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NEOGENOMICS INC Form 10-K March 12, 2012 Table of Contents

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# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

### **FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2011

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: 005-54384

# NEOGENOMICS, INC.

(Exact name of registrant as specified in its charter)

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#### Edgar Filing: NEOGENOMICS INC - Form 10-K

Nevada (State or other jurisdiction of

74-2897368 (IRS Employer

incorporation or organization)

**Identification No.)** 

12701 Commonwealth Drive, Suite 9, Fort Myers, FL 33913

(Address of principal executive offices, Zip code)

(239) 768-0600

(Registrant s telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None.

Securities registered pursuant to Section 12(g) of the Act: Common Stock par value \$0.001 per share

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 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 whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer " Accelerated Filer "

Non-accelerated filer " (Do not check if smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): "Yes x No

As of June 30, 2011, the aggregate market value of the registrant s common stock held by non-affiliates of the registrant was approximately \$40.6 million, based on the closing price of the registrant s common stock of \$1.30 per share on June 30, 2011.

The number of shares outstanding of the registrant s Common Stock, par value \$0.001 per share, as of March 8, 2012: 44,835,817

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### NEOGENOMICS, INC.

#### FORM 10-K ANNUAL REPORT

### For the Fiscal Year Ended December 31, 2011

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**Signatures** 

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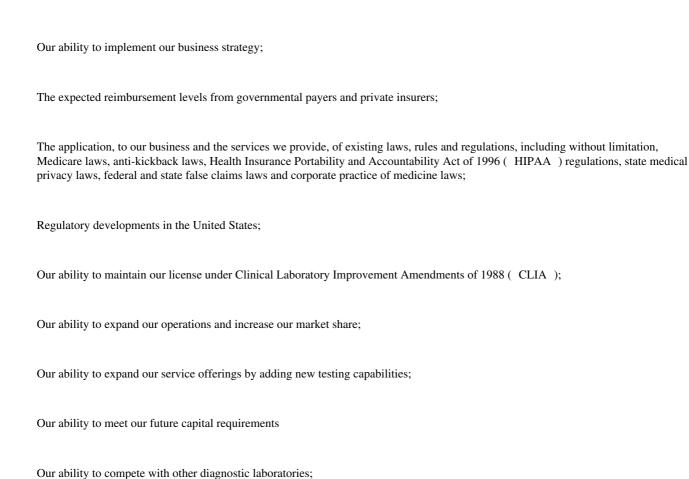
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#### PART I

#### FORWARD-LOOKING STATEMENTS

The information in this Annual Report on Form 10-K contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ), which are subject to the safe harbor created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would an are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve known and unknown risks and uncertainties that could cause our actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, the risks set forth in Part I, Item 1A, Risk Factors in this Annual Report on Form 10-K and in our other filings with the Securities and Exchange Commission.

Forward-looking statements include, but are not limited to, statements about:



Our ability to hire and retain sufficient managerial, sales, clinical and other personnel to meet our needs;

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Our ability to successfully scale our business, including expanding our facilities, our backup systems and infrastructure; and

The accuracy of our estimates regarding reimbursement, expenses, future revenues and capital requirements.

These forward-looking statements represent our management s beliefs and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K, and the documents that we reference in this Annual Report on Form 10-K and have filed as exhibits, completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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#### ITEM 1. DESCRIPTION OF BUSINESS

NeoGenomics, Inc., a Nevada corporation (referred to individually as the Parent Company or collectively with its subsidiaries as NeoGenomics, we, us, our or the Company in this Form 10-K) is the registrant for SEC reporting purposes. Our common stock is listed on the OTCQB Market under the symbol NGNM.

#### Overview

We operate a network of cancer-focused testing laboratories whose mission is to improve patient care through exceptional genetic and molecular testing services. Our vision is to become America s premier cancer testing laboratory by delivering uncompromising quality, exceptional service and innovative products and solutions. The Company has laboratory locations in Ft. Myers and Tampa, Florida; Irvine, California; and Nashville, Tennessee, and currently offers the following types of testing services:

- a) Cytogenetics testing the study of normal and abnormal chromosomes and their relationship to disease. Cytogenetic studies are often utilized to assist in refining treatment options for hematopoietic cancers such as leukemia and lymphoma;
- Fluorescence In-Situ Hybridization (FISH) testing a branch of cancer genetics that focuses on detecting and locating the presence or absence of specific DNA sequences and genes on chromosomes;
- c) Flow cytometry testing a rapid way to measure the characteristics of cell populations. Cells from peripheral blood, bone marrow aspirate, lymph nodes, and other areas are labeled with selective fluorescent antibodies and quantified according to their surface antigens. These fluorescent antibodies bind to specific cell surface antigens and are used to identify malignant cell populations. Flow cytometry is typically performed in conjunction with morphology testing which looks at smears on glass slides for abnormal cell populations;
- d) Immunohistochemistry ( IHC ) testing the process of identifying cell proteins in a tissue section utilizing the principle of antibodies binding specifically to antigens. Specific surface cytoplasmic or nuclear markers are characteristic of cellular events such as proliferation or cell death (apoptosis). IHC is also widely used to understand the distribution and localization of differentially expressed proteins; and
- e) Molecular testing a rapidly emerging cancer diagnostic tool focusing on the analysis of DNA and RNA, as well as the structure and function of genes at a molecular level. Molecular testing employs multiple technologies including point mutation analysis, sequencing analysis, DNA fragment length analysis, and real-time polymerase chain reaction (RT-PCR) RNA analysis.

All of these testing services are widely utilized to inform the diagnosis and prognosis of various types and subtypes of cancer and to help predict a patient s potential response to specific therapies. NeoGenomics offers testing services on both a tech-only basis, where NeoGenomics performs the technical component of the testing (specimen set-up, staining, imaging, sorting and categorization of cells, chromosomes, genes or DNA) and the client physician performs the related professional interpretation component (analyzing the laboratory data, developing the diagnosis or prognosis as well as preparing and writing the final report), as well as on a full service or global basis where NeoGenomics performs both the technical component and the professional interpretation component.

#### **Operating Segment**

We have one reportable operating segment that delivers testing services to hospitals, pathologists, oncologists, other clinicians and researchers. Also, at December 31, 2011, all of our services were provided within the United States and all of our assets were in the United States.

#### **Market Opportunity**

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The medical testing laboratory market can be broken down into three primary segments:

Clinical Pathology testing,

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Anatomic Pathology testing, and

Genetic and Molecular testing.

Clinical Pathology testing covers high volume, highly automated, lower complexity tests on easily procured specimens such as blood and urine. Clinical lab tests often involve testing of a less urgent nature, for example, cholesterol testing and testing associated with routine physical exams.

Anatomic Pathology testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely performed Anatomic Pathology procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies.

Genetic and molecular testing typically involves analyzing chromosomes, genes, proteins and/or DNA/RNA sequences for abnormalities. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically M.D. or Ph.D. level) to certify results and typically yields the highest reimbursement levels of the three market segments.

The field of cancer genetics is evolving rapidly and new tests are being developed at an accelerated pace. Based on medical and scientific discoveries over the last 10 years, cancer testing falls into one of three categories: diagnostic testing, prognostic testing and predictive testing. Of the three, the fastest growing area is predictive testing, which is utilized by clinicians to predict a patient s response to the various treatment options in order to deliver personalized medicine that is optimized to that patient s particular circumstances.

We estimate that the United States market for genetic and molecular testing is divided among approximately 360 laboratories. Approximately two thirds of these laboratories are attached to academic institutions and primarily provide clinical services to their affiliated university hospitals and associated physicians. We believe that the remaining one third of the market is quite fragmented and that less than 20 laboratories market their services nationally. We estimate that the top 20 laboratories account for approximately 50% of market revenues for genetic and molecular testing.

We believe that the key factors influencing the rapid market growth for cancer testing include: (i) cancer is primarily a disease of the elderly one in four senior citizens is likely to develop some form of cancer during the rest of their lifetime once they turn sixty, and now that the baby boomer generation has started to reach this age range, the incidence rates of cancer are rising; (ii) every year more and more genes and genomic pathways are implicated in the development and/or clinical course of cancer; and (iii) increasingly, new drugs are being targeted to certain cancer subtypes and pathways which require companion diagnostic testing. Laboratory tests are needed to identify the type and subtype of cancer and the proper treatment regimen for each individual patient in order to deliver personalized medicine to the patient. These factors have driven explosive growth in the development of new genetic and molecular tests. We estimate a \$10-12 billion total market opportunity for cancer testing in the United States, about \$3-5 billion of which is derived from genetic and molecular testing with the remaining portion derived from more traditional anatomic pathology testing services that are complementary to and often ordered with the genetic and molecular testing services we offer.

#### **Our Focus**

Our primary focus is to provide high complexity, cancer-related laboratory testing services to hospitals, community-based pathology practices, and clinicians throughout the United States. We currently perform analyses for hematopoietic cancers such as leukemia and lymphoma (blood and lymphoid tumors) and solid tumor cancers such as breast, lung, colon, and bladder cancer. For hematopoietic cancers, we typically analyze bone marrow aspirate and peripheral blood specimens. For solid tumor cancers, we typically analyze formalin fixed, paraffin embedded tissue samples or urine.

The cancer testing services we offer to community-based pathologists are designed to be a natural extension of, and complementary to, the services that they perform within their own practices. We believe our relationship as a non-competitive partner to community-based pathology practices empowers them to expand their breadth of testing and provide a menu of services that matches or exceeds the level of service found in academic centers of excellence around the country. Community-based pathology practices typically

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order our services on a tech-only basis, which allows them to participate in the diagnostic process by performing the professional interpretation services without having to make the investment in laboratory personnel or equipment needed to perform the technical component of the tests.

In areas where we do not provide services to community-based pathology practices, we may directly serve oncology, dermatology, urology and other clinician practices that prefer to have a direct relationship with a laboratory for cancer-related genetic and molecular testing services. We typically service these types of clients with a global service offering where we perform both the technical and professional components of the tests ordered. Increasingly, however, larger clinician practices have begun to internalize pathology testing, and our tech-only service offering allows these larger clinician practices to also participate in the diagnostic process by performing the professional interpretation services.

#### **Competitive Strengths**

#### Turnaround Times

We strive to provide industry leading turnaround times for test results to our clients nationwide. By providing information to physicians in a rapid manner, they can begin treating their patients as soon as possible. We believe our average 4-5 day turn-around time for our cytogenetics testing services, our average 3-4 day turn-around time for FISH testing services, and our average 1 day turn-around time for flow cytometry testing services are industry-leading benchmarks for national laboratories. Our consistent timeliness of results is a competitive strength and a driver of additional testing requests by our referring physicians. Quick turn-around times allow for the performance of other adjunctive tests within an acceptable diagnosis window in order to augment or confirm results and more fully inform treatment options. We believe that our rapid turnaround times are a key differentiator of NeoGenomics versus other national laboratories, and our clients often cite them as a key factor in their relationship with us.

#### Medical Team

Our team of medical professionals and Ph.Ds. are specialists in the field of genetics and oncology. Our medical team is led by our Chief Medical Officer, Dr. Maher Albitar, a renowned hematopathologist with extensive experience in molecular and genetic testing. Prior to joining NeoGenomics, Dr. Albitar was Medical Director for Hematopathology and Oncology at the Quest Nichols Institute and Chief R&D Director for Hematopathology and Oncology for Quest Diagnostics. He also served as Section Chief for Leukemia at the University of Texas M. D. Anderson Cancer Center. In addition to Dr. Albitar, we currently employ five full-time M.D.s as our medical directors and pathologists, two Ph.Ds. as our scientific directors and cytogeneticists, and four part-time M.D.s acting as consultants and backup pathologists for case sign out purposes.

#### Extensive Tech-Only Service Offerings

We launched the first tech-only FISH testing services in the United States in 2006, and we currently have the most extensive menu of tech-only FISH services in the country. Indeed, we believe we are the only national laboratory offering tech-only FISH services for hematopoietic cancers in the U.S. We also offer tech-only flow cytometry and immunohistochemistry testing services. These types of testing services generally allow the professional interpretation component of a test to be billed separately from the technical component. Our NeoFISH<sup>TM</sup>, NeoFLOW<sup>TM</sup> and other tech-only service offerings allow properly trained and credentialed community-based pathologists to extend their own practices by performing professional interpretations services, which allows them to better service the needs of their local clientele without the need to invest in the lab equipment and personnel required to perform the technical component of genetic and molecular testing.

Our tech-only services are designed to give pathologists the option to choose, on a case by case basis, whether they want to order just the technical information and images relating to a specific test so they can perform the professional interpretation, or order global services and receive a comprehensive test report which includes a NeoGenomics Pathologist s interpretation of the test results. Our clients appreciate the flexibility to access NeoGenomics medical staff for difficult or complex cases or when they are otherwise unavailable to perform professional interpretations. We believe this innovative approach to serving the

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needs of pathology client s results in longer term, more committed client relationships that are more akin to strategic partnerships. Our extensive tech-only service offerings have differentiated NeoGenomics and allowed us to compete more effectively against larger, more entrenched competitors in our niche of the industry.

#### Global Service Offerings

We also offer a full set of global services to meet the needs of those clients who are not credentialed and trained in interpreting genetic tests and who are looking for specialists to interpret the testing results for them. In our global service offerings, our lab performs the technical component of the tests and our M.D.s and Ph.Ds. provide the interpretation services. Our professional staff is also available for post testing consultative services. These clients rely on the expertise of our medical team to give them the answers they need in a timely manner to help inform their diagnoses and treatment decisions. Many of our tech-only clients also rely on our medical team for difficult or challenging cases by ordering our global testing services on a case by case basis. Our Genetic Pathology Solutions (GPS) report summarizes all relevant case data from our global services on one summary report. When providing global services, NeoGenomics performs both the technical and professional component of the test, which results in a higher reimbursement level.

#### Client Education Programs

We believe we have one of the most extensive client education programs in the genetic and molecular testing industry. We train pathologists how to use and interpret genetic testing services so that they can then participate in our tech-only service offerings. Our educational programs include an extensive library of on-demand training modules, online courses, and custom tailored on-site training programs that are designed to prepare clients to utilize our tech-only services. Each year, we also regularly sponsor seminars and webinars on emerging topics of interest in our field. Our medical staff is involved in many aspects of our training programs.

#### Laboratory Information System (LIS)

We believe we have a state-of-the-art Laboratory Information System ( LIS ) that interconnects our locations and provides flexible reporting solutions to clients. This system allows us to standardize testing and deliver uniform test results and images throughout our network, regardless of the location that any specific portion of a test is performed within our network. This allows us to move specimens and image analysis work between locations to better balance our workload. Our LIS also allows us to offer highly specialized and customizable reporting solutions to our tech-only clients. For instance, our tech-only NeoFISH<sup>TM</sup> and NeoFLOW<sup>TM</sup> applications allow our community-based pathologist clients to tailor individual reports to their specifications and incorporate only the images they select and then issue and sign-out such reports from our system with their own logos at the top. Our customized reporting solution even allows our clients to incorporate test results performed on ancillary tests not performed at NeoGenomics into summary report templates. This feature has been well-received by clients. In May 2011, we obtained the source code to our LIS. This has given us greater control and flexibility over the customized functionality we develop and offer to clients and allows us to make improvements in a more timely manner.

#### National Direct Sales Force

Our direct sales force has been trained extensively in cancer genetic testing and consultative selling skills to service the needs of clients. Our sales representatives ( Territory Business Managers ) are organized into three regions (Northeast, Southeast and West). These sales representatives all utilize Salesforce.com to manage their territories, and we have integrated all of the important customer care functionality within our LIS into Salesforce.com so that our Territory Business Managers can stay informed of emerging issues and opportunities within their regions. As of January 31, 2012, we had twenty Territory Business Managers, one Managed Care Specialist, and three Regional Managers.

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Client Care

Our Customer Care Specialists ( CCS ) are organized by region into territories that service not only our external clients, but also work very closely with and support our sales team. A client receives personalized assistance when dealing with their dedicated CCS because each CCS understands their clients—specific needs. When problems or questions do arise, the CCS is responsible for providing answers to the client. CCS—shandle everything from arranging specimen pickup to managing questions that arise during the test process to delivering test results in order to deliver exceptional services to our clients.

#### Geographic Locations

Many high complexity laboratories within the cancer testing niche have frequently operated a core facility on either the West Coast or the East Coast to service the needs of their customers around the country. We believe our clients and prospects desire to do business with a laboratory with national breadth and a local presence. We have four facilities, two large laboratory locations in Fort Myers, Florida and Irvine, California and two smaller laboratory locations in Nashville, Tennessee and Tampa, Florida. Our objective is to operate one lab with four locations , in order to deliver standardized test results. We intend to continue to develop and open new laboratories or expand our current facilities as market situations dictate and business opportunities arise.

#### Scientific Pipeline

In the past few years our field has experienced a rapid increase in tests that are tied to specific genomic pathways. These predictive tests are typically individualized for a small sub-set of patients with a specific subtype of cancer. The therapeutic target in the genomic pathways is typically a small molecule found at the level of the cell surface, within the cytoplasm and/or within the nucleus. These genomic pathways, known as the Hallmarks of Cancer, contain a target-rich environment for small-molecule anti-therapies. These anti-therapies target specific mutations in the major cancer pathways such as the Proliferation Pathway, the Apoptotic Pathway, the Angiogenic Pathway, the Metastasis Pathway, and the Signaling Pathways and Anti-Signaling Pathways.

As an example, recently the FDA approved a small molecule anti-therapy drug (Xalkori) that targets a mutation in the ALK gene for a small sub-set of patients with Non-Small Cell Lung Cancer (NSCLC). Approximately 50-61% of patients with an ALK gene rearrangement will respond to this therapy. To identify patients eligible for this specific small-molecule therapy, an FDA-approved FISH test that NeoGenomics and certain other laboratories offer, must be performed. This ALK FISH test is considered a companion diagnostic test and it is critical that this test be performed and the patient found to have an ALK mutation before therapy can be administered. Tests such as the ALK FISH test allow our clients to direct individualized treatments to each cancer patient in a timely manner. We are increasingly focused on attempting to develop new predictive tests such as this in our new product development pipeline.

#### Strategic Licensing Agreement with Health Discovery Corp

In January 2012, we entered into a Master License Agreement (the License Agreement ) with Health Discovery Corporation (HDC), pursuant to which we were granted an exclusive worldwide license to utilize HDC s extensive intellectual property portfolio to develop and commercialize laboratory developed tests (LDTs) and other products relating to hematopoietic and solid tumor cancers. HDC owns intellectual property and know-how, including some 84 issued and pending patents related to support vector machine (SVM), recursive feature elimination (SVM-RFE), fractal genomic modeling (FGM) and other pattern recognition technology as well as certain patents relating to digital image analysis, biomarker discovery, and gene and protein-based diagnostic, prognostic, and predictive testing.

Under the terms of the License Agreement, we may, subject to certain limitations, use, develop, make, have made, modify, sell, and commercially exploit products and services in the fields of laboratory testing, molecular diagnostics, clinical pathology, anatomic pathology and digital image analysis relating to the development, marketing, production or sale of any LDTs or other products used for diagnosing, ruling out, predicting a response to treatment, and/or monitoring treatment of any hematopoietic and solid tumor cancers excluding cancers affecting the retina and breast cancer (collectively, the Field ).

The License Agreement allows us to develop and sell any gene, gene-product or protein-based LDTs based on HDC s technology in the Field and provides for sublicensing rights and the assignment of the License Agreement, in whole or in part, in our discretion. The License Agreement further provides us with

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access to certain HDC personnel and consulting resources in the fields of mathematics and in genetic and molecular test development. The licensed technology also includes, among other things, certain tests, algorithms and computer software which have already been developed by HDC. Initially, we intend to focus on developing prostate, pancreatic, and colon cancer LDTs. In addition, we plan to develop interpretation software that will help to automate the analysis of cytogenetics and flow cytometry tests.

Strategic Supply Agreement with Abbott Molecular

In July 2009, we entered into a Strategic Supply Agreement with Abbott Molecular, Inc., a wholly-owned subsidiary of Abbott Laboratories. Under the terms of this agreement, NeoGenomics has the rights to develop and launch three laboratory developed tests based on intellectual property developed and/or licensed by Abbott. We launched the first of these tests in February 2010, a FISH test for the diagnosis of melanoma (called Melanosite<sup>TM</sup>), and we are currently working on other potential new FISH assays under the agreement. In conjunction with the Strategic Supply Agreement, Abbott Laboratories, Inc., the parent company of Abbott Molecular, purchased 3.5 million shares of our common stock, which represented an approximately 8.0% stake in NeoGenomics outstanding common stock at December 31, 2011.

#### **Sales and Marketing**

We continue to grow our testing volumes and revenue due to our investment in sales and marketing. As of January 31, 2012, NeoGenomics—sales and marketing team totaled 41 individuals, including 20 Territory Business Managers (sales representatives), one Managed Care Specialist, three Regional Business Unit Directors (regional managers), six marketing and management professionals and 11 customer care specialists.

Our revenue, requisition and test metrics for the year ended December 31, 2011 and 2010 are as follows:

	FY 2011	FY 2010	% Change
Client Requisitions Received (Cases)	49,235	38,443	28.1%
Number of Tests Performed	76,288	57,332	33.1%
Average Number of Tests/Requisition	1.55	1.49	4.0%
Total Testing Revenue	\$ 43,484,000	\$ 34,371,000	26.5%
Average Revenue/Requisition	\$ 883	\$ 894	(1.2)%
Average Revenue/Test	\$ 570	\$ 600	(4.9)%

We experienced 26.5% year-over-year revenue growth to \$43.5 million in 2011 from \$34.4 million in 2010 as a result of a broad based increase in the number of new clients, including one new client with over 30 locations, and the further penetration of existing clients in 2011. Our average revenue/test decreased approximately 5% to approximately \$570 in 2011 from \$600 in 2010 as a result of: a) an approximately 50% decrease in the average reimbursement for bladder cancer FISH testing as a result of Medicare and several insurance carriers reducing reimbursement beginning in January 2011, b) a 1.75% decrease in reimbursement for all Medicare tests covered under the clinical lab fee schedule which affected all our Cytogenetics and Molecular tests and c) the Medicare servicing agent in the Southeast reduced the maximum allowable number of markers reimbursable for flow cytometry testing in late 2010 and the California Medicare servicing agent followed suit in June 2011.

Within the subspecialty field of hematopathology, our scientific expertise and service offerings allow us to be able to perform multiple tests on each specimen received if ordered by our physician clients. Many physicians believe that a comprehensive approach to the diagnosis and prognosis of blood and lymph node disease to be the standard of care throughout the country. As the average number of tests per requisition changes, the average revenue per requisition changes accordingly.

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#### **Seasonality**

The majority of our testing volume is dependent on patients being treated by hematology/oncology professionals and other healthcare providers. The volume of our testing services generally declines modestly during the summer vacation season, year-end holiday periods and other major holidays, particularly when those holidays fall during the middle of the week. In addition, the volume of our testing tends to decline due to adverse weather conditions, such as excessively hot or cold spells, heavy snow, hurricanes or tornados in certain regions, consequently reducing revenues and cash flows in any affected period. Therefore, comparison of the results of successive periods may not accurately reflect trends for future periods.

#### Competition

The genetic and molecular testing niche of the laboratory testing industry is highly competitive and, given the opportunities in this industry, we expect it to become even more competitive. There has been a high pace of consolidation in the industry in recent years and several large players have entered the market. In late 2010 and early 2011, two of our closest competitors were acquired. General Electric Healthcare Services purchased Clarient, Inc. and Novartis, A.G. purchased Genoptix, Inc. Competitive factors in genetic and molecular testing generally include the reputation of the laboratory, range of services offered, pricing, convenience of sample collection and pick-up, quality of analysis and reporting, medical staff, timeliness of delivery of completed reports (i.e. turnaround times) and post-reporting follow-up for clients.

Our competitors in the United States are numerous and include major national medical testing laboratories, in-house physician laboratories and hospital laboratories. Many of these competitors have greater financial resources and production capabilities. These companies may succeed in developing service offerings that are more effective than any that we have or may develop, and may also prove to be more successful than we are in marketing such services. In addition, technological advances or different approaches developed by one or more of our competitors may render our service offerings obsolete, less effective or uneconomical.

We intend to continue to gain market share by offering industry-leading turnaround times, a broad service menu, high-quality test reports, new proprietary tests, enhanced post-test consultation services, and the personal attention from our direct sales force. In addition, we believe our flexible reporting solutions, which enable clients to report out customized results in a secure, real-time environment, will allow us to continue to gain market share.

#### **Suppliers**

The Company orders its laboratory and research supplies from large national laboratory supply companies such as Abbott Laboratories, Fisher Scientific, Invitrogen, Cardinal Health, Ventana and Beckman Coulter. Other than as discussed below, we do not believe any disruption from any one of these suppliers would have a material effect on our business. The Company orders the majority of its FISH probes from Abbott Laboratories. As a result of Abbott s dominance of this marketplace and the absence of any meaningful competitive alternatives, if there was a disruption in the supply of these probes, and we did not have inventory available, it could have a material effect on our business. This risk cannot be completely offset due to the fact that Abbott has patent protection which limits other vendors from supplying many of these probes.

#### **Dependence on Major Clients**

We currently market our services to pathologists, oncologists, urologists, other clinicians, hospitals and other clinical laboratories. During 2011, we performed 76,288 individual tests. For the years ended December 31, 2011 and 2010, one new client with multiple locations accounted for 11.3% and 1.2% respectively, of total revenue. All others were less than 5% of total revenue individually.

#### Payer Mix

In 2011, approximately 43% of our revenue was derived from Medicare and other Government payers, 29% from commercial insurance companies, 26% from clients such as hospitals and other reference laboratories, 1% from all others including patients, and the remainder in general year-end accruals. In 2010, approximately 46% of our revenue was derived from Medicare and other Government payers, 30% from commercial insurance companies, 23% from clients such as hospitals and other reference laboratories, and 1% from all others including patients and general year-end accruals.

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#### **Trademarks**

The NeoGenomics name and logo has been trademarked with the United States Patent and Trademark Office. We have also trademarked the brand names NeoFISH, NeoFlow, MelanoSITE, and DermFISH.

#### **Number of Employees**

As of December 31, 2011, we had 230 full-time equivalent employees. In addition, 8 other individuals, including 4 pathologists and a Ph.D. cytogenetics director, serve as consultants to the Company on a regular basis. The Company also had 10 temporary contract personnel at December 31, 2011. On December 31, 2010, we had 177 full-time equivalent employees, 8 consultants and 3 temporary contract personnel serving on a regular basis. Our employees are not represented by any union and we believe our employee relations are good.

#### **Government Regulation**

The laboratory business is subject to extensive governmental regulation at the federal, state and local levels. The laboratories are required to be licensed by the states, certified by the federal government to participate in the Medicare and Medicaid programs, and are subject to extensive requirements as a condition of participation in various governmental health benefits programs. The failure to comply with any of the applicable federal and state laws, regulations, and reimbursement guidelines could have a material adverse effect on the Company s business. The applicable laws and regulations, and the interpretations of them, change frequently and there can be no assurance that the Company will not be subject to audit, inquiry, or investigation with respect to some aspect of its operations. Some of the federal and state laws and regulations are described below under Clinical Laboratory Operations, Anti-Fraud and Abuse Laws, The False Claims Act, Confidentiality of Health Information, and Food and Drug Administration .

#### **Clinical Laboratory Operations**

#### Licensure and Accreditation

The Company operates clinical laboratories in Fort Myers and Tampa, Florida, Nashville, Tennessee, and Irvine, California. The laboratories are licensed as required by the states in which they are located. In addition, the laboratories in Fort Myers, Florida and Tennessee are licensed by the State of New York as they accept clinical specimens obtained in New York. All of the NeoGenomics laboratories are certified in accordance with the Clinical Laboratory Improvement Amendments, as amended ( CLIA ). Under CLIA, the U.S. Department of Health and Human Services ( HHS ) establishes quality standards for each category of testing performed by the laboratory. The categories of testing include waived, moderate complexity, and high complexity. NeoGenomics laboratories are categorized as high complexity. Three of the four site locations for NeoGenomics laboratories are also accredited by the College of American Pathologists ( CAP ) and actively participate in CAP s proficiency testing programs for all tests offered by the Company. Our Tampa, Florida facility is a read-only laboratory and therefore, CAP accreditation is not necessary. Proficiency testing programs require the participating laboratories to test specimens that they receive from the testing entity and return the results. The testing entity, conducting an approved program, analyzes the results returned and provides to the Company a quality control report assessing the results. An important component of a quality assurance program is to establish whether the laboratory s test results are accurate and valid.

The federal and state certification and licensure programs establish standards for the operation of clinical laboratories, including, but not limited to, qualifications of personnel and quality control. Compliance with such standards is verified by periodic inspections by inspectors employed by federal and state regulatory agencies and accrediting organizations. The Company has a Quality Assurance team, which is comprised of representatives of all departments of the Company, conducts routine internal surveys and requires corrective action reports in response to the findings.

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Quality of Care

Our mission is to improve patient care through quality cancer genetic diagnostic services. By delivering exceptional service and innovative solutions, we aspire to become America s premier cancer testing laboratory. The quality of care provided to clients and their patients is of paramount importance to us. We maintain quality control processes, including standard operating procedures, controls, performance measurement and reporting mechanisms. Our employees are committed to providing accurate, reliable, and consistent services at all times. Any concerns regarding the quality of testing or services provided by the Company are immediately communicated to NeoGenomics Medical Team, Company management and, if necessary, the Manager for Quality Systems, the Compliance Department or Human Resources Department.

#### Compliance Program

The health care industry is highly regulated and scrutinized with respect to fraud, abusive billing practices, and improper financial relationships between health care companies and their referral sources. The Office of the Inspector General of HHS (the OIG) has published compliance guidance, including the Compliance Program Guidance for Clinical Laboratories in August of 1998, and advisory opinions. The Company has implemented a Compliance Program which is overseen by the Board of Directors. Its objective is to ensure compliance with the myriad federal and state laws, regulations and governmental guidance applicable to our business. Our program consists of training/education of employees and monitoring and auditing Company practices. The Board of Directors has formed a Compliance Committee of the Board which meets regularly to discuss all compliance-related issues that may affect the Company. The Company continuously reviews its policies and procedures as new regulations and interpretations come to light to comply with applicable regulations. The Director of Compliance reports directly to the Compliance Committee.

#### Hotline

As part of its Compliance Program, the Company provides a hotline for employees who wish to anonymously or confidentially report suspected violations of our codes of conduct, policies/procedures, or laws and regulations. Employees are strongly encouraged to report any suspected violation if they do not feel the problem can be appropriately addressed through the normal chain of command. The hotline does not replace other resources available to Employees, including supervisors, managers and human resources staff, but is an alternate channel available 24 hours a day, 365 days a year. The hotline forwards all reports to the Director of Compliance who is responsible for investigating, reporting to the Compliance Committee, and documenting the disposition of each report. The hotline forwards any calls pertaining to the financial statements or financial issues to the Chair of the Audit Committee. The Company does not allow any retaliation against an employee who reports a compliance related issue.

#### **Anti-Fraud and Abuse Laws**

The federal laws governing Medicare, Medicaid, and other federal health benefits, as well as other state and federal laws, regulate certain aspects of the relationships between health care providers, including clinical laboratories, and their referral sources, including physicians, hospitals, other laboratories, and other entities. The federal anti-kickback laws, referred to as the Medicare and Medicaid Anti-Fraud and Abuse Amendments to the Social Security Act (the Anti-Kickback Statute ), prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration, either directly or indirectly, in return for, or to induce: (i) the referral of an individual for a service for which payment may be made by Medicare and Medicaid or other federal health benefit programs; or (ii) the purchasing, leasing, ordering or arranging for, or recommending the purchase, lease or order of, any service or item for which payment may be made by Medicare, Medicaid or other federal health benefit programs. Violations of federal anti-kickback laws and regulations are punishable as a felony, by civil money penalties, and exclusion from participation in Medicare, Medicaid and other federal health benefit programs. Most states have similar laws with both criminal and civil penalties.

Because of the broad proscriptions of the Anti-Kickback Statute, subsequent federal law required the HHS to publish regulations to guide the health care community in structuring relationships that would not violate the law. The OIG published regulations outlining certain categories of relationships between health

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care providers and persons or entities that may have a referral relationship that would be deemed not to violate the Anti-Kickback Statute. These regulations are known as the Safe Harbor Regulations (the Safe Harbor Regulations) because persons who enter into transactions that comply with all of the criteria for an applicable safe harbor will not be subject to prosecution under the Anti-Kickback Statute. The Safe Harbor Regulations are narrowly drafted to avoid inadvertently immunizing prohibited conduct. A relationship or transaction that does not meet all of the criteria of an applicable Safe Harbor Regulation is not deemed to be illegal. Rather it may be subject to additional scrutiny. The Company endeavors to comply with the Safe Harbor Regulations, but there can be no assurance that the Company would not be subject to investigation and, if investigated, that relationships could be found not to comply with the Safe Harbor Regulations.

#### **Medicare Payment Guidelines**

The Company has various billing arrangements with its clients and with third party payers, including the Medicare program. The Company may perform the entire test and render a professional interpretation in which case the Company would bill globally, for both the technical and professional components, either directly to the payer or to the client. Alternatively, the Company may perform the technical component of the test only and either bill the payer directly or bill the client. Client billing arrangements are priced competitively at fair market value. These client billing arrangements may implicate the prohibition of the Medicare program against charging the Medicare or Medicaid programs fees substantially in excess of the Company s usual and customary charges. These billing arrangements may also implicate the federal Stark Law and the federal and state anti-kickback statutes.

Federal law authorizes the Secretary of HHS to suspend or exclude providers from participation in the Medicare and Medicaid programs if they charge Medicare or state Medicaid programs fees—substantially in excess—of their—usual charges. The OIG has stated in commentary to various final and proposed regulations its position that this statute has limited applicability to the current Medicare reimbursement system which either mandates prospective payment or provides for services to be reimbursed based on a fee schedule. The OIG indicated, in the Federal Register of September 2, 1998, that it would expect the statutory authority to exclude providers based on a determination that their fees were substantially in excess of their usual charges would—have declining relevance within the Medicare reimbursement system. However, in the Federal Register of September 15, 2003, the OIG requested, in a Notice of Proposed Rule-Making, comments as to whether any services reimbursed under the physician fee schedule should be subject to these regulations. The OIG further stated that—we note that ancillarly services, such as laboratory tests and drugs, would remain subject to these regulations, even when furnished by physicians [F.R., Vol. 68, No. 178, September 15, 2003 at 53940].

In several Advisory Opinions, the OIG has provided additional guidance regarding the possible application of this law, as well as the applicability of the anti-kickback laws to pricing arrangements. The OIG concluded in an Advisory Opinion issued in 1999 [OIG Advisory Opinion No. 99-13] that an arrangement under which a laboratory offered substantial discounts to physicians for laboratory tests billed directly to the physicians could potentially trigger the substantially in excess provision and might violate the anti-kickback law, because the discounts could be viewed as being provided to the physician in exchange for the physician s referral to the laboratory of non-discounted Medicare business, unless the discounts could otherwise be justified.

The Centers for Medicare and Medicaid Services promulgated, in 2009, a revision to the regulation that prohibits the mark up of purchased diagnostic services [42 C.F.R. §414.50] (the Anti-Markup Rule ). The Anti-Markup Rule prohibits a physician or other supplier from marking up the price paid for the technical or professional component of a diagnostic test that was ordered by the billing physician or supplier and which was performed by a physician who does not share a practice with the billing physician or supplier. The billing physician is prohibited from billing the Medicare program an amount greater than the lesser of: (i) the performing supplier s net charge to the billing physician; (ii) the billing physician s actual charge; or (iii) the fee schedule amount for the test that would be allowed if the performing supplier billed directly.

In light of the various federal regulations and guidance from the OIG, the Company endeavors to price its products competitively while endeavoring to meet applicable statutes and regulations.

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#### **Physician Self-Referral Laws**

The federal law referred to as the Stark Law , named after Rep. Fortney Pete Stark, prohibits physicians who have a financial relationship with an entity from referring Medicare and Medicaid patients to that entity for the provision of designated health services unless the transaction meets an exception to the law. The Company is subject to the Stark law in that laboratory services are classified as a designated health service. The prohibited financial relationships include investment and compensation arrangements.

Some states in which the Company is engaged have enacted similar physician self-referral laws. For example, the Florida Patient Self-Referral Act of 1992, as amended, (the Act ) is similar to the Stark law, but is narrower in some respects and broader in others. Clinical laboratory services are similarly classified as a designated health service in the Act. But, the Act applies to investment interests, and, unlike the Stark Law, does not address compensation arrangements. The penalties for a violation of the Act include forfeiture of all payments received, civil money penalties, and disciplinary action by the applicable licensing board.

The Stark Law is a *per se* statute in that intent to violate the statute, unlike the Anti-Kickback Statute, is immaterial. A violation of the Stark Law renders any reimbursements improper and requires the provider to forfeit any funds received in violation of the Stark Law. In addition a violation of the Stark Law exposes the parties to civil and criminal penalties. The Company endeavors to structure its financial relationships in compliance with the Stark Law and with similar state physician self-referral laws.

#### **The False Claims Act**

The Federal False Claims Act prohibits any person or entity from knowingly presenting, or causing to be presented, to the U.S. government, or to a Medicare program contractor, a false or fraudulent claim for payment, or knowingly making or using a false record or statement to have a false claim paid by the government, or conspiring to defraud the U.S. government, or knowingly making or using a false statement to conceal and obligation to pay the government. A violation of the Federal False Claims Act is punishable by a civil penalty of \$5,500 to \$11,000 plus three times the amount of damages. Private parties may bring an action on behalf of the U.S. Government by filing a *qui tam* case. The private party, called a relator, is entitled to a share of the proceeds from any recovery or settlement. As most *qui tam* cases are filed by current or former employees, an effective compliance program plays a crucial role in reducing the Company s exposure to liability. It is also a criminal offense, under Title 18 U.S. Code, Section 287, for a person or entity to make a claim against the United States or any department or agency, knowing the claim to be false, fictitious or fraudulent. The penalty is imprisonment of not more than five years. The Federal False Claims Act has been an effective enforcement tool for the federal government. Many states have enacted similar false claims acts as well.

The Company seeks to structure its arrangements with physicians and other clients to be in compliance with the Anti-Kickback Statute, Stark Law, state laws, and the Federal False Claims Act and to stay abreast of current developments and changes in the law and regulations. However, these laws and regulations are complex and subject to interpretation. Consequently, we are unable to ascertain with certainty that any of our transactions will not be subject to scrutiny and, if scrutinized, will not result in sanctions or penalties. The Company has taken and will continue to take actions to endeavor to ensure compliance with the myriad federal and state laws that govern our business.

#### **Confidentiality and Security of Personal Health Information**

The Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA) contains provisions that protect individually identifiable health information from unauthorized use or disclosure by covered entities and their business associates. The Office for Civil Rights of HHS, the agency responsible for enforcing HIPAA, has published regulations to address the privacy (the Privacy Rule) and security (the Security Rule) of protected health information (PHI). The Company is a covered entity and has adopted policies and procedures to comply with the Privacy Rule and the Security Rule. The health care facilities and providers that refer specimens to the Company are also bound by HIPAA.

HIPAA also required that all providers who transmit claims for health care goods or services electronically utilize standard transaction and data sets and to standardize national provider identification codes. The Company has taken necessary steps to comply with HIPAA regulations, utilizes standard transaction data sets, and has obtained and implemented national provider identifiers, or NPIs, as the standard unique health identifier in filing and processing health care claims and other transactions.

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The American Recovery and Reinvestment Act ( ARRA ) recently enacted the HITECH Act which extends the scope of HIPAA to permit enforcement against business associates for a violation, establishes new requirements to notify the Office for Civil Rights of HIPAA of a breach of HIPAA, and allows the Attorneys General of the states to bring actions to enforce violations of HIPAA. Rules implementing various aspects of HIPAA are continuing to be developed.

In addition to the HIPAA Privacy Rule and Security Rule described above, the Company is subject to state laws regarding the handling and disclosure of patient records and patient health information. These laws vary widely. Penalties for violation include sanctions against a laboratory s licensure as well as civil or criminal penalties. Additionally, private individuals may have a right of action against the Company for a violation of a state s privacy laws. We believe we are in material compliance with current state laws regarding the confidentiality of health information and will continue to monitor and comply with new or changing state laws.

The Fair and Accurate Credit Transactions Act of 2003, enacted on Dec. 4, 2003, directed the Federal Trade Commission to implement regulations to protect consumers against identity theft. The Federal Trade Commission issued what are referred to as the Red Flag Rules , but the effective date for enforcement has been delayed several times. The Red Flag Rules are now subject to enforcement as of January 1, 2011. The Red Flag Program Clarification Act of 2010 ( RFPCA ) gave some relief to health care providers by changing the definition of creditor , thereby narrowing the application to health care providers who do not otherwise obtain or use consumer reports or furnish information to consumer reporting agencies in connection with a credit transaction. Health care providers who act as a creditor to any of its patients with respect to a covered account are required to implement an identity theft protection program to safeguard patient information. A creditor includes any entity that regularly in the course of business obtains or uses consumer reports in connection with credit transactions, furnishes information to a consumer reporting agency in connection with a credit transaction, or advances funds to or on behalf of a person based on the person s obligation to repay the funds or repayable from specific property pledged by or on behalf of the person. But, a creditor, as defined in the RFPCA, that advances funds on behalf of a person for expenses incidental to a services provided by the creditor to that person is not subject to the Red Flag Rules. The Company has developed a written program designed to identify and detect the relevant warning signs or red flags and establish appropriate responses to prevent and mitigate identity theft in order to comply with the Red Flag Rules. We are also developing a plan to update the program, and the program will be managed by senior management staff under the policy direction of our Board of Directors. The Company intends to take such steps as necessary to determine the extent to which the Red Flag Rules apply to it and to take such steps as necessary to comply.

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#### ITEM 1A. RISK FACTORS

We are subject to various risks that may materially harm our business, financial condition and results of operations. An investor should carefully consider the risks and uncertainties described below and the other information in this filing before deciding to purchase our common stock. If any of these risks or uncertainties actually occurs, our business, financial condition or operating results could be materially harmed. In that case, the trading price of our common stock could decline or we may be forced to cease operations.

#### We May Not Be Able To Implement Our Business Strategies Which Could Impair Our Ability To Continue Operations

Implementation of our business strategies will depend in large part on our ability to (i) attract and maintain a significant number of clients; (ii) effectively provide acceptable products and services to our clients; (iii) develop and license new products and technologies; (iv) obtain adequate financing on favorable terms to fund our business strategies; (v) maintain appropriate procedures, policies, and systems; (vi) hire, train, and retain skilled employees and management; (vii) continue to operate with increasing competition in the medical laboratory industry; (viii) establish, develop and maintain name recognition; and (ix) establish and maintain beneficial relationships with third-party insurance providers and other third party payers. Our inability to obtain or maintain any or all these factors could impair our ability to implement our business strategies successfully, which could have material adverse effects on our results of operations and financial condition.

#### We May Be Unsuccessful In Managing Our Growth Which Could Prevent The Company From Operating Profitably

Our recent growth has placed, and is expected to continue to place, a significant strain on our managerial, operational and financial resources. To manage our potential growth, we must continue to implement and improve our operational and financial systems and to expand, train and manage our employee base. We may not be able to effectively manage the expansion of our operations and our systems and our procedures or controls may not be adequate to support our operations. Our management may not be able to achieve the rapid execution necessary to fully exploit the market opportunity for our products and services. Any inability to manage growth could have a material adverse effect on our business, results of operations, potential profitability and financial condition. Part of our business strategy may be to acquire assets or other companies that will complement our existing business. At this time, we are unable to predict whether or when any material transaction will be completed should negotiations commence. If we proceed with any such transaction, we may not be able to effectively integrate the acquired operations with our own operations. We may also seek to finance any such acquisition by debt financings or issuances of equity securities and such financing may not be available on acceptable terms or at all.

# We May Experience Discontinuation Or Recalls Of Existing Testing Products Or Failures To Develop, Or Acquire, Licenses For New Or Improved Testing Technologies.

From time to time, manufacturers discontinue or recall reagents, test kits or instruments used by the Company to perform laboratory testing. Such discontinuations or recalls could adversely affect the Company s costs, testing volume and revenue.

Our industry is subject to changing technology and new product introductions. The Company success will depend, in part, on its ability to develop, acquire or license new and improved technologies on favorable terms and to obtain appropriate coverage and reimbursement for these technologies. The Company may not be able to negotiate acceptable licensing arrangements and it cannot be certain that such arrangements will yield commercially successful diagnostic tests. If the Company is unable to license these testing methods at competitive rates, its research and development costs may increase as a result. In addition, if the Company is unable to license new or improved technologies to expand its testing operations, its testing methods may become outdated when compared with the Company s competition and testing volume and revenue may be materially and adversely affected.

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We May Incur Greater Costs Than Anticipated, Which Could Result In Sustained Losses

We use reasonable efforts to assess and predict the expenses necessary to pursue our business strategies. However, implementing our business strategies may require more employees, capital equipment, supplies or other expenditure items than management has predicted. Similarly, the cost of compensating additional management, employees and consultants or other operating costs may be more than we estimate, which could result in ongoing and sustained losses.

We Rely On A Limited Number Of Third Parties For Manufacture And Supply Of Certain Of Our Critical Laboratory Instruments And Materials, And We May Not Be Able To Find Replacement Suppliers Or Manufacturers In A Timely Manner In The Event Of Any Disruption, Which Could Adversely Affect Our Business.

We rely on third parties for the manufacture and supply of some of our critical laboratory instruments, equipment and materials that we need to perform our specialized diagnostic services, and rely on a limited number of suppliers for certain laboratory materials and some of the laboratory equipment with which we perform our diagnostic services. Generally, we do not have long-term contracts with our suppliers and manufacturers that commit them to supply equipment and materials to us. Because we cannot ensure the actual production or manufacture of such critical equipment and materials, or the ability of our suppliers to comply with applicable legal and regulatory requirements, we may be subject to significant delays caused by interruption in production or manufacturing. If any of our third party suppliers or manufacturers were to become unwilling or unable to provide this equipment or these materials in required quantities or on our required timelines, we would need to identify and acquire acceptable replacement sources on a timely basis. While we have developed alternate sourcing strategies for most of the equipment and materials we use, we cannot be certain that these strategies will be effective and even if we were to identify other suppliers and manufacturers for the equipment and materials we need to perform our specialized diagnostic services, there can be no assurance that we will be able to enter into agreements with such suppliers and manufacturers or otherwise obtain such items on a timely basis or on acceptable terms, if at all. In addition, some of the reagents we use to perform certain FISH tests are covered by patents and thus are only available from one supplier. If we encounter delays or difficulties in securing necessary laboratory equipment or materials, including consumables, we would face an interruption in our ability to perform our specialized diagnostic services and experience other disruptions that would adversely affect our business, results of operations and financial condition.

We May Face Fluctuations In Results Of Operations Which Could Negatively Affect Our Business Operations And We Are Subject To Seasonality In Our Business

As a result of the relatively limited information available on our competitors, we may not have sufficient internal or industry-based historical financial data upon which to calculate anticipated operating expenses. Management expects that our results of operations may also fluctuate significantly in the future as a result of a variety of factors, including, but not limited to: (i) the continued rate of growth, usage and acceptance of our products and services; (ii) demand for our products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) our ability to attract, retain and motivate qualified personnel; (vi) the initiation, renewal or expiration of significant contracts with our major clients; (vii) pricing changes by us, our suppliers or our competitors; (viii) seasonality; and (ix) general economic conditions and other factors. Accordingly, future sales and operating results are difficult to forecast. Our expenses are based in part on our expectations as to future revenues and to a significant extent are relatively fixed, at least in the short-term. We may not be able to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in relation to our expectations would have an immediate adverse impact on our business, results of operations and financial condition. In addition, we may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short-term material adverse affect on our business, results of operations and financial condition and may not result in the long-term benefits intended. Furthermore, in Florida, currently our primary referral market for lab testing services, a meaningful percentage of the population, returns to homes in the Northern U.S. to avoid the hot summer months. This combined with the usual summer vacation schedules of our clients usually results in seasonality in our business. Because of all of the foregoing factors, our operating results could be less than the expectations of investors in future periods.

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We Substantially Depend Upon Third Parties For Payment Of Services, Which Could Have A Material Adverse Affect On Our Cash Flows And Results Of Operations

The Company is a clinical medical laboratory that provides medical testing services to doctors, hospitals, and other laboratories on patient specimens that are sent to the Company. In the case of most specimen referrals that are received for patients that are not in-patients at a hospital or institution or otherwise sent by another reference laboratory, the Company generally has to bill the patient—s insurance company or a government program for its services. As such it relies on the cooperation of numerous third party payers, including but not limited to Medicare, Medicaid and various insurance companies, in order to get paid for performing services on behalf of the Company—s clients. Wherever possible, the amount of such third party payments is governed by contractual relationships in cases where the Company is a participating provider for a specified insurance company or by established government reimbursement rates in cases where the Company is an approved provider for a government program such as Medicare. However, the Company does not have a contractual relationship with some of the insurance companies with whom it deals, nor is it necessarily able to become an approved provider for all government programs. In such cases, the Company is deemed to be a non-participating provider and there is no contractual assurance that the Company is able to collect the amounts billed to such insurance companies or government programs. Currently, the Company is not a participating provider with some of the insurance companies it bills for its services. Until such time as the Company becomes a participating provider with such insurance companies, there can be no contractual assurance that the Company will be paid for the services it bills to such insurance companies, and such third parties may change their reimbursement policies for non-participating providers in a manner that may have a material adverse effect on the Company—s cash flow or results of operations.

## Our Business Is Subject To Rapid Scientific Change, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

The market for genetic and molecular testing services is characterized by rapid scientific developments, evolving industry standards and customer demands, and frequent new product introductions and enhancements. For example, new tests developed by our competitors may prove superior and replace our existing tests. Our future success will depend in significant part on our ability to continually improve our offerings in response to both evolving demands of the marketplace and competitive service offerings, and we may be unsuccessful in doing so.

# The Market For Our Services Is Highly Competitive, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

The market for genetic and molecular testing services is highly competitive and competition is expected to continue to increase. We compete with other commercial medical laboratories in addition to the in-house laboratories of many major hospitals and physician practices. Many of our existing competitors have significantly greater financial, human, technical and marketing resources than we do. Some physicians and hospitals have made the decision to internalize testing rather than using an outsourced laboratory such as NeoGenomics. One of our suppliers has opened its own laboratory which compete directly against us. Our competitors may develop products and services that are superior to ours or that achieve greater market acceptance than our offerings. We may not be able to compete successfully against current and future sources of competition and in such case, this may have a material adverse effect on our business, results of operations and financial condition.

## We Face The Risk Of Capacity Constraints, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

We compete in the market place primarily on three factors: a) the quality and accuracy of our test results; b) the speed or turn-around times of our testing services; and c) our ability to provide after-test support to those physicians requesting consultation. Any unforeseen increase in the volume of clients could strain the capacity of our personnel and systems, which could lead to inaccurate test results, unacceptable

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turn-around times, or customer service failures. In addition, as the number of clients and cases increases, our products, services, and infrastructure may not be able to scale accordingly. Any failure to handle higher volume of requests for our products and services could lead to the loss of established clients and have a material adverse effect on our business, results of operations and financial condition. If we produce inaccurate test results, our clients may choose not to use us in the future. This could severely harm our business, results of operations and financial condition. In addition, based on the importance of the subject matter of our tests, inaccurate results could result in improper treatment of patients, and potential liability for us.

# We May Fail To Protect Our Facilities, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

The Company s operations are dependent in part upon its ability to protect its laboratory operations against physical damage from fire, floods, hurricanes, earthquakes, power loss, telecommunications failures, break-ins and similar events. The Company does not presently have an emergency back-up generator in place at its Nashville, Tennessee or Irvine California laboratory locations that can mitigate to some extent the effects of a prolonged power outage. The occurrence of any of these events could result in interruptions, delays or cessations in service to clients, which could have a material adverse effect on our business, results of operations and financial condition.

# The Steps Taken By The Company To Protect Its Proprietary Rights May Not Be Adequate, Which Could Result In Infringement Or Misappropriation By Third-Parties

We regard our copyrights, trademarks, trade secrets and similar intellectual property as critical to our success, and we rely upon trademark and copyright law, trade secret protection and confidentiality and/or license agreements with our employees, clients, partners and others to protect our proprietary rights. The steps taken by us to protect our proprietary rights may not be adequate or third parties may infringe or misappropriate our copyrights, trademarks, trade secrets and similar proprietary rights. In addition, other parties may assert infringement claims against us.

#### We Are Dependent On Key Personnel And Need To Hire Additional Qualified Personnel In Order For Our Business To Succeed

Our performance is substantially dependent on the performance of our senior management and key technical personnel. In particular, our success depends substantially on the continued efforts of our senior management team, which currently is composed of a small number of individuals. The loss of the services of any of our executive officers, our medical staff, our laboratory directors or other key employees could have a material adverse effect on our business, results of operations and our financial condition. Our future success also depends on our continuing ability to attract and retain highly qualified technical and managerial personnel. Competition for such personnel is intense and we may not be able to retain our key managerial and technical employees or may not be able to attract and retain additional highly qualified technical and managerial personnel in the future. The inability to attract and retain the necessary technical and managerial personnel could have a material adverse effect upon our business, results of operations and financial condition.

# The Failure To Obtain Necessary Additional Capital To Finance Growth And Capital Requirements, Could Adversely Affect Our Business, Financial Condition And Results Of Operations

We may seek to exploit business opportunities that require more capital than we have currently available. We may not be able to raise such capital on favorable terms or at all. If we are unable to obtain such additional capital, we may be required to reduce the scope of our anticipated expansion, which could adversely affect our business, financial condition and results of operations.

As of December 31, 2011, we had cash and cash equivalents of approximately \$2,628,000, restricted cash of \$500,000 and we had approximately \$1,100,000 of availability under our credit facility with CapitalSource.

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Even if we are able to access the full amount available under our credit facility with CapitalSource, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, there could be a material adverse effect on our long-term business, operating results, financial condition and prospects.

Proposed Government Regulation Of Laboratory Developed Tests ( LDT s ) May Result In Delays To Launching Certain Laboratory Tests and Increase Our Costs To Implement New Tests

We frequently develop testing procedures to provide diagnostic results to tests that are not available using Federal Drug Administration (FDA) approved test kits. The FDA has been considering changes to the way that laboratories are allowed to offer these LDT s. Currently all such tests are conducted and offering under CLIA and individual state licensing procedures. The FDA is considering requiring FDA approval on a portion of those currently offered non-FDA approved tests, as well as a modified approach that may require some additional oversight short of the full FDA approval process. There are currently no formal definitions, procedures or FDA processes on how such approvals would be handled but there is a risk that this could delay the offering of certain tests and result in additional validation costs and fees. There is also an associated risk for NeoGenomics that some tests currently offered might need to be subject to approval by the FDA.

#### Healthcare Reform Programs May Impact Our Business And The Pricing We Receive For Our Services.

In March of 2010, health care reform legislation known as the Patient Protection and Affordable Care Act was passed into law (the Affordable Care Act ). The Affordable Care Act contains several provisions that seek to limit Medicare spending in the future. One key provision is the establishment of Accountable Care Organizations under which hospitals and physicians will be able to share savings that result from cost control efforts. We cannot predict what the final business models will be, nor can we predict with certainty the future impact on our business. There is the possibility that these organizations will seek to lower reimbursement for the services we provide and some may potentially restrict access to our services. These changes could have an adverse and material impact on our operations. In furtherance of health care reform and the reduction in health care expenditures, the Affordable Care Act contains numerous provisions to be implemented through 2018. There can be no assurance at this time that the implementation of these provisions will not have a material adverse effect on the business of the Company.

Steps Taken By Government Payers, Such As Medicare And Medicaid To Control The Utilization and Reimbursement Of Healthcare Services, Including Esoteric Testing May Diminish Our Net Revenue

We face efforts by government payers to reduce utilization as well as reimbursement for laboratory testing services.

From time to time, Congress has legislated or Clinical Laboratory Fee Schedule formulas adverse to sustainable payment rates, and has reduced, delayed, or modified updates to the Medicare Physician Fee Schedule or Clinical Lab Fee Schedule. The Physician Fee Schedule assigns relative value units to each procedure or service, and a conversion factor is applied to calculate the reimbursement. The Physician Fee Schedule is subject to adjustment on an annual basis. The formula used to calculate the fee schedule conversion factor, known as the Sustainable Growth Rate (SGR), would have resulted in significant decreases in payment for most physician services for each year since 2003. However, since that time Congress has intervened repeatedly to prevent these payment reductions, and the conversion factor has been increased or frozen for the subsequent year. Decreases in payment will occur in future years unless Congress acts to change the formula used to calculate the fee schedule or continues to legislate modifications to the Sustainable Growth Rate each year. In late 2011, Congress acted to provide a zero update in the physician fee schedule payments in 2011 instead of a payment reduction of approximately 27.4% but only delayed the payment reduction until February 29, 2012. On February 22, 2012 legislation was enacted which further extends the implementation of the SGR reductions until after December 31, 2012. In the event that the SGR reductions in the Medicare Physician Fee Schedule are not further modified prospectively, either by statutory intervention or by modifying the formula to determine the Physician Fee Schedule, the Company could face a material reduction in the Medicare reimbursements it receives for certain of its laboratory tests. Reductions in the Medicare Physician Fee Schedule or the Clinical Laboratory Fee Schedule could have a material adverse effect on our business, operating results, financial condition and prospects.

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In addition, certain other legislation which was set to expire on December 31, 2011, then subsequently extended through February 29, 2012, which grandfathered the implementation of new reimbursement procedures for the technical component of Medicare tests performed for certain hospital clients (known as the TC Grandfather legislation) was extended through June 30, 2012 to permit a phase out of the policy. As a result, reference labs like the Company that meet the grandfathering criteria can bill Medicare directly for the technical component of certain laboratory tests for grandfathered hospitals. In the event that the TC Grandfather legislation is not further extended after June 30, 2012 the Company will be required to bill the hospitals ordering such services for the technical component of those tests the Company previously billed to Medicare. In such case, there can be no assurance that the hospital clients of the Company will contract to pay for such tests at existing Medicare rates or will continue to order such tests from the Company in the same volumes as they have been historically, which could have a material adverse effect on our business, operating results, financial condition and prospects.

The Center for Medicare Services ( CMS ) adopts policies, from time to time, limiting or excluding coverage for certain of the tests that we perform. Many state governments are under budget pressures and are also considering reductions to their Medicaid fees. Further, Medicare can perform audits for overutilization of billed services. Even though all tests performed by us are ordered by our clients, who establish the medical necessity for the tests, we may be subject to recoupment of payments, as the recipient of Medicare payments for such tests, in the event that CMS determines that the tests failed to meet all applicable criteria for payment. When CMS revises its coverage policies, our costs generally increase due to the complexity and additional administrative requirements. Furthermore, Medicaid reimbursement and regulations vary by state, and we are subject to varying administrative and billing regulations, which affect the complexity of servicing such programs and our administrative costs.

During the last several years, the federal government has sponsored programs to expand the number of Medicare beneficiaries participating in managed care programs, called Medicare Advantage programs, and has encouraged such beneficiaries to switch from the traditional fee for service Medicare program to Medicare Advantage programs. There has been rapid growth of health insurance and managed care plans offering Medicare Advantage programs and growth in beneficiary enrollment in these programs. Also in recent years, many states have increasingly mandated that Medicaid beneficiaries enroll in managed care arrangements. If these efforts continue to be successful, we may experience a further shift of traditional Medicare and Medicaid beneficiaries to managed care programs. As a result, the Company would be required to contract with those managed care programs to offer services to their participating providers and members. There can be no assurance that the managed care programs and the Company will enter into agreements at rates of payment similar to those the Company realizes from its non-managed care lines of business. Recently, state budget pressures have encouraged states to consider several courses that may impact our business, such as delaying payments, restricting coverage eligibility, service coverage restrictions and imposing taxes on our services.

We expect these initiatives to continue and, if they do, to reduce reimbursements, to impose more stringent cost controls and to reduce utilization of clinical test services. These efforts, including changes in law or regulations that may occur in the future, may have a material adverse impact on our business, operating results, financial condition and prospects.

#### Our Net Revenue Will Be Diminished If Payers Do Not Adequately Cover Or Reimburse Our Services

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications or services. Third party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing tests or for tests we discover and develop. In addition, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payers. Any pricing

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pressure exerted by these third party payers on our clients may, in turn, be exerted by our clients on us. If government and other third party payers do not provide adequate coverage and reimbursement for our tests, our operating results, cash flows or financial condition may decline.

#### Third Party Billing Is Extremely Complicated And Results In Significant Additional Costs To Us

Billing for laboratory services is extremely complicated. The customer refers the tests; the payer is the party that pays for the tests, and the two are not usually the same. Depending on the billing arrangement and applicable law, we need to bill various payers, such as patients, insurance companies, Medicare, Medicaid, doctors and employer groups, hospitals and other laboratories, all of which have different billing requirements. Additionally, our billing relationships require us to undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. Insurance companies also impose routine external audits to evaluate payments made, which adds further complexity to the billing process.

Among others, the primary factors which complicate our billing practices are:

pricing differences between our fee schedules and the reimbursement rates of the payers;

disputes with payers as to which party is responsible for payment; and

disparity in coverage and information requirements among various carriers.

We incur significant additional costs as a result of our participation in the Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory testing are subject to considerable and complex federal and state regulations. The additional costs we expect to incur include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and clients; (3) implementing compliance procedures and oversight; (4) collections and legal costs; and (5) costs associated with, among other factors, challenging coverage and payment denials and providing patients with information regarding claims processing and services, such as advanced beneficiary notices.

# Our Operations Are Subject To Strict Laws Prohibiting Fraudulent Billing And Other Abuse, And Our Failure To Comply With Such Laws Could Result In Substantial Penalties

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recovery of non-fraudulent overpayments. A large number of laboratories have been forced by the federal and state governments, as well as by private payers, to enter into substantial settlements under these laws. In particular, if an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity submits, or causes another to submit, a false claim for reimbursement to the federal government. Submitting a claim with reckless disregard or deliberate ignorance of its truth or falsity could also result in substantial civil liability. A trend affecting the healthcare industry is the increased use of the federal False Claims Act and, in particular, actions under the False Claims Act s whistleblower or qui tam provisions to challenge the reimbursement practices of providers and suppliers. Those provisions allow a private individual to bring an action on behalf of the government alleging that the defendant has submitted fraudulent claims for payment to the federal government. The government must decide whether to intervene in the lawsuit and whether to prosecute the case. If it declines to do so, the individual may pursue the case alone, although the government must be kept apprised of the progress of the lawsuit. Whether or not the federal government intervenes in the case, it will receive the majority of any recovery. The successful qui tam relator who brought the case is entitled to a portion of the proceeds in addition to attorneys fees and costs. In addition, various states have enacted laws modeled after the federal False Claims Act. Government investigations of clinical laboratories have been on

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The Failure To Comply With Significant Government Regulation And Laboratory Operations May Subject The Company To Liability, Penalties Or Limitation Of Operations

As discussed in the Government Regulation section of our business description, we are subject to extensive state and federal regulatory oversight. Our laboratory locations may not pass inspections conducted to ensure compliance with CLIA or with any other applicable licensure or certification laws. The sanctions for failure to comply with CLIA or state licensure requirements might include the inability to perform services for compensation or the suspension, revocation or limitation of the laboratory location s CLIA certificate or state license, as well as civil and/or criminal penalties. In addition, any new legislation or regulation or the application of existing laws and regulations in ways that we have not anticipated could have a material adverse effect on the Company s business, results of operations and financial condition. Existing federal laws governing Medicare and Medicaid, as well as some other state and federal laws, also regulate certain aspects of the relationship between healthcare providers, including clinical and anatomic laboratories, and their referral sources, including physicians, hospitals and other laboratories. Certain provisions of these laws, known as the anti-kickback law and the Stark Laws, contain extremely broad proscriptions. Violation of these laws may result in criminal penalties, exclusion from Medicare and Medicaid, and significant civil monetary penalties. We seek to structure our arrangements with physicians and other clients to be in compliance with the anti-kickback, Stark and state laws, and to keep up-to-date on developments concerning their application by various means, including consultation with legal counsel. However, we are unable to predict how these laws will be applied in the future and the arrangements into which we enter may become subject to scrutiny thereunder. Furthermore, HIPAA, and other state privacy laws contain provisions that affect the handling of claims and other patient information that are, or have been, transmitted electronically and regulate the general disclosure of patient records and protected health information. These provisions, which address security and confidentiality of patient information as well as the administrative aspects of claims handling, have very broad applicability and they specifically apply to healthcare providers, which include physicians and clinical laboratories. Although we believe we have complied with the Standards, Security and Privacy rules under HIPAA and state privacy laws, an audit of our procedures and systems could find deficiencies. Such deficiencies, if found, could have a material adverse effect on the Company s business, results of operations and financial condition and subject us to liability.

A Failure To Comply With Governmental Payer Regulations Could Result In Our Being Excluded From Participation In Medicare, Medicaid Or Other Governmental Payer Programs, Which Would Decrease Our Revenues And Adversely Affect Our Results Of Operations And Financial Condition

Tests which are reimbursable from Medicare and Medicaid accounted for approximately 43% and 46% of our revenues for the years ended December 31, 2011 and 2010, respectively. The Medicare program imposes extensive and detailed requirements on diagnostic service providers, including, but not limited to, rules that govern how we structure our relationships with physicians, how and when we submit reimbursement claims and how we provide our specialized diagnostic services. Our failure to comply with applicable Medicare, Medicaid and other governmental payer rules could result in our inability to participate in a governmental payer program, an obligation to repay funds already paid to us for services performed, civil monetary penalties, criminal penalties and/or limitations on the operational function of our laboratory. If we were unable to receive reimbursement under a governmental payer program, a substantial portion of our revenues would be lost, which would adversely affect our results of operations and financial condition.

#### Our Business Could Be Harmed By Future Interpretations Of Clinical Laboratory Mark-Up Prohibitions

Our laboratory currently uses the services of outside reference laboratories to provide certain complementary laboratory services to those services provided directly by our laboratory. Although Medicare policies do not prohibit certain independent-laboratory-to-independent-laboratory referrals and subsequent mark-up for services, California and other states have rules and regulations that prohibit or limit the mark-up of these laboratory-to-laboratory services. A challenge to our charge-setting procedures under these rules and regulations could have a material adverse effect on our business, results of operations and financial condition.

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#### Failure To Comply With The HIPAA Security And Privacy Regulations May Increase Our Operational Costs

The HIPAA privacy and security regulations establish comprehensive federal standards with respect to the uses and disclosures of Protected Health Information (PHI) by health plans and healthcare providers, in addition to setting standards to protect the confidentiality, integrity and availability of electronic PHI. The regulations establish a complex regulatory framework on a variety of subjects, including, for example, the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, a patient s right to access, amend and receive an accounting of certain disclosures of PHI; the content of notices of privacy practices for PHI, and administrative, technical and physical safeguards required of entities that use or receive PHI electronically. We have implemented policies and procedures related to compliance with the HIPAA privacy and security regulations, as required by law. The privacy regulations establish a uniform federal standard and do not supersede state laws that may be more stringent. Therefore, we are required to comply with both federal privacy regulations and varying state privacy laws. The federal privacy regulations restrict our ability to use or disclose patient identifiable laboratory data, without patient authorization, for purposes other than payment, treatment or healthcare operations (as defined by HIPAA), except for disclosures for various public policy purposes and other permitted purposes outlined in the privacy regulations. The privacy and security regulations provide for significant civil fines, criminal penalties, and other sanctions for wrongful use or disclosure of PHI. Although the HIPAA statute and regulations do not expressly provide for a private right of action for damages, we also could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information. Additionally, the recent amendments to HIPAA provide that the state Attor

Changes In Regulations, Payer Policies Or Contracting Arrangements With Payers Or Changes In Other Laws, Regulations Or Policies May Adversely Affect Coverage Or Reimbursement For Our Specialized Diagnostic Services, Which May Decrease Our Revenues And Adversely Affect Our Results Of Operations And Financial Condition

Governmental payers, as well as private insurers and private payers, have implemented and will continue to implement measures to control the cost, utilization and delivery of healthcare services, including clinical laboratory and pathology services. Congress has considered, from time to time and has implemented changes to laws and regulations governing healthcare service providers, including specialized diagnostic service providers. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals will not use our services if third party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local and third party payer regulations or policies may decrease our revenues and adversely affect our results of operations and financial condition. We will continue to be a non-contracting provider until such time as we enter into contracts with third party payers with whom we are not currently contracted. Because a portion of our revenues is from third-party payers with whom we are not currently contracted, it is likely that we will be required to make positive or negative adjustments to accounting estimates with respect to contractual allowances in the future, which may adversely affect our results of operations, our credibility with financial analysts and investors, and our stock price.

#### We Are Subject To Security Risks Which Could Harm Our Operations

The HITECH Act imposed restrictions and penalties on covered entities and their business associates to deter breaches of security. As a result, the remedial actions required, the reporting requirements, and sanctions for a breach are more stringent, especially if the security of the covered entity is electronic health records system does not conform to certain security standards. The Company is electronic health records system is periodically modified to meet applicable security standards. Despite the implementation of various security measures by us, our infrastructure may be vulnerable to computer viruses, break-ins and similar disruptive problems caused by our clients or others. Computer viruses, break-ins or other security problems could lead to interruption, delays or cessation in service to our clients. Further, such break-ins, whether electronic or physical could also potentially jeopardize the security of confidential information stored in our computer systems as it relates to clients and other parties connected through us, which may deter potential clients and give rise to uncertain liability to parties whose security or privacy has been infringed. A significant security breach could result in loss of clients, damage to our reputation, direct damages, costs of repair and detection, costs to remedy the breach, and other expenses. The occurrence of any of the foregoing events could have a material adverse effect on our business, results of operations and financial condition.

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#### We Must Hire And Retain Qualified Sales Representatives To Grow Our Sales

Our ability to retain existing clients for our specialized diagnostic services and attract new clients is dependent upon retaining existing sales representatives and hiring and training new sales representatives, which is an expensive and time-consuming process. We face intense competition for qualified sales personnel and our inability to hire or retain an adequate number of sales representatives could limit our ability to maintain or expand our business and increase sales. Even if we are able to increase our sales force, our new sales personnel may not commit the necessary resources or provide sufficient high quality service and attention to effectively market and sell our services. If we are unable to maintain and expand our marketing and sales networks or if our sales personnel do not perform to our standards, we may be unable to maintain or grow our existing business and our results of operations and financial condition will likely suffer accordingly. If a sales representative ceases employment, we risk the loss of client goodwill based on the impairment of relationships developed between the sales representative and the healthcare professionals for whom the sales representative was responsible. This is particularly a risk if the representative goes to work for a competitor, as the healthcare professionals that are our clients may choose to use a competitor s services based on their relationship with our former sales representative.

Performance Issues, Service Interruptions Or Price Increases By Our Shipping Carrier Could Adversely Affect Our Business, Results Of Operations And Financial Condition, And Harm Our Reputation And Ability To Provide Our Specialized Diagnostic Services On A Timely Basis

Expedited, reliable shipping is essential to our operations. One of our marketing strategies entails highlighting the reliability of our point-to-point transport of patient samples. We rely heavily on a single carrier, FedEx Corporation for reliable and secure point-to-point transport of patient samples to our laboratory and enhanced tracking of these patient samples. Should FedEx encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions by delivery services we use would adversely affect our ability to receive and process patient samples on a timely basis. If FedEx or we were to terminate our relationship, we would be required to find another party to provide expedited, reliable point-to-point transport of our patient samples. There are only a few other providers of such nationwide transport services, and there can be no assurance that we will be able to enter into arrangements with such other providers on acceptable terms, if at all. Finding a new provider of transport services would be time-consuming and costly and result in delays in our ability to provide our specialized diagnostic services. Even if we were to enter into an arrangement with such provider, there can be no assurance that they will provide the same level of quality in transport services currently provided to us by FedEx. If the new provider does not provide the required quality and reliable transport services, it could adversely affect our business, reputation, results of operations and financial condition.

We Use Biological And Hazardous Materials That Require Considerable Expertise And Expense For Handling, Storage Or Disposal And May Result In Claims Against Us

We work with hazardous materials, including chemicals, biological agents and compounds, blood samples and other human tissue that could be dangerous to human health and safety or the environment. Our operations also produce hazardous and biohazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair business efforts. If we do not comply with applicable regulations, we may be subject to fines and penalties. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Our general liability insurance and/or workers compensation insurance policy may not cover damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our operations could be suspended or otherwise adversely affected.

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Our Ability To Comply With The Financial Covenants In Our Credit Agreements Depends Primarily On Our Ability To Generate Substantial Operating Cash Flow

Our ability to comply with the financial covenants under our credit agreement with CapitalSource will depend primarily on our success in generating substantial operating cash flow. Our credit agreement contains numerous financial and other restrictive covenants, including restrictions on purchasing and selling assets, paying dividends to our shareholders, and incurring additional indebtedness. Our failure to meet these covenants could result in a default and acceleration of repayment of the indebtedness under our credit facility. If the maturity of our indebtedness were accelerated, we may not have sufficient funds to pay such indebtedness. In such event, our lenders would be entitled to proceed against the collateral securing the indebtedness, which includes all of our entire accounts receivable, to the extent permitted by our credit agreements and applicable law.

#### We Have Potential Conflicts Of Interest Relating To Our Related Party Transactions Which Could Harm Our Business

We have potential conflicts of interest relating to existing agreements we have with certain of our directors, officers, principal shareholders, shareholders and employees. Potential conflicts of interest can exist if a related party director or officer has to make a decision that has different implications for us and the related party. If a dispute arises in connection with any of these agreements, if not resolved satisfactorily to us, our business could be harmed. There can be no assurance that the above or any future conflicts of interest will be resolved in our favor. If not resolved, such conflicts could harm our business.

#### We Are Subject To A Shareholders Agreement That Governs The Election Of Certain Members Of Our Board Of Directors

The Company and certain stockholders of the Company are parties to a Shareholders Agreement that, among other provisions, gives Aspen Select Healthcare, LP ( Aspen ), our largest shareholder, the right to elect three out of the eight directors authorized for our Board and to nominate one mutually acceptable independent director. In addition, Michael Dent and the executive management of the Company have the right to elect one director for our Board Directors until the earlier of (i) Dr. Dent s resignation as an officer or director of the Company or (ii) the sale by Dr. Dent of 50% or more of the number of shares of our common stock that he held on March 21, 2005. Accordingly, it is anticipated that Aspen and other parties to the Shareholders Agreement will continue to have the ability to effectively elect a number of the members of our Board of Directors.

#### No Foreseeable Dividends

We do not anticipate paying dividends on our common stock in the foreseeable future. Rather, we plan to retain earnings, if any, for the operation and expansion of our business.

#### There May Not Be A Viable Public Market For Our Common Stock

We cannot predict the extent to which investor interest in our Company will sustain an active trading market for our common stock on the OTCQB Market or any other stock market on which we may be listed or how liquid any such market might remain. If an active public market is not sustained, it may be difficult for our stockholders to sell their shares of common stock at a price that is attractive to them, or at all.

#### We May Become Involved In Securities Class Action Litigation That Could Divert Management s Attention And Harm Our Business

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of diagnostic companies. These broad market fluctuations may cause the market price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because clinical laboratory service companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management s attention and resources, which could adversely affect our business.

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If Any Securities Analyst Downgrades Our Common Stock Or Our Sector, The Price Of Our Common Stock Could Be Negatively Affected

Securities analysts may publish reports about us or our industry containing information about us that may affect the trading price of our common stock. If a securities or industry analyst downgrades the outlook for our common stock or one of our competitors stocks or chooses to terminate coverage of our common stock, the trading price of our common stock may be negatively affected.

If Penny Stock Regulations Impose Restrictions On The Marketability Of Our Common Stock, The Ability Of Our Stockholders To Sell Shares Of Our Stock Could Be Impaired

The SEC has adopted regulations that generally define a penny stock to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share subject to certain exceptions. Exceptions include equity securities issued by an issuer that has (i) net tangible assets of at least \$2,000,000, if such issuer has been in continuous operation for more than three years, or (ii) net tangible assets of at least \$5,000,000, if such issuer has been in continuous operation for less than three years, or (iii) average revenue of at least \$6,000,000 for the preceding three years. Our common stock is currently trading at under \$5.00 per share. Although we currently meet all of the exceptions, if at a later time we fail to meet one of the exceptions, our common stock will be considered a penny stock. Broker/dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stocks. Moreover, broker/dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor. These requirements, among others, may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to resell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

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#### ITEM 2. PROPERTIES

We operate a regional network of laboratories. All our facilities are leased and we believe that they are sufficient to meet our needs at existing volume levels and that, if needed, additional space will be available at a reasonable cost. The following table summarizes our facilities by location:

Location	Purpose	Square footage
Fort Myers, Florida	Corporate headquarters and laboratory	29,700
Irvine, California	Laboratory	14,800
Nashville, Tennessee	Laboratory	5,400
Tampa, Florida	Laboratory	3,439

The Company has signed a lease for a new location for our Irvine, California facility which we will begin to occupy in May 1, 2012 upon expiration of our existing lease. The facility is 17,666 square feet.

In January 2012 the Company also leased an additional 2,341 square feet of space adjacent to our current Tampa, Florida facility.

Our rapid growth may require securing additional space in 2012 and 2013.

#### ITEM 3. LEGAL PROCEEDINGS

From time to time the Company is engaged in legal proceeding in the ordinary course of business. We do not believe any current legal proceedings are material to our business.

#### ITEM 4. MINE SAFETY DISCLOSURES

Not applicable

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#### 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 is quoted on the OTCQB Market under the symbol NGNM . Set forth below is a table summarizing the high and low bid quotations for our common stock during the last two fiscal years.

QUARTER	HIC	GH BID	LOW BID	
4 <sup>th</sup> Quarter 2011	\$	1.84	\$	0.96
3 <sup>rd</sup> Quarter 2011	\$	1.50	\$	1.05
2 <sup>nd</sup> Quarter 2011	\$	1.51	\$	1.15
1st Quarter 2011	\$	1.67	\$	1.12
4 <sup>th</sup> Quarter 2010	\$	1.30	\$	0.95
3 <sup>rd</sup> Quarter 2010	\$	1.29	\$	0.95
2 <sup>nd</sup> Quarter 2010	\$	1.48	\$	1.15
1st Quarter 2010	\$	1.65	\$	1.15

The above table is based on over-the-counter quotations. These quotations reflect inter-dealer prices, without retail mark-up, markdown or commissions, and may not necessarily represent actual transactions. All historical data was obtained from the www.OTCBB.com web site.

#### **Holders of Common Stock**

As of March 8, 2012, there were 566 stockholders of record of our common stock, although there are more beneficial owners.

#### Dividends

We have never declared or paid cash dividends on our common stock. We intend to retain all future earnings to finance future growth and therefore we do not anticipate paying any cash dividends in the foreseeable future. In addition, certain financing agreements entered into by the Company may limit our ability to pay dividends in the future.

#### Securities Authorized for Issuance Under Equity Compensation Plans (a)

Plan Catagory	Number of securities to be issued upon exercise of outstanding options, warrants and	Weighted average exercise price of outstanding options, warrants and rights		Number of securities remaining available for future issuance under equity compensation	
Plan Category	rights	II	gnts	plans	
Equity compensation plans approved by security holders:					
Amended and Restated Equity Incentive					
1 2	4 420 170	Ф	0.00	044.906 ( )	
Plan ( Equity Incentive Plan )	4,429,170	\$	0.88	944,896 (e)	
Employee Stock Purchase Plan ( ESPP )			N/A	55,711	
Equity compensation plans not approved					
by security holders (b), (c), (d)	1,425,000	\$	1.13		

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Total	5.854.170	\$ 0.93	1,102,175

(a) As of December 31, 2011.

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- (b) Includes an outstanding option to purchase 350,000 shares of common stock granted to Robert P. Gasparini, our Chief Scientific Officer, outside the Company s Equity Incentive Plan on March 12, 2008. The options have an exercise price of \$0.80 per share and vests based on the achievement of certain performance milestones. In the event of a change of control of the Company, all unvested portions of the option will vest in full. Unless sooner terminated pursuant to the terms of the stock option agreement, the option will terminate on March 12, 2015.
- (c) Includes outstanding warrants to purchase 625,000 shares of common stock at an exercise price of \$1.05 per share granted to Douglas M. VanOort on March 16, 2009. The warrants vest based on the achievement of certain performance milestones. In the event of a change of control of the Company with a share price in excess of \$4.00 per share, all unvested warrants will vest immediately. Unless sooner terminated pursuant to the terms of the warrant agreement, the warrants will terminate on March 15, 2014.
- (d) Includes outstanding warrants to purchase 450,000 shares of common stock at an exercise price of \$1.50 per share granted to Steven C. Jones on May 3, 2010. These warrants vest based on the passage of time and based on the achievement of certain milestones. In the event of a change of control of the Company all unvested warrants will vest immediately. Unless sooner terminated pursuant to the terms of the warrant agreement, the warrants will terminate on May 3, 2017.
- (e) The Company s Equity Incentive Plan was amended and restated on March 3, 2009, and subsequently approved by shareholders holding a majority of the shares outstanding, to allow for the issuance of an aggregate of up to 6,500,000 shares under the plan.

Currently, the Company s Equity Incentive Plan, as amended and restated on October 31, 2006 and again amended and restated on March 3, 2009, and the Company s ESPP, dated October 31, 2006, are the only equity compensation plans in effect.

#### **Recent Sales of Unregistered Securities**

No sales of unregistered securities were made during the quarter ended December 31, 2011. The Company has previously reported in certain Quarterly Reports on Form 10-Q and Current Reports on Form 8-K other sales of unregistered securities during the year ended December 31, 2011.

#### Item 6. Selected Financial Data

We are a smaller reporting company as defined by Regulations S-K and as such, are not required to provide the information contained in this item pursuant to Regulation S-K.

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## ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

NeoGenomics, Inc., a Nevada corporation (referred to individually as the Parent Company or collectively with its subsidiary as NeoGenomics, we, us, our or the Company in this Form 10-K) is the registrant for SEC reporting purposes. Our common stock is listed on the OTCQB Market under the symbol NGNM.

### Introduction

The following discussion and analysis should be read in conjunction with the Consolidated Financial Statements, and the Notes thereto included in this Form 10-K. The information contained below includes statements of management s beliefs, expectations, hopes, goals and plans that, if not historical, are forward-looking statements subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. For a discussion on forward-looking statements, see the information set forth in the Introductory Note to this Annual Report under the caption Forward Looking Statements , which information is incorporated herein by reference.

## **Overview**

We operate a network of cancer-focused testing laboratories whose mission is to improve patient care through exceptional genetic and molecular testing services. Our vision is to become America s premier cancer testing laboratory by delivering uncompromising quality, exceptional service and innovative products and solutions. The Company has laboratory locations in Ft. Myers and Tampa, Florida; Irvine, California; and Nashville, Tennessee, and currently offers the following types of testing services:

- a) Cytogenetics testing the study of normal and abnormal chromosomes and their relationship to disease. Cytogenetic studies are often utilized to assist in refining treatment options for hematopoietic cancers such as leukemia and lymphoma;
- b) Fluorescence In-Situ Hybridization (FISH) testing a branch of cancer genetics that focuses on detecting and locating the presence or absence of specific DNA sequences and genes on chromosomes;
- c) Flow cytometry testing a rapid way to measure the characteristics of cell populations. Cells from peripheral blood, bone marrow aspirate, lymph nodes, and other areas are labeled with selective fluorescent antibodies and quantified according to their surface antigens. These fluorescent antibodies bind to specific cell surface antigens and are used to identify malignant cell populations. Flow cytometry is typically performed in conjunction with morphology testing which looks at smears on glass slides for abnormal cell populations;
- d) Immunohistochemistry ( IHC ) testing the process of identifying cell proteins in a tissue section utilizing the principle of antibodies binding specifically to antigens. Specific surface cytoplasmic or nuclear markers are characteristic of cellular events such as proliferation or cell death (apoptosis). IHC is also widely used to understand the distribution and localization of differentially expressed proteins; and
- e) Molecular testing a rapidly emerging cancer diagnostic tool focusing on the analysis of DNA and RNA, as well as the structure and function of genes at a molecular level. Molecular testing employs multiple technologies including point mutation analysis, sequencing analysis, DNA fragment length analysis, and real-time polymerase chain reaction (RT-PCR) RNA analysis.

All of these testing services are widely utilized to inform the diagnosis and prognosis of various types and subtypes of cancer and to help predict a patient s potential response to specific therapies. NeoGenomics offers testing services on both a tech-only basis, where NeoGenomics performs the technical component of the testing (specimen set-up, staining, imaging, sorting and categorization of cells, chromosomes, genes or DNA) and the client physician performs the related professional interpretation component (analyzing the laboratory data, developing the diagnosis or prognosis as well as preparing and writing the final report), as well as on a full service or global basis where NeoGenomics performs both the technical component and the professional interpretation component.

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#### **Operating Segment**

We have one reportable operating segment that delivers testing services to hospitals, pathologists, oncologists, other clinicians and researchers. Also, at December 31, 2011, all of our services were provided within the United States and all of our assets were in the United States.

## **Market Opportunity**

The medical testing laboratory market can be broken down into three primary segments:

Clinical Pathology testing,

Anatomic Pathology testing, and

Genetic and Molecular testing.

Clinical Pathology testing covers high volume, highly automated, lower complexity tests on easily procured specimens such as blood and urine. Clinical lab tests often involve testing of a less urgent nature, for example, cholesterol testing and testing associated with routine physical exams.

Anatomic Pathology testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely performed Anatomic Pathology procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies.

Genetic and molecular testing typically involves analyzing chromosomes, genes, proteins and/or DNA/RNA sequences for abnormalities. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically M.D. or Ph.D. level) to certify results and typically yields the highest reimbursement levels of the three market segments.

The field of cancer genetics is evolving rapidly and new tests are being developed at an accelerated pace. Based on medical and scientific discoveries over the last 10 years, cancer testing falls into one of three categories: diagnostic testing, prognostic testing and predictive testing. Of the three, the fastest growing area is predictive testing, which is utilized by clinicians to predict a patient s response to the various treatment options in order to deliver personalized medicine that is optimized to that patient s particular circumstances.

We estimate that the United States market for genetic and molecular testing is divided among approximately 360 laboratories. Approximately two thirds of these laboratories are attached to academic institutions and primarily provide clinical services to their affiliated university hospitals and associated physicians. We believe that the remaining one third of the market is quite fragmented and that less than 20 laboratories market their services nationally. We estimate that the top 20 laboratories account for approximately 50% of market revenues for genetic and molecular testing.

We believe that the key factors influencing the rapid market growth for cancer testing include: (i) cancer is primarily a disease of the elderly one in four senior citizens is likely to develop some form of cancer during the rest of their lifetime once they turn sixty, and now that the baby boomer generation has started to reach this age range, the incidence rates of cancer are rising; (ii) every year more and more genes and genomic pathways are implicated in the development and/or clinical course of cancer; and (iii) increasingly, new drugs are being targeted to certain cancer subtypes and pathways which require companion diagnostic testing. Laboratory tests are needed to identify the type and subtype of cancer and the proper treatment regimen for each individual patient in order to deliver personalized medicine to the patient. These factors have driven explosive growth in the development of new genetic and molecular tests. We estimate a \$10-12 billion total market opportunity for cancer testing in the United States, about \$3-5 billion of which is derived from genetic and molecular testing with the remaining portion derived from more traditional anatomic pathology testing services that are complementary to and often ordered with the genetic and molecular testing services we offer.

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## **Our Focus**

Our primary focus is to provide high complexity, cancer-related laboratory testing services to hospitals, community-based pathology practices, and clinicians throughout the United States. We currently perform analyses for hematopoietic cancers such as leukemia and lymphoma (blood and lymphoid tumors) and solid tumor cancers such as breast, lung, colon, and bladder cancer. For hematopoietic cancers, we typically analyze bone marrow aspirate and peripheral blood specimens. For solid tumor cancers, we typically analyze formalin fixed, paraffin embedded tissue samples or urine.

The cancer testing services we offer to community-based pathologists are designed to be a natural extension of, and complementary to, the services that they perform within their own practices. We believe our relationship as a non-competitive partner to community-based pathology practices empowers them to expand their breadth of testing and provide a menu of services that matches or exceeds the level of service found in academic centers of excellence around the country. Community-based pathology practices typically order our services on a tech-only basis, which allows them to participate in the diagnostic process by performing the professional interpretation services without having to make the investment in laboratory personnel or equipment needed to perform the technical component of the tests.

In areas where we do not provide services to community-based pathology practices, we may directly serve oncology, dermatology, urology and other clinician practices that prefer to have a direct relationship with a laboratory for cancer-related genetic and molecular testing services. We typically service these types of clients with a global service offering where we perform both the technical and professional components of the tests ordered. Increasingly, however, larger clinician practices have begun to internalize pathology testing, and our tech-only service offering allows these larger clinician practices to also participate in the diagnostic process by performing the professional interpretation services.

## **Competitive Strengths**

#### Turnaround Times

We strive to provide industry leading turnaround times for test results to our clients nationwide. By providing information to physicians in a rapid manner, they can begin treating their patients as soon as possible. We believe our average 4-5 day turn-around time for our cytogenetics testing services, our average 3-4 day turn-around time for FISH testing services, and our average 1 day turn-around time for flow cytometry testing services are industry-leading benchmarks for national laboratories. Our consistent timeliness of results is a competitive strength and a driver of additional testing requests by our referring physicians. Quick turn-around times allow for the performance of other adjunctive tests within an acceptable diagnosis window in order to augment or confirm results and more fully inform treatment options. We believe that our rapid turnaround times are a key differentiator of NeoGenomics versus other national laboratories, and our clients often cite them as a key factor in their relationship with us.

## Medical Team

Our team of medical professionals and Ph.Ds. are specialists in the field of genetics and oncology. Our medical team is led by our Chief Medical Officer, Dr. Maher Albitar, a renowned hematopathologist with extensive experience in molecular and genetic testing. Prior to joining NeoGenomics, Dr. Albitar was Medical Director for Hematopathology and Oncology at the Quest Nichols Institute and Chief R&D Director for Hematopathology and Oncology for Quest Diagnostics. He also served as Section Chief for Leukemia at the University of Texas M. D. Anderson Cancer Center. In addition to Dr. Albitar, we currently employ five full-time M.D.s as our medical directors and pathologists, two Ph.Ds. as our scientific directors and cytogeneticists, and four part-time M.D.s acting as consultants and backup pathologists for case sign out purposes.

## Extensive Tech-Only Service Offerings

We launched the first tech-only FISH testing services in the United States in 2006, and we currently have the most extensive menu of tech-only FISH services in the country. Indeed, we believe we are the only national laboratory offering tech-only FISH services for hematopoietic cancers in the U.S. We also offer tech-only flow cytometry and immunohistochemistry testing services. These types of testing services generally allow the professional interpretation component of a test to be

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billed separately from the technical component. Our NeoFISH<sup>TM</sup>, NeoFLOW<sup>TM</sup> and other tech-only service offerings allow properly trained and credentialed community-based pathologists to extend their own practices by performing professional interpretations services, which allows them to better service the needs of their local clientele without the need to invest in the lab equipment and personnel required to perform the technical component of genetic and molecular testing.

Our tech-only services are designed to give pathologists the option to choose, on a case by case basis, whether they want to order just the technical information and images relating to a specific test so they can perform the professional interpretation, or order global services and receive a comprehensive test report which includes a NeoGenomics Pathologist s interpretation of the test results. Our clients appreciate the flexibility to access NeoGenomics medical staff for difficult or complex cases or when they are otherwise unavailable to perform professional interpretations. We believe this innovative approach to serving the needs of pathology client s results in longer term, more committed client relationships that are more akin to strategic partnerships. Our extensive tech-only service offerings have differentiated NeoGenomics and allowed us to compete more effectively against larger, more entrenched competitors in our niche of the industry.

## Global Service Offerings

We also offer a full set of global services to meet the needs of those clients who are not credentialed and trained in interpreting genetic tests and who are looking for specialists to interpret the testing results for them. In our global service offerings, our lab performs the technical component of the tests and our M.D.s and Ph.Ds. provide the interpretation services. Our professional staff is also available for post testing consultative services. These clients rely on the expertise of our medical team to give them the answers they need in a timely manner to help inform their diagnoses and treatment decisions. Many of our tech-only clients also rely on our medical team for difficult or challenging cases by ordering our global testing services on a case by case basis. Our Genetic Pathology Solutions (GPS) report summarizes all relevant case data from our global services on one summary report. When providing global services, NeoGenomics performs both the technical and professional component of the test, which results in a higher reimbursement level.

## Client Education Programs

We believe we have one of the most extensive client education programs in the genetic and molecular testing industry. We train pathologists how to use and interpret genetic testing services so that they can then participate in our tech-only service offerings. Our educational programs include an extensive library of on-demand training modules, online courses, and custom tailored on-site training programs that are designed to prepare clients to utilize our tech-only services. Each year, we also regularly sponsor seminars and webinars on emerging topics of interest in our field. Our medical staff is involved in many aspects of our training programs.

# Laboratory Information System (LIS)

We believe we have a state-of-the-art Laboratory Information System (LIS) that interconnects our locations and provides flexible reporting solutions to clients. This system allows us to standardize testing and deliver uniform test results and images throughout our network, regardless of the location that any specific portion of a test is performed within our network. This allows us to move specimens and image analysis work between locations to better balance our workload. Our LIS also allows us to offer highly specialized and customizable reporting solutions to our tech-only clients. For instance, our tech-only NeoFISH<sup>TM</sup> and NeoFLOW<sup>TM</sup> applications allow our community-based pathologist clients to tailor individual reports to their specifications and incorporate only the images they select and then issue and sign-out such reports from our system with their own logos at the top. Our customized reporting solution even allows our clients to incorporate test results performed on ancillary tests not performed at NeoGenomics into summary report templates. This feature has been well-received by clients. In May 2011, we obtained the source code to our LIS. This has given us greater control and flexibility over the customized functionality we develop and offer to clients and allows us to make improvements in a more timely manner.

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National Direct Sales Force

Our direct sales force has been trained extensively in cancer genetic testing and consultative selling skills to service the needs of clients. Our sales representatives ( Territory Business Managers ) are organized into three regions (Northeast, Southeast and West). These sales representatives all utilize Salesforce.com to manage their territories, and we have integrated all of the important customer care functionality within our LIS into Salesforce.com so that our Territory Business Managers can stay on top of emerging issues and opportunities within their regions. As of January 31, 2012, we had twenty Territory Business Managers, one Product Specialist, and three Regional Managers.

## Client Care

Our Customer Care Specialists ( CCS ) are organized by region into territories that service not only our external clients, but also work very closely with and support our sales team. A client receives personalized assistance when dealing with their dedicated CCS because each CCS understands their clients—specific needs. When problems or questions do arise, the CCS is responsible for providing answers to the client. CCS—s handle everything from arranging specimen pickup to managing questions that arise during the test process to delivering test results in order to deliver exceptional services to our clients.

#### Geographic Locations

Many high complexity laboratories within the cancer testing niche have frequently operated a core facility on either the West Coast or the East Coast to service the needs of their customers around the country. We believe our clients and prospects desire to do business with a laboratory with national breadth and a local presence. We have four facilities, two large laboratory locations in Fort Myers, Florida and Irvine, California and two smaller laboratory locations in Nashville, Tennessee and Tampa, Florida. We pride ourselves on operating one lab with four locations that can deliver standardized test results. We intend to continue to develop and open new laboratories or expand our current facilities as market situations dictate and business opportunities arise.

## Scientific Pipeline

In the past few years our field has experienced a rapid increase in tests that are tied to specific genomic pathways . These predictive tests are typically individualized for a small sub-set of patients with a specific subtype of cancer. The therapeutic target in the genomic pathways is typically a small molecule found at the level of the cell surface, within the cytoplasm and/or within the nucleus. These genomic pathways, known as the Hallmarks of Cancer , contain a target-rich environment for small-molecule anti-therapies . These anti-therapies target specific mutations in the major cancer pathways such as the Proliferation Pathway, the Apoptotic Pathway, the Angiogenic Pathway, the Metastasis Pathway, and the Signaling Pathways and Anti-Signaling Pathways.

As an example, recently the FDA approved a small molecule anti-therapy drug (Xalkori) that targets a mutation in the ALK gene for a small sub-set of patients with Non-Small Cell Lung Cancer (NSCLC). Approximately 50-61% of patients with an ALK gene rearrangement will respond to this therapy. To identify patients eligible for this specific small-molecule therapy, an FDA-approved FISH test that NeoGenomics and certain other laboratories offer, must be performed. This ALK FISH test is considered a companion diagnostic test and it is critical that this test be performed and the patient found to have an ALK mutation before therapy can be administered. Tests such as the ALK FISH test allow our clients to direct individualized treatments to each cancer patient in a timely manner. We are increasingly focused on attempting to develop new predictive tests such as this in our new product development pipeline.

## Strategic Licensing Agreement with Health Discovery Corp

In January 2012, we entered into a Master License Agreement (the License Agreement ) with Health Discovery Corporation (HDC), pursuant to which we were granted an exclusive worldwide license to utilize HDC s extensive intellectual property portfolio to develop and commercialize laboratory developed tests (LDTs) and other products relating to hematopoietic and solid tumor cancers. HDC owns intellectual property and know-how, including some 84 issued and pending patents related to support vector machine (SVM), recursive feature elimination (SVM-RFE), fractal genomic modeling (FGM) and other pattern recognition technology as well as certain patents relating to digital image analysis, biomarker discovery, and gene and protein-based diagnostic, prognostic, and predictive testing.

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Under the terms of the License Agreement, we may, subject to certain limitations, use, develop, make, have made, modify, sell, and commercially exploit products and services in the fields of laboratory testing, molecular diagnostics, clinical pathology, anatomic pathology and digital image analysis relating to the development, marketing, production or sale of any LDTs or other products used for diagnosing, ruling out, predicting a response to treatment, and/or monitoring treatment of any hematopoietic and solid tumor cancers excluding cancers affecting the retina and breast cancer (collectively, the Field ).

The License Agreement allows us to develop and sell any gene, gene-product or protein-based LDTs based on HDC s technology in the Field and provides for sublicensing rights and the assignment of the License Agreement, in whole or in part, in our discretion. The License Agreement further provides us with access to certain HDC personnel and consulting resources in the fields of mathematics and in genetic and molecular test development. The licensed technology also includes, among other things, certain tests, algorithms and computer software which have already been developed by HDC. Initially, we intend to focus on developing prostate, pancreatic, and colon cancer LDTs. In addition, we plan to develop interpretation software that will help to automate the analysis of cytogenetics and flow cytometry tests.

Strategic Supply Agreement with Abbott Molecular

In July 2009, we entered into a Strategic Supply Agreement with Abbott Molecular, Inc., a wholly-owned subsidiary of Abbott Laboratories. Under the terms of this agreement, NeoGenomics has the rights to develop and launch three laboratory developed tests based on intellectual property developed and/or licensed by Abbott. We launched the first of these tests in February 2010, a FISH test for the diagnosis of melanoma (called Melanosite<sup>TM</sup>), and we are currently working on other potential new FISH assays under the agreement. In conjunction with the Strategic Supply Agreement, Abbott Laboratories, Inc., the parent company of Abbott Molecular, purchased 3.5 million shares of our common stock, which represented an approximately 8.0% stake in NeoGenomics outstanding common stock at December 31, 2011.

## **Critical Accounting Policies**

The preparation of financial statements in conformity with United States generally accepted accounting principles requires our management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Our management routinely makes judgments and estimates about the effects of matters that are inherently uncertain. For a complete description of our significant accounting policies, see Note B to our Consolidated Financial Statements included in this Annual Report on Form 10-K.

Our critical accounting policies are those where we have made difficult, subjective or complex judgments in making estimates, and/or where these estimates can significantly impact our financial results under different assumptions and conditions. Our critical accounting policies are:

Revenue Recognition

Accounts Receivable

Stock Based Compensation

# Revenue Recognition

The Company recognizes revenues in accordance with the Securities and Exchange Commission s Staff Accounting Bulletin Topic 13.A.1 and FASB ASC 605-10-S99-1, and ASC Topic 954, when (a) the price is fixed or determinable, (b) persuasive evidence of an arrangement exists, (c) the service is performed and (d) collectability of the resulting receivable is reasonably assured.

The Company s specialized diagnostic services are performed based on a written test requisition form and revenues are recognized once the diagnostic services have been performed, and the results have been delivered to the ordering physician. These diagnostic services are billed to various payers, including

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Medicare, commercial insurance companies, other directly billed healthcare institutions such as hospitals and clinics, and individuals. The Company reports revenues from contracted payers, including Medicare, certain insurance companies and certain healthcare institutions, based on the contractual rate, or in the case of Medicare, published fee schedules. The Company reports revenues from non-contracted payers, including certain insurance companies and individuals, based on the amount expected to be collected. The difference between the amount billed and the amount estimated to be collected from non-contracted payers is recorded as an allowance to arrive at the reported net revenues. The expected revenues from non-contracted payers are based on the historical collection experience of each payer or payer group, as appropriate. The Company records revenues from patient pay tests net of a large discount and as a result initially recognizes minimal revenue on those tests. Therefore we believe that we are already recording revenue in accordance with ASU No. 2011-07: Health Care Entities (Topic 954) Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities. The Company regularly reviews its historical collection experience for non-contracted payers and adjusts its expected revenues for current and subsequent periods accordingly. The following is the percentage break-down of net revenue by Payer class:

Payer Class	FY 2011	FY 2010
Government	43%	46%
Commercial Insurance	29%	30%
Client	26%	23%
Patient	1%	1%
Unbilled Revenue	1%	0%
Total	100%	100%

# Trade Accounts Receivable and Allowance For Doubtful Accounts

Accounts receivable are reported, net of an allowance for doubtful accounts, which is estimated based on the aging of accounts receivable with each payer category and the historical data on bad debts in these aging categories. In addition, the allowance is adjusted periodically for other relevant factors, including regularly assessing the state of our billing operations in order to identify issues which may impact the collectability of receivables or allowance estimates. Revisions to the allowance are recorded as an adjustment to bad debt expense within general and administrative expenses. After appropriate collection efforts have been exhausted, specific receivables deemed to be uncollectible are charged against the allowance in the period they are deemed uncollectible. Recoveries of receivables previously written-off are recorded as credits to the allowance. Total adjustments for incremental revenue from tests in which we underestimated the revenue in previous years from collections we received in the current year are not material to the Company s results of operations in any period presented. Our estimates of net revenue are subject to change based on the contractual status and payment policies of the third party payers with whom we deal. We regularly refine our estimates in order to make our estimated revenue as accurate as possible based on our most recent collection experience with each third party payer.

The following tables present the dollars and percentage of the Company s gross accounts receivable from customers outstanding by aging category at December 31, 2011 and 2010:

## NEOGENOMICS AGING OF RECEIVABLES BY PAYER GROUP

December 31, 2011

Payer Group	0-30	%	31-60	%	61-90	%	91-120	%	>120	%	Total	%
Client	\$ 1,016,372	10%	\$ 1,008,912	10%	\$ 296,940	3%	\$ 159,387	2%	\$ 157,500	2%	\$ 2,639,111	27%
Commercial												
Insurance	920,210	9%	652,010	6%	379,880	4%	272,969	3%	1,582,400	16%	3,807,469	38%
Medicaid	24,510	0%	28,097	0%	32,425	0%	46,792	1%	201,379	2%	333,203	3%
Medicare	1,127,747	11%	242,574	2%	206,050	2%	159,863	2%	783,755	8%	2,519,989	25%
Private Pay	13,760	0%	94,377	1%	114,766	1%	113,719	1%	115,466	1%	452,088	4%
Unbilled												
Revenue	292,406	3%		0%		0%		0%		0%	292,406	3%

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Total \$3,395,005 33% \$2,025,970 19% \$1,030,061 10% \$752,730 9% \$2,840,500 29% \$10,044,266 100%

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December 31, 2010

Payer Group		0-30	%	31-60	%	61-90	%	91-120	%	>120	%	Total	%
Client	\$	253,788	4%	\$ 571,918	9%	\$ 284,528	4%	\$ 116,460	2%	\$ 164,895	2%	\$ 1,391,589	21%
Commercial													
Insurance		560,548	8%	333,348	5%	224,682	3%	222,443	3%	1,242,956	18%	2,583,977	37%
Medicaid		36,926	1%	41,700	1%	21,595	%	50,922	1%	187,908	3%	339,051	6%
Medicare		710,264	11%	224,610	3%	435,758	7%	99,699	1%	242,739	4%	1,713,070	26%
Private Pay		30,241	0%	81,688	1%	79,206	2%	48,559	1%	154,763	2%	394,367	6%
Unbilled													
Revenue		272,564	4%		0%		0%		0%		0%	272,564	4%
Total	\$ 1	,864,331	28%	\$ 1,253,264	19%	\$ 1,045,769	16%	\$ 538,083	8%	\$ 1,993,171	29%	\$ 6,694,608	100%

The following table represents our allowance balances at each balance sheet date presented and that allowance as a percentage of gross accounts receivable:

	Decemb	December 31,			
	2011	2010	Change		
Allowance for doubtful accounts	\$ 2,150,000	\$ 1,459,000	\$ 691,000		
As a % of gross accounts receivable	21.4%	21.8%			

# Stock Based Compensation.

The Company accounts for stock-based compensation in accordance with FASB ASC Topic 718 Compensation Stock Compensation. ASC Topic 718 requires recognizing compensation costs for all share-based payment awards made to employees and directors based upon the awards grant-date fair value.

For stock options, the Company uses a trinomial lattice option-pricing model to estimate the grant-date fair value of stock option awards, and recognizes compensation cost on a straight-line basis over the awards requisite service periods. The Company s periodic expense is adjusted for actual forfeitures.

See Note B Summary of Significant Accounting Policies - Stock-Based Compensation and Note F Stock Based Compensation in the Notes to Consolidated Financial Statements for more information regarding the assumptions used in our valuation of stock-based compensation.

## Results of Operations for the year ended December 31, 2011 as compared with the year ended December 31, 2010

The following table presents the condensed consolidated statements of operations as a percentage of revenue:

	For the year	For the year ended		
	Decembe	December 31.		
	2011	2010		
NET REVENUE	100.0%	100.0%		
COST OF REVENUE	55.3%	54.1%		
GROSS PROFIT	44.7%	45.9%		
OPERATING EXPENSES:				
General and administrative	29.6%	32.8%		

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Sales and marketing	16.0%	21.8%
TOTAL OPERATING EXPENSES	45.6%	54.6%
Other (income) and expense Interest (income) expense, net	(0.0)% 1.8%	(1.1)% 2.0%
NET INCOME (LOSS)	(2.7)%	(9.6)%

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#### Revenue

The Company s specialized diagnostic services are performed based on a written test requisition form and revenues are recognized once the diagnostic services have been performed, and the results have been delivered to the ordering physician. These diagnostic services are billed to various payers, including Medicare, commercial insurance companies, other directly billed healthcare institutions such as hospitals and clinics, and individuals. The Company reports revenues from contracted payers, including Medicare, certain insurance companies and certain healthcare institutions, based on the contractual rate, or in the case of Medicare, published fee schedules. The Company reports revenues from non-contracted payers, including certain insurance companies and individuals, based on the amount expected to be collected. The difference between the amount billed and the amount estimated to be collected from non-contracted payers is recorded as an allowance to arrive at the reported net revenues. The expected revenues from non-contracted payers are based on the historical collection experience of each payer or payer group, as appropriate. The Company records revenues from patient pay tests net of a large discount and as a result initially recognizes minimal revenue on those tests. Therefore we believe that we are already recording revenue in accordance with ASU No. 2011-07: Health Care Entities (Topic 954) Presentation and Disclosure of Patient Service Revenue, Provision for Bad Debts, and the Allowance for Doubtful Accounts for Certain Health Care Entities. The Company regularly reviews its historical collection experience for non-contracted payers and adjusts its expected revenues for current and subsequent periods accordingly.

Our revenue, requisition and test metrics for the year ended December 31, 2011 and 2010 are as follows:

FY FY 2011 2010

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