NEOGENOMICS INC
Form 10-K
March 29, 2010

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, 2009
or

o 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: 333-72097

NEOGENOMICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	74-2897368
(State or other jurisdiction of incorporation or organization)	(IRS Employer 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: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o 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 o 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 o

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 o No o

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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 o	Accelerated Filer o
Non-accelerated filer o (Do not check if smaller reporting company)	Smaller reporting company x

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

As of June 30, 2009, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $27.2 million, based on the closing price of the registrant's common stock of $1.34 per share on June 30, 2009.

The number of shares outstanding of the registrant's Common Stock, par value $0.001 per share, as of March 24, 2010: 37,255,092

NEOGENOMICS, INC.
FORM 10-K ANNUAL REPORT
For the Fiscal Year Ended December 31, 2009

Table of Contents

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," "woul similar expressions 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:

- The expected reimbursement levels from governmental payors and private insurers;
- The application, to our business and the services we provide, of existing laws, rules and regulations, including without limitation, Medicare laws, anti-kickback laws, Health Insurance Portability and Accountability Act of 1996 ("HIPAA") regulations, state medical privacy laws, federal and state false claims laws and corporate practice of medicine laws;
- Regulatory developments in the United States;
- Our ability to maintain our license under Clinical Laboratory Improvement Amendments of 1988 ("CLIA");
- Our ability to expand our operations and increase our market share;
- Our ability to expand our service offerings by adding new testing capabilities;
- Our ability to compete with other diagnostic laboratories;
- Our ability to hire and retain sufficient managerial, sales, clinical and other personnel to meet our needs;
- 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.

ITEM 1. DESCRIPTION OF BUSINESS

NeoGenomics, Inc., a Nevada corporation (referred to individually as the "Parent Company" or collectively with all of its subsidiaries as "NeoGenomics" or the "Company" in this Form 10-K) is the registrant for SEC reporting purposes. Our common stock is listed on the OTC Bulletin Board under the symbol "NGNM".

Overview

NeoGenomics operates a network of cancer-focused testing laboratories whose mission is to improve patient care through exceptional cancer genetic diagnostic, prognostic and predictive 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's laboratory network currently offers the following types of testing services:

a) cytogenetics testing, which analyzes human chromosomes;

b) Fluorescence In-Situ Hybridization ("FISH") testing, which analyzes abnormalities at the chromosomal and gene levels;

c) flow cytometry testing, which analyzes gene expression of specific markers inside cells and on cell surfaces;

d) immunohistochemistry testing, which analyzes the distribution of tumor antigens in specific cell and tissue types, and

e) molecular testing which involves analysis of DNA and RNA to diagnose and predict the clinical significance of various genetic sequence disorders.

All of these testing services are widely utilized in the diagnosis, prognosis, and prediction for response to therapy of various types of cancers.

Market Opportunity

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

- clinical lab testing,
- anatomic pathology testing, and
- genetic and molecular testing.

Clinical laboratories are typically engaged in 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 ("AP") testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely performed AP procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies.

Genetic and molecular testing typically involves analyzing chromosomes, genes or DNA/RNA sequences for abnormalities. New tests are being developed at an accelerated pace, thus this market niche continues to expand rapidly. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically MD or PhD level) to certify results and typically yields the highest reimbursement levels of the three market

segments.

The market for cancer testing is growing rapidly. Key factors influencing this growth are: (i) cancer is primarily a disease of the elderly and now that the baby boomer generation has started to turn sixty, the U.S. is experiencing a significant increase in the number of senior citizens, (ii) the American Cancer Society estimates that one in four senior citizens will develop some form of cancer during the rest of their lifetime, and (iii) every year more and more genes are discovered to have a specific link to cancer, which then enables a genetic or molecular test to be developed. We estimate that the Company addresses a $5-6 billion total United States market opportunity, about half of which is derived from genetic and molecular testing with the other half derived from more traditional anatomic pathology testing services that are complementary to and often ordered with the genetic testing services we offer.

Our Focus

NeoGenomics' primary focus is to provide high complexity laboratory testing for community-based pathology, oncology, dermatology and urology markets in the United States and the Caribbean. We focus on community-based practitioners for two reasons: First, academic pathologists and associated clinicians tend to have their testing needs met within the confines of their university affiliation. Secondly, most of the cancer care in the United States is administered by community based practitioners due to ease of local access. We currently provide our services to pathologists and oncologists that perform bone marrow and/or peripheral blood sampling for the diagnosis of blood and lymphoid tumors (leukemias and lymphomas) and archival tissue referred for analysis of solid tumors such as breast cancer. We also serve community-based urologists by providing a FISH-based genetic test for the diagnosis of bladder cancer and early detection of recurrent disease.

The high complexity cancer testing services we offer to community-based pathologists are designed to be a natural extension of and complementary to the services that our pathologist clients perform within their own practices. Because fee-for-service pathologists derive a significant portion of their annual revenue from the interpretation of cancer biopsy specimens, they represent an important market segment to us. We believe our relationship as a non-competitive partner to the community-based pathologist empowers these pathologists to expand their testing breadth and provide a menu of services that matches or exceeds the level of service found in academic centers of excellence around the country.

We also believe that we can provide a competitive choice to those larger oncology practices that prefer to have a direct relationship with a laboratory for cancer genetic testing services. Our regionalized approach allows us strong interactions with clients and our innovative Genetic Pathology Solutions ("GPS") report summarizes all relevant case data on one summary report.

Competitive Strengths

Turnaround Times

At NeoGenomics, we strive to provide industry leading turnaround times to our clients nationwide and to provide information so that physicians can provide their patients with the correct treatment as soon as possible.

We believe our average 4-5 day turn-around time for our cytogenetics testing services and our average 3-4 day turn-around time for FISH testing services continue to be industry-leading benchmarks for national laboratories. The consistent timeliness of results is a competitive strength in cytogenetics and FISH testing and a driver of additional testing requests by our referring physicians. Quick turn-around times for cytogenetics and FISH tests allow for the performance of other tests to augment or confirm results and improve patient care. Without rapid turnaround times, there is an increased chance that the test results will not be returned within an acceptable diagnostic window when other adjunctive diagnostic test results are required. We believe our turn-around times result in our referring physicians requesting more of our testing services and give us a significant competitive advantage in marketing our services against those of other competing laboratories.

National Direct Sales Force

NeoGenomics has assembled a strong direct sales force. Our sales representatives ("Territory Business Managers") are organized into four regions (Northeast, Southeast, Central and West). These sales representatives are trained extensively in cancer genetic testing and consultative selling skills. As of March 24, 2010, we had 24 Territory Business Managers and four Regional Managers.

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 exclusively launch three laboratory developed tests (LDTs) 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, and expect to launch the second test in early 2011 and the third in 2012. In conjunction with the Strategic Supply Agreement, Abbott Laboratories purchased a 9.6% stake in NeoGenomics.

New FISH Test for Melanoma

In February 2010, we launched the first of the three tests developed pursuant to the Strategic Supply Agreement with Abbott under the trade name MelanoSITE™. MelanoSITE™ is a four probe FISH test that can be used as a diagnostic aid to traditional histopathologic evaluation in diagnosing melanoma. In conjunction with histopathology, the MelanoSITE™ test can help improve classification of melanocytic neoplasms with conflicting morphologic criteria and help insure proper follow-up. Differential diagnosis of moderate to severely atypical nevi versus true melanoma is one of the most challenging areas in dermatopathology. While most melanomas can be readily distinguished from nevi on histopathologic examination, we estimate there are about 5% of cases that are ambiguous and show conflicting morphologic criteria. Diagnostic ambiguity has significant adverse consequences for patients and the healthcare system at large. Failure to recognize melanoma is potentially fatal, but labeling a benign lesion as malignant can lead to unwarranted wide re-excisions, sentinel lymph node biopsies, adjuvant toxic therapeutic interventions and the emotional strain of facing a diagnosis of cancer. Considering the large number of biopsies done in the U.S. to either confirm or rule out melanoma, diagnostic uncertainty of this scale represents a significant challenge to the U.S. healthcare system. We believe the MelanoSITE™ test will help address this diagnostic uncertainty and help to reduce the medical costs associated with melanoma by providing a more accurate diagnosis.

The performance characteristics of the MelanoSITE™ test were established in a multicenter validation study involving over 500 cases, which resulted in a sensitivity (a measure of true positives and false negatives) of 77% and a specificity (a measure of true negatives and false positives) of 97%. Importantly, based on our study, the MelanoSITE™ test has a negative predictive value (NPV) of over 98%. This means that dermatopathologists and dermatologists can be confident that a patient with a negative test result has a very low likelihood of having melanoma. Therefore, the clinician may not need to perform a wide re-excision of the lesion, potentially scarring a patient for life, and may not need to perform a sentinel lymph node biopsy which can potentially lead to further complications such as lymphedema. We expect the marketing and selling of the MelanoSITE™ test to be a major focus of the Company during 2010.

Client Care

NeoGenomics 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. CCS's handle everything from arranging specimen pickup to delivering the results to fulfill NeoGenomics' objective of delivering

exceptional services to our clients.

Geographic Locations

In 2009, we continued an aggressive campaign to regionalize our laboratory operations around the country to be closer to our clients. Many high complexity laboratories within the cancer testing niche have frequently operated a core facility on one or both coasts to service the needs of their customers around the country. We believe that our clients and prospects desire to do business with a laboratory with national breadth and a local presence. NeoGenomics' has four facilities. The Chatsworth California location is a small office laboratory for our pathologists. and we have three main laboratory locations in Fort Myers, Florida; Irvine California; and Nashville Tennessee and all facilities have the appropriate state licenses and Clinical Laboratory Improvement Act, as amended ("CLIA"), and College of American Pathologists ("CAP") accreditations and are currently receiving specimens. As situations dictate and opportunities arise, we will continue to develop and open new laboratories, linked together by our optimized Laboratory Information System ("LIS"), to better meet the regionalized needs of our clients.

Laboratory Information System

NeoGenomics has what we believe is a state of the art LIS that interconnects our locations and provides flexible reporting options to clients. This system allows us to deliver uniform test results throughout our network, regardless of where the lab that performs any specific test is located. This allows us to move specimens between locations to better balance our workload. Our LIS also allows us to offer highly specialized services to certain sub-segments of our client base. For instance, our tech-only NeoFISHTM and NeoFLOWTM applications allow our community-based pathologist clients to tailor individual reports to their own customizable report templates. This feature has been well-received by our tech-only clients.

Scientific Pipeline

The field of cancer genetics is rapidly evolving, and we are committed to developing and offering new tests to meet the needs of the market place based on the latest scientific discoveries. During 2009, in addition to the validation work performed for our exclusive Melanoma FISH test, the Company made significant strides in developing the capability to perform molecular diagnostic testing in-house. We believe that by adding additional types of tests to our product offering, we will be able to increase our testing volumes through our existing client base as well as more easily attract new clients via the ability to package our testing services more appropriately to the needs of the market. We expect to launch at least five new molecular tests in fiscal year 2010.

Competition

We operate in segments of the medical testing laboratory industry that are highly competitive. Competitive factors in the genetic and molecular testing business 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 medical testing 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 products obsolete, less effective or uneconomical.

We estimate that the United States market for genetic and molecular testing is divided among approximately 300 laboratories. Approximately 80% of these laboratories are attached to academic institutions and primarily provide clinical services to their affiliate university hospitals. We believe that the remaining 20% 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 intend to continue to gain market share by offering industry-leading turnaround times, a broad service menu, high-quality test reports, bringing new tests to market, and enhanced post-test consultation services through our direct sales force. In addition, we have a fully integrated and interactive internet-enabled LIS that enables us to report real time results to clients in a secure environment.

Global Products

We offer a full set of global services to meet the needs of our clients to improve patient care. In our global service offerings, our lab performs the technical component of tests, and our M.D.s and Ph.D.'s interpret the test results for our clients (known as the professional component). This product line provides a comprehensive testing service to those clients who are not credentialed and trained in interpreting genetic and molecular tests. Global products also allow NeoGenomics to derive a higher level of reimbursement than would otherwise be possible with a tech-only test. This product also services the needs of physicians who are looking for ways to save their time.

We increased our professional level staffing for global requisitions requiring interpretation. Importantly, in April 2008 we recruited two well-known hematopathologists to NeoGenomics at our Irvine, California laboratory location, enabling this west coast facility to become the mirror image of our main facility in Fort Myers, Florida. We currently employ four full-time MDs as our medical directors and pathologists, two PhDs as our scientific directors and cytogeneticists, and one part-time MD acting as a consultant and backup pathologist for case sign out purposes. We have plans to hire several more pathologists in 2010 as our product mix continues to expand beyond tech-only services and more sales emphasis is focused on our ability to issue consolidated reporting with case interpretation under our Genetic Pathology Solutions ("GPS") product line.

Tech-Only Products

In 2006, NeoGenomics launched what we believe was the first technical component only ("tech-only") FISH product offering in the United States. Tech-only products allow our community-based pathology clients that are properly trained and credentialed to provide services to clinicians based on established and trusted relationships. These pathologist clients perform the professional interpretation of results themselves and bill for such work under the physician fee schedule. For tech-only FISH, NeoGenomics performs the technical component of the test (specimen set-up, staining, sorting and categorization of cells, chromosomes, genes or DNA, etc) and the pathology client performs the professional component. This allows NeoGenomics to partner with its pathology clients and provides for close collaboration in meeting market needs. Prior to the advent of tech-only products, pathologists who did not have a genetic lab would have had to send all of the work out to a reference lab. Utilizing NeoFISHTM, pathologist clients are empowered to extend the outreach efforts of their practices and exert a high level of involvement in the delivery of high quality patient care.

NeoFLOWTM tech-only flow cytometry was launched as a companion service to NeoFISHTM in late 2007. We believe the NeoFLOWTM service offering will continue to be a key growth driver for the Company in 2010. Moreover, the combination of NeoFLOWTM and NeoFISHTM strengthens and differentiates NeoGenomics and allows us to compete more favorably against larger, more entrenched competitors in our testing niche.

Sales and Marketing

We continue to grow our testing volumes and revenue due to our expanding field sales footprint. As of March 24, 2010, NeoGenomics' sales and marketing team totaled 35 individuals, including 24 Territory Business Managers (sales representatives), one Account Service Managers, four Regional Managers and six marketing and management professionals. During 2009, we made significant investments in sales and marketing personnel and we expect to realize the positive effects of those investments in 2010.

As a result of our expanding sales force, we experienced 47% year-over-year revenue growth to $29.5 million in 2009 from $20.0 million in 2008. Our average revenue/requisition increased 15% to $931 in 2009 from $808 in 2008 due to a higher mix on global products with interpretation and an increase of higher revenue flow cytometry testing as a percentage of our total revenue.

	FY 2009	FY 2008	% Increase
Client Requisitions Received (Cases)	31,638	24,780	28%
Number of Tests Performed	45,675	32,539	40%
Average Number of Tests/Requisition	1.44	1.31	10%
Total Testing Revenue	$ 29,469,000	$ 20,015,000	47%
Average Revenue/Requisition	$ 931	$ 808	15%
Average Revenue/Test	$ 645	$ 615	5%

Within the subspecialty field of hematopathology, our scientific expertise and product offering allows us to be able to perform multiple tests on each specimen received. 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 performed per requisition increases, we believe this will help to generate significant synergies and efficiencies in our operations and our sales and marketing activities.

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 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.

Distribution Methods

The Company currently performs the vast majority of its testing services at each of its three main clinical laboratory locations: Fort Myers, Florida, Nashville, Tennessee and Irvine, California, and then produces a report for the requesting physician. We also have a facility for our California medical staff in Chatsworth, California. Services performed in-house include cytogenetics, FISH, flow cytometry, morphology, immunohistochemistry, and some molecular testing. The Company currently outsources approximately half of its molecular testing to third parties, but expects to validate and perform the majority of this testing in-house during 2010 to better meet client demand and quality requirements.

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 and as a result of their dominance of that marketplace and the absence of any 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 Laboratories has patent protection which limits other vendors from supplying these probes.

Dependence on Major Clients

We currently market our services to pathologists, oncologists, urologists, hospitals and other clinical laboratories. During 2009, we performed 45,675 individual tests. Ongoing sales efforts have decreased dependence on any given source of revenue. Notwithstanding this fact, one key client accounts for a disproportionately large case volume and revenue total. For the years ended December 31, 2009 and 2008, one client with multiple locations accounted for 10% and 22% respectively, of total revenue. As a result of this one customer bringing certain tests in-house, this client represented less than 5% of our fourth quarter 2009 revenue. All others were less than 5% of total revenue individually.

Payor Mix

In 2009, approximately 49% of our revenue was derived from Medicare claims, 26% from commercial insurance companies, 24% from clients such as hospitals and other reference laboratories, and 1% from all others including patients. As of December 31, 2008, Medicare and one commercial insurance provider accounted for 28% and 9% of the Company's total accounts receivable balance, respectively. There is no other significant concentration in our payor mix.

Trademarks

The "NeoGenomics" name and logo has been trademarked with the United States Patent and Trademark Office. We have also trademarked the brand names MelanoSITE and DermFISH related to our melanoma FISH test.

Number of Employees

As of December 31, 2009, we had 166 full-time equivalent employees. In addition, eight other individuals, including three pathologists and a Ph.D. cytogenetics director, serve as consultants to the Company on a regular basis. On December 31, 2008, we had 114 full-time equivalent employees and six consultants 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, Florida, Nashville, Tennessee, Irvine, California and Chatsworth, California. The Chatsworth California location is a small office laboratory for our pathologists. The

laboratories are licensed as required by the states in which they are located. In addition, the laboratory in Tennessee is licensed by the State of New York as it accepts clinical specimens obtained in New York. All of the NeoGenomics laboratories are certified in accordance with the Clinical Laboratories Improvement Act, 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. The 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. 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's Quality Assurance team, which is comprised of representatives of all departments of the Company, also conducts routine internal surveys and requires corrective actions in response to the findings.

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 strong 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 Company management and, if necessary, 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 that is overseen by the senior management of the Company. 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 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.

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 Compliance Officer 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 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 payors, 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 payor or to the client. Alternatively, the Company may perform the technical component of the test only and either bill the payor 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 "[w]e note that ancillary 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 2008, 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 billing for the technical or professional component of a diagnostic test that was ordered by the physician or supplier and was performed by a physician who does not share a practice with the billing physician or supplier 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. There has been considerable commentary and the regulation has been amended to attempt to clarify the regulation.

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.

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, and 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 of 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.

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 of Civil Rights of HHS 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 June 1, 2010. 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 extends, renews or continues credit or which defers payment for goods or services. Since the Company routinely extends credit by billing for its services after such services are provided, the Company meets the definition of a “creditor” under the Red Flag Rules. Accordingly, the Company has developed a written program designed to identify and detect the relevant warning signs – or “red flags” – of identity theft 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 it may be covered by the Red Flag Rule and take such steps as necessary to comply.

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) obtain adequate financing on favorable terms to fund our business strategies; (iv) maintain appropriate procedures, policies, and systems; (v) hire, train, and retain skilled employees and management; (vi) continue to operate with increasing competition in the medical laboratory industry; (vii) establish, develop and maintain name recognition; and (viii) establish and maintain beneficial relationships with third-party insurance providers and other third party payors. 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 Becoming Profitable

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

We used reasonable efforts to assess and predict the expenses necessary to pursue our business plan. However, implementing our business plan 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 a patent 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 our limited operating history and 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.

16

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 payors, 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 many 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 the majority 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. 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. Many of our existing competitors have significantly greater financial, human, technical and marketing resources than we do. 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 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 and Chatsworth, 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 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.

On February 1, 2008, we entered in a revolving credit facility with CapitalSource Finance, LLC ("CapitalSource"), which allows us to borrow up to $3,000,000 based on a formula which is tied to our eligible accounts receivable that are aged less than 150 days. As of December 31, 2009, we had cash and cash equivalents of approximately $1,630,000, restricted cash of $1,000,000 and we had approximately $2,447,000 of availability under this credit facility. If we were unable to obtain sufficient working capital financing from CapitalSource or sell enough of our products, we would need to secure other sources of funding, including possibly equity financing, in order to satisfy our working capital needs. This line expires on January 31, 2011, and we have the risk that it may not be renewed or a suitable replacement found. The CapitalSource credit facility line has financial covenants which are measured on a

monthly basis and which must continue to be met by the Company. We failed to meet our fixed charge coverage ratio for the test periods ended January 31, 2010 and February 28, 2010 and received a waiver on March 26, 2010. In the event that we do not continue to meet the requirements by such financial covenants or we otherwise default on the terms of the CapitalSource credit facility and we are unable to obtain a waiver of such default or obtain Capital Source's agreement to amend the facility, there is a risk that Capital Source could stop lending under the facility and demand that all amounts outstanding under the facility be paid immediately by the Company.

On November 5, 2008, the Company and Fusion Capital Fund II, LLC, an Illinois limited liability company ("Fusion Capital"), entered into a Common Stock Purchase Agreement (the "Purchase Agreement"). We only have the right to receive $50,000 every four business days under the Purchase Agreement unless our stock price equals or exceeds $0.75, in which case we can sell greater amounts to Fusion Capital as the price of our common stock increases. Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business day that the market price of our common stock is less than $0.45. Since we registered 3,000,000 shares for sale under the Purchase Agreement by Fusion Capital pursuant to a registration statement on Form S-1 filed on November 28, 2008, the selling price of our common stock to Fusion Capital will have to average at least $2.67 per share for us to receive the maximum proceeds of $8.0 million. Assuming a purchase price of $1.50 per share (the closing sale price of the common stock on December 31, 2009) and the purchase by Fusion Capital of the full 3,000,000 shares under the Purchase Agreement, proceeds to us would only be $4,500,000 unless we choose to register more than 3,000,000 shares, which we have the right, but not the obligation, to do. Subject to approval by our board of directors, we have the right but not the obligation to sell more than 3,000,000 shares to Fusion Capital. In the event we elect to sell more than 3,000,000 shares to Fusion Capital, we will be required to file a new registration statement and have it declared effective by the U.S. Securities and Exchange Commission.

The extent we rely on Fusion Capital as a source of funding will depend on a number of factors, including the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. Specifically, Fusion Capital shall not have the right nor the obligation to purchase any shares of our common stock on any business days that the market price of our common stock is less than $0.45. If obtaining sufficient financing from Fusion Capital were to prove unavailable or prohibitively dilutive and if we are unable to sell enough of our products, we will need to secure another source of funding in order to satisfy our working capital needs.

Even if we are able to access the full $3.0 million from CapitalSource and the full $8.0 million under the Purchase Agreement with Fusion Capital, 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 business, operating results, financial condition and prospects.

Proposed Government Regulation Of Laboratory Developed Tests ("LDT's") May Result In Delays To 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 methods. 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 offered under approval by CLIA and individual state licensing procedures: the FDA is considering requiring FDA approval on a portion of those currently offered non-FDA approved tests. 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 to us.

Steps Taken By Government Payors, 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 formulas adverse to sustainable payment rates, and has reduced, delayed, or modified updates to the Medicare Physician 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, 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 2008, Congress acted to provide a 1.1% increase in physician fee schedule payments in 2009. The calendar year 2010 update to the conversion factor for the physician fee schedule, based on the statutory formula, is a payment reduction of 21.2 %. To temporarily prevent this reduction to the physician fee schedule, an extension of the 2009 conversion factor through February 28, 2010 was included in legislation enacted on December 19, 2009. However, legislation was enacted in early March of 2010 to delay the implementation of the reduction until September 30, 2010. In the event that the reduction in the Medicare physician fee schedule is 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 could have a material adverse effect on our business, operating results, financial condition and prospects.

In addition, certain other legislation expired on December 31, 2009 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). As a result of the expiration of the TC Grandfather legislation, reference labs like the Company could no longer bill Medicare directly for the technical component of laboratory tests for grandfathered hospitals. However the recently enacted Patient Protection and Affordable Care Act, HR 3590, extended the TC Grandfather provision through December 31, 2010. In the event that the TC Grandfather legislation is not further extended, Company would 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 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.

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 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. 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 Payors 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 payors, including governmental payors such as Medicare and private payors, 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 payors. Any pricing pressure exerted by these third party payors on our clients may, in turn, be exerted by our clients on us. If government and other third party payors 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 Will Result In Significant Additional Costs To Us

Billing for laboratory services is extremely complicated. The customer refers the tests; the payor 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 payors, 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 payors;
- disputes with payors 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 payors, 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 knowingly 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 a fraudulent claim 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. In addition, various states have enacted laws modeled after the federal False Claims Act. Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future.

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 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 patient 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 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.

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

Billable tests which are reimbursable from Medicare and Medicaid accounted for approximately 49% and 47% of our revenues for the years ended December 31, 2009 and 2008, respectively. The Medicare program imposes extensive and detailed requirements on diagnostic services 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 payor rules could result in our inability to participate in a governmental payor program, our returning 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 payor 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.

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 the circumstances under which uses and disclosures of PHI are permitted or required without a specific authorization by the patient, including but not limited to treatment purposes, activities to obtain payments for services and health care operations activities; a patient's rights 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 "floor" 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 fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties. Although the HIPAA statute and regulations do not expressly provide for a private right of 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.

Changes In Regulations, Payor Policies Or Contracting Arrangements With Payors 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 payors, as well as private insurers and private payors, 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 payors do not provide adequate coverage and reimbursement for them. These changes in federal, state, local and third party payor 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 payors with whom we are not currently contracted. Because a portion of our revenues is from third-party payors 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.

23

We Are Subject To Security Risks Which Could Harm Our Operations

Despite the implementation of various security measures by us, our infrastructure is 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, 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.

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 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 high 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 the departed 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, and also our local courier, 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.

24

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.

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 substantially 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 Effectively Controlled By Existing Stockholders And Therefore Other Stockholders Will Not Be Able To Direct The Company

Effective voting control of the Company is held by a relatively small group of stockholders. These stockholders effectively retain control of our Board of Directors and determine all of our corporate actions. In addition, the Company and stockholders owning and/or having the right to vote 12,204,730 shares, or approximately 32.8% of the Company’s voting shares outstanding as of March 24, 2010, have executed a Shareholders’ Agreement that, among other provisions, gives Aspen Select Healthcare, LP (“Aspen”), our largest stockholder, the right to elect three out of the eight directors authorized for our Board and nominate one mutually acceptable independent director and Dr. Michael T. Dent, our founder, the right to nominate one director. Accordingly, it is anticipated that Aspen and other parties to the Shareholders’ Agreement will continue to have the ability to effectively elect a controlling number of the members of our Board of Directors. Such concentration of ownership may also have the effect of delaying or preventing a

change in control of the Company.

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 OTC Bulletin Board 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.

If We Are Not The Subject Of Securities Analyst Reports Or 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. There are many publicly traded companies active in the healthcare industry, which may mean it will be less likely that we receive analysts' coverage, which in turn could affect the price of our common stock. In addition, 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 also 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 fall under one 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.

None

ITEM 2. DESCRIPTION OF PROPERTY

We operate a regional network of laboratories. All our facilities are leased and we believe that they are sufficient to meet our needs for the foreseeable future 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	25,700
Irvine, California	Laboratory	14,800
Chatsworth, California	Pathology Laboratory	1,200
Nashville, Tennessee	Laboratory	5,400

ITEM 3. LEGAL PROCEEDINGS

On November 9th, 2009, the Company was notified by the Civil Division of the U.S. Department of Justice ("DOJ") that a "Qui Tam" Complaint ("Complaint") had been filed under seal by a private individual against a number of health care companies, including the Company. The Complaint is an action to recover damages and civil penalties arising from alleged false or fraudulent claims and statements submitted or caused to be submitted by the defendants to Medicare. The DOJ has not made any decision whether to join the action. The Company believes the allegations in the Complaint are without merit and intends to vigorously defend itself if required to do so.

ITEM 4. (REMOVED AND RESERVED)

PART II

ITEM 5. MARKET FOR THE COMPANY'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market Information

Our common stock is quoted on the OTC Bulletin Board 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	HIGH BID	LOW BID
4th Quarter 2009	$ 1.80	$ 1.41
3rd Quarter 2009	$ 2.25	$ 1.32
2nd Quarter 2009	$ 1.49	$ 0.92
1st Quarter 2009	$ 1.19	$ 0.56
4th Quarter 2008	$ 1.05	$ 0.56
3rd Quarter 2008	$ 1.15	$ 0.83
2nd Quarter 2008	$ 1.35	$ 0.86
1st Quarter 2008	$ 1.15	$ 0.72

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.NASDAQ.com web site.

Holders of Common Stock

As of March 24, 2010, there were 495 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 Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders:			
Amended and Restated Equity Incentive Plan ("Equity Incentive Plan")	4,861,653	$ 0.85	1,039,299(d)
Employee Stock Purchase Plan ("ESPP")	-	N/A	275,356
Equity compensation plans not approved by security holders	975,000(b,c)	$ 0.96	-
Total	5,836,653	$ 0.87	

(a) As of December 31, 2009.

(b) Includes an outstanding option to purchase 350,000 shares of common stock granted to Robert P. Gasparini, our President and Chief Science 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 Doug 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) 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, 2009. 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, 2009.

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.

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" or the "Company" in this Form 10-K) is the registrant for SEC reporting purposes. Our common stock is listed on the OTC Bulletin Board 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

NeoGenomics operates a network of cancer-focused testing laboratories whose mission is to improve patient care through exceptional cancer genetic diagnostic, prognostic and predictive 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's laboratory network currently offers the following types of testing services:

a) cytogenetics testing, which analyzes human chromosomes;

b) Fluorescence In-Situ Hybridization ("FISH") testing, which analyzes abnormalities at the chromosomal and gene levels;

c) flow cytometry testing, which analyzes gene expression of specific markers inside cells and on cell surfaces;

d) immunohistochemistry testing, which analyzes the distribution of tumor antigens in specific cell and tissue types, and

e) molecular testing which involves analysis of DNA and RNA to diagnose and predict the clinical significance of various genetic sequence disorders.

All of these testing services are widely utilized in the diagnosis, prognosis, and prediction for response to therapy of various types of cancers.

Market Opportunity

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

- clinical lab testing,
- anatomic pathology testing, and
- genetic and molecular testing.

Clinical laboratories are typically engaged in 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 ("AP") testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely performed AP procedures include the preparation and interpretation of pap smears, skin biopsies, and tissue biopsies.

Genetic and molecular testing typically involves analyzing chromosomes, genes or DNA/RNA sequences for abnormalities. New tests are being developed at an accelerated pace, thus this market niche continues to expand rapidly. Genetic and molecular testing requires highly specialized equipment and credentialed individuals (typically MD or PhD level) to certify results and typically yields the highest reimbursement levels of the three market segments.

The market for cancer testing is growing rapidly. Key factors influencing this growth are: (i) cancer is primarily a disease of the elderly and now that the baby boomer generation has started to turn sixty, the U.S. is experiencing a significant increase in the number of senior citizens, (ii) the American Cancer Society estimates that one in four senior citizens will develop some form of cancer during the rest of their lifetime, and (iii) every year more and more genes are discovered to have a specific link to cancer, which then enables a genetic or molecular test to be developed. We estimate that the Company addresses a $5-6 billion total United States market opportunity, about half of which is derived from genetic and molecular testing with the other half derived from more traditional anatomic pathology testing services that are complementary to and often ordered with the genetic testing services we offer.

Our Focus

NeoGenomics' primary focus is to provide high complexity laboratory testing for community-based pathology, oncology, dermatology and urology markets in the United States and the Caribbean. We focus on community-based practitioners for two reasons: First, academic pathologists and associated clinicians tend to have their testing needs met within the confines of their university affiliation. Secondly, most of the cancer care in the United States is administered by community based practitioners due to ease of local access. We currently provide our services to pathologists and oncologists that perform bone marrow and/or peripheral blood sampling for the diagnosis of blood and lymphoid tumors (leukemias and lymphomas) and archival tissue referred for analysis of solid tumors such as breast cancer. We also serve community-based urologists by providing a FISH-based genetic test for the diagnosis of bladder cancer and early detection of recurrent disease.

The high complexity cancer testing services we offer to community-based pathologists are designed to be a natural extension of and complementary to the services that our pathologist clients perform within their own practices. Because fee-for-service pathologists derive a significant portion of their annual revenue from the interpretation of cancer biopsy specimens, they represent an important market segment to us. We believe our relationship as a non-competitive partner to the community-based pathologist empowers these pathologists to expand their testing breadth and provide a menu of services that matches or exceeds the level of service found in academic centers of excellence around the country.

We also believe that we can provide a competitive choice to those larger oncology practices that prefer to have a direct relationship with a laboratory for cancer genetic testing services. Our regionalized approach allows us strong interactions with clients and our innovative Genetic Pathology Solutions ("GPS") report summarizes all relevant case data on one summary report.

Competitive Strengths

Turnaround Times

At NeoGenomics, we strive to provide industry leading turnaround times to our clients nationwide and to provide information so that physicians can provide their patients with the correct treatment as soon as possible.

We believe our average 4-5 day turn-around time for our cytogenetics testing services and our average 3-4 day turn-around time for FISH testing services continue to be industry-leading benchmarks for national laboratories. The

consistent timeliness of results is a competitive strength in cytogenetics and FISH testing and a driver of additional testing requests by our referring physicians. Quick turn-around times for cytogenetics and FISH tests allow for the performance of other tests to augment or confirm results and improve patient care. Without rapid turnaround times, there is an increased chance that the test results will not be returned within an acceptable diagnostic window when other adjunctive diagnostic test results are required. We believe our turn-around times result in our referring physicians requesting more of our testing services and give us a significant competitive advantage in marketing our services against those of other competing laboratories.

National Direct Sales Force

NeoGenomics has assembled a strong direct sales force. Our sales representatives ("Territory Business Managers") are organized into four regions (Northeast, Southeast, Central and West). These sales representatives are trained extensively in cancer genetic testing and consultative selling skills. As of March 24, 2010, we had 24 Territory Business Managers and four Regional Managers.

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 exclusively launch three laboratory developed tests (LDTs) 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, and expect to launch the second test in early 2011 and the third in 2012. In conjunction with the Strategic Supply Agreement, Abbott Laboratories purchased a 9.6% stake in NeoGenomics.

New FISH Test for Melanoma

In February 2010 we launched the first of the three tests developed pursuant to the Strategic Supply Agreement with Abbott under the trade name MelanoSITE™. MelanoSITE™ is a four probe FISH test that can be used as a diagnostic aid to traditional histopathologic evaluation in diagnosing melanoma. In conjunction with histopathology, the MelanoSITE™ test can help improve classification of melanocytic neoplasms with conflicting morphologic criteria and help insure proper follow-up. Differential diagnosis of moderate to severely atypical nevi versus true melanoma is one of the most challenging areas in dermatopathology. While most melanomas can be readily distinguished from nevi on histopathologic examination, we estimate there are about 5% of cases that are ambiguous and show conflicting morphologic criteria. Diagnostic ambiguity has significant adverse consequences for patients and the healthcare system at large. Failure to recognize melanoma is potentially fatal, but labeling a benign lesion as malignant can lead to unwarranted wide re-excisions, sentinel lymph node biopsies, adjuvant toxic therapeutic interventions and the emotional strain of facing a diagnosis of cancer. Considering the large number of biopsies done in the U.S. to either confirm or rule out melanoma, diagnostic uncertainty of this scale represents a significant challenge to the U.S. healthcare system. We believe the MelanoSITE™ test will help address this diagnostic uncertainty and help to reduce the medical costs associated with melanoma by providing a more accurate diagnosis.

The performance characteristics of the MelanoSITE™ test were established in a multicenter validation study involving over 500 cases, which resulted in a sensitivity (a measure of true positives and false negatives) of 77% and a specificity (a measure of true negatives and false positives) of 97%. Importantly, based on our study, the MelanoSITE™ test has a negative predictive value (NPV) of over 98%. This means that dermatopathologists and dermatologists can be confident that a patient with a negative test result has a very low likelihood of having melanoma. Therefore, the clinician may not need to perform a wide re-excision of the lesion, potentially scarring a patient for life, and may not need to perform a sentinel lymph node biopsy which can potentially lead to further complications such as lymphedema. We expect the marketing and selling of the MelanoSITE™ test to be a major focus of the Company during 2010.

Client Care

NeoGenomics 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. CCS's handle everything from arranging specimen pickup to delivering the results to fulfill NeoGenomics' objective of delivering

exceptional services to our clients.

Geographic Locations

In 2009, we continued an aggressive campaign to regionalize our laboratory operations around the country to be closer to our clients. Many high complexity laboratories within the cancer testing niche have frequently operated a core facility on one or both coasts to service the needs of their customers around the country. We believe that our clients and prospects desire to do business with a laboratory with national breadth and a local presence. NeoGenomics' has four facilities. The Chatsworth California location is a small office laboratory for our pathologists. and we have three main laboratory locations in Fort Myers, Florida; Irvine California; and Nashville Tennessee and all facilities have the appropriate state licenses and Clinical Laboratory Improvement Act, as amended ("CLIA"), and College of American Pathologists ("CAP") accreditations and are currently receiving specimens. As situations dictate and opportunities arise, we will continue to develop and open new laboratories, linked together by our optimized Laboratory Information System ("LIS"), to better meet the regionalized needs of our clients.

Laboratory Information System

NeoGenomics has what we believe is a state of the art LIS that interconnects our locations and provides flexible reporting options to clients. This system allows us to deliver uniform test results throughout our network, regardless of where the lab that performs any specific test is located. This allows us to move specimens between locations to better balance our workload. Our LIS also allows us to offer highly specialized services to certain sub-segments of our client base. For instance, our tech-only NeoFISHTM and NeoFLOWTM applications allow our community-based pathologist clients to tailor individual reports to their own customizable report templates. This feature has been well-received by our tech-only clients.

Scientific Pipeline

The field of cancer genetics is rapidly evolving, and we are committed to developing and offering new tests to meet the needs of the market place based on the latest scientific discoveries. During 2009, in addition to the validation work performed for our exclusive Melanoma FISH test, the Company made significant strides in developing the capability to perform molecular diagnostic testing in-house. We believe that by adding additional types of tests to our product offering, we will be able to increase our testing volumes through our existing client base as well as more easily attract new clients via the ability to package our testing services more appropriately to the needs of the market. We expect to launch at least five new molecular tests in 2010.

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 SEC Staff Accounting Bulletin Topic 13.A.1 (ASC 605-10-S99-1), "Revenue Recognition", 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, the results have been delivered to the ordering physician, the payor has been identified and eligibility and insurance have been verified. These diagnostic services are billed to various payors, including Medicare, commercial insurance companies, other directly billed healthcare institutions such as hospitals and clinics, and individuals. The Company reports revenues from contracted payors, 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 payors, including certain insurance companies and individuals, based on the amount expected to be collected. The difference between the amount billed and the amount expected to be collected from non-contracted payors is recorded as a contractual allowance to arrive at the reported revenues. The expected revenues from non-contracted payors are based on the historical collection experience of each payor or payor group, as appropriate. In each reporting period, the Company reviews its historical collection experience for non-contracted payors and adjusts its expected revenues for current and subsequent periods accordingly. As a result of the economic climate in the United States, we have used shorter and more current time horizons in analyzing historical experience.

Trade Accounts Receivable and Allowance For Doubtful Accounts

We record accounts receivable net of estimated discounts, contractual allowances and allowances for bad debts. We provide for accounts receivable that could become uncollectible in the future by establishing an allowance to reduce the carrying value of such receivables to their estimated net realizable value. We estimate this allowance based on the aging of our accounts receivable and our historical collection experience for each type of payer. Receivables are charged off to the allowance account at the time they are deemed uncollectible. In the event that the actual amount of payment received differs from the previously recorded estimate of an account receivable, an adjustment to revenue is made in the current period at the time of final collection and settlement. During 2009, we recorded approximately $279,000 of net total incremental revenue from tests in which we underestimated the revenue in 2008 relative to the amounts that we ultimately received in 2009. This was approximately 0.9% of our total 2009 fiscal year revenue and 1.4% of our 2008 fiscal year revenue. During 2008, we recorded approximately $259,000 of net total incremental revenue from tests in which we underestimated the revenue in 2007 relative to the amounts that we ultimately received in 2008. This was approximately 1.3% of our total 2008 fiscal year revenue and 2.3% of our 2007 fiscal year revenue. These adjustments 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 net accounts receivable from customers outstanding by aging category at December 31, 2009 and 2008. All of our receivables were pending approval by third-party payers as of the date that the receivables were recorded:

NEOGENOMICS AGING OF RECEIVABLES BY PAYOR GROUP

December 31, 2009

Payor Group	0-30	%	30-60	%	60-90	%	90-120	%	120-150	%	>150	%	Total