customers

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:



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.

i*Lynx 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 Blueprint℠ 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:

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 *Status*First CHF NT-proBNP test in conjunction with a reader will aid physicians in diagnosing patients presenting with CHF symptoms according to class 1 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 *Status*First™ 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 dieletrophorectic (DEP) separator for cell/pathogen separation. The third grant is aimed at developing an on-chip real-time DNA amplification for BWA detection. The total awards of these grants totaled approximately $1.5 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