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

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PART I

FORWARD-LOOKING STATEMENTS

The information in this Annual Report on Form 10-K contains "forward-looking statements" and information within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "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.