

NEOGENOMICS INC
Form 10KSB
April 14, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-KSB

(Mark One)

Annual report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934.

For the fiscal year ended December 31, 2007

or

Transition report pursuant to section 13 or 15(d) of the Securities Exchange Act 1934

Commission File Number: 333-72097

NEOGENOMICS, INC.
(Name of small business issuer in its charter)

Nevada

74-2897368

(State or other jurisdiction of
Identification No.)

(IRS Employer

incorporation or organization)

12701 Commonwealth Drive, Suite 9 Fort Myers, FL 33913
(Address of principal executive offices, Zip code)

(239) 768-0600
(Issuer's telephone number)

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

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

Indicate by check mark if the Company is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.

Indicate by check mark whether the Company (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will be contained, to the best of Company's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

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

The Company's revenues for the fiscal year ended December 31, 2007 were approximately \$11,505,000.

The aggregate market value of the voting stock held by non-affiliates of the Company at March 31, 2008 was approximately \$17,956,000 (based on 17,603,888 shares held by non-affiliates and a closing share price of \$1.02/share on March 31, 2008). Shares of common stock held by each officer and director and by each person who owns 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other persons.

As of March 31, 2008, 31,407,545 shares of common stock were outstanding.

Transitional Small Business Disclosure Format: Yes No

PART I

FORWARD-LOOKING STATEMENTS

This Form 10-KSB contains “forward-looking statements” relating to 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-KSB), which represent the Company’s current expectations or beliefs including, but not limited to, statements concerning the Company’s operations, performance, financial condition and growth. For this purpose, any statements contained in this Form 10-KSB that are not statements of historical fact are forward-looking statements. Without limiting the generality of the foregoing, words such as “may”, “anticipation”, “intend”, “could”, “estimate” or “continue” or the negative or other comparable terminology are intended to identify forward-looking statements. These statements by their nature involve substantial risks and uncertainties, such as credit losses, dependence on management and key personnel, variability of quarterly results, and the ability of the Company to continue its growth strategy and competition, certain of which are beyond the Company’s control. Should one or more of these risks or uncertainties materialize or should the underlying assumptions prove incorrect, actual outcomes and results could differ materially from those indicated in the forward-looking statements.

Any forward-looking statement speaks only as of the date on which such statement is made, and the Company undertakes no obligation to update any forward-looking statement or statements to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events. New factors emerge from time to time and it is not possible for management to predict all of such factors, nor can it assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

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-KSB) is the registrant for SEC reporting purposes. Our common stock is listed on the NASDAQ Over-The-Counter Bulletin Board (the “OTCBB”) under the symbol “NGNM.”

NeoGenomics operates a network of cancer-focused testing laboratories. The Company’s growing network of laboratories currently offers the following types of testing services to pathologists, oncologists, urologists, hospitals, and other laboratories throughout the United States:

- 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; and
- d) 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 and prognosis of various types of cancer.

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 base pairs of DNA or RNA 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 average revenue per test of the three market segments. The estimated size of this market is \$4-5 Billion and growing at an annual rate of greater than 25%.

NeoGenomics’, primary focus is to provide high complexity laboratory testing for the community-based pathology and oncology marketplace. Within these key market segments, we currently provide our services to pathologists and oncologists in the United States that perform bone marrow and/or peripheral blood sampling for the diagnosis of blood and lymphoid tumors (leukemias and lymphomas) and archival tissue referral for analysis of solid tumors such as breast cancer. A secondary strategic focus targets community-based urologists due to the availability of UroVysion®, a FISH-based test for the initial diagnosis of bladder cancer and early detection of recurrent disease. 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, not in academic centers, due to ease of local

access. Moreover, within the community-based pathologist segment it is not our intent to willingly compete with our customers for testing services that they may seek to perform themselves. Fee-for-service pathologists for example, derive a significant portion of their annual revenue from the interpretation of biopsy specimens. Unlike other larger laboratories, which strive to perform 100% of such testing services themselves, we do not compete with our customers for such specimens. Rather, our high complexity cancer testing focus is a natural extension of and complementary to many of the services that our community-based customers often perform within their own practices. As such, we believe our relationship as a non-competitive consultant, empowers these physicians 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.

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We continue to make progress growing our testing volumes and revenue beyond our historically focused effort in Florida due to our expanding field sales footprint. As of March 15, 2008, NeoGenomics' sales and marketing organization totaled 16 individuals, and we have received business from 24 states throughout the country. Recent, key hires included various territory business managers (sales representatives) in the Northeastern, Southeastern, and Western states. We intend to continue to add additional sales and marketing personnel throughout FY 2008. As more sales representatives are added, we believe that the base of our business outside of Florida will continue to grow and ultimately eclipse that which is generated within the state.

We are successfully competing in the marketplace based on the quality and comprehensiveness of our test results, and our innovative flexible levels of service, industry-leading turn-around times, regionalization of laboratory operations and ability to provide after-test support to those physicians requesting consultation.

2007 saw the refinement of our industry leading NeoFISHTM technical component-only FISH service offering. Upon the suggestion of our installed customer base, we made numerous usability and technical enhancements throughout last year. The result has been a product line for NeoGenomics that continues to resonate very well with our client pathologists. Utilizing NeoFISHTM, such clients are empowered to extend the outreach efforts of their practices and exert a high level of sign out control over their referral work in a manner that was previously unobtainable.

NeoFLOWTM tech-only flow cytometry was launched as a companion service to NeoFISHTM in late 2007. While not a first to market product line for NeoGenomics, the significant breadth of the service offering together with high usability scores from early customers indicate NeoFLOWTM will be a key growth driver in 2008. Moreover, the combination of NeoFLOWTM and NeoFISHTM serves to strengthen the market differentiation of each product line for NeoGenomics and allows us to compete more favorably against larger, more entrenched competitors in our testing niche.

At the risk of becoming known solely as a technical component-only laboratory, we increased our professional level staffing for global requisitions requiring interpretation in 2007. We currently employ two full-time MDs as our medical directors and pathologists, two PhDs as our scientific directors and cytogeneticists, and two part-time MDs acting as consultants and backup pathologists for case sign out purposes. We have plans to hire several more hematopathologists in 2008 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 (GPSTM) product line.

We believe NeoGenomics average 3-5 day turn-around time for our cytogenetics services continues to remain an industry-leading benchmark for national laboratories. The timeliness of results continues to increase the usage patterns of cytogenetics and act as a driver for other add-on testing requests by our referring physicians. Based on anecdotal information, we believe that typical cytogenetics labs have 7-14 day turn-around times on average with some labs running as high as 21 days. Traditionally, longer turn-around times for cytogenetics tests have resulted in fewer FISH and other molecular tests being ordered since 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 available. We believe our turn-around times result in our referring physicians requesting more of our testing services in order to augment or confirm other diagnostic tests, thereby giving us a significant competitive advantage in marketing our services against those of other competing laboratories.

In 2007 we continued an aggressive campaign to regionalize our laboratory operations around the country to be closer to our customers. 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. Informal surveys of customers and prospects uncovered a desire to do business with a laboratory with national breadth but with a more local presence. In such a scenario, specimen integrity, turnaround-time of results, client service support, and interaction with our medical staff are all enhanced. In 2007, NeoGenomics' three laboratory locations in Fort Myers, FL; Irvine, CA; and Nashville TN each received the appropriate state, Clinical Laboratory Improvement Amendments (CLIA), and College of American Pathologists (CAP) licenses and accreditations are now receiving specimens. As situations dictate and opportunities arise, we will continue to develop and open new laboratories, seamlessly linked together by our optimized Laboratory Information System (LIS), to better meet the regionalized needs of our customers.

2007 also brought much progress in the NeoGenomics Contract Research Organization ("CRO") division based at our Irvine, CA facility. This division was created to take advantage of our core competencies in genetic and molecular high complexity testing and act as a vehicle to compete for research projects and clinical trial support contracts in the biotechnology and pharmaceutical industries. The CRO division will also act as a development conduit for the validation of new tests which can then be transferred to our clinical laboratories and be offered to our clients. We envision the CRO as a way to infuse some intellectual property into the mix of our services and in time create a more "vertically integrated" laboratory that can potentially offer additional clinical services of a more proprietary nature.

2007 brought the first revenue to NeoGenomics' CRO division. Traditionally, the initial revenue stream is rather small due to the size of contracts closed and this was the case for NeoGenomics' CRO last year. As pharmaceutical and biotechnology clients increase their commitment to lead drugs in development the size and scope of the projects outsourced to their CRO partners increases in tandem, and that is what we expect to occur in 2008.

As NeoGenomics grows, we anticipate offering additional tests that broaden our focus from genetic and molecular testing to more traditional types of anatomic pathology testing (i.e. immunohistochemistry) that are complementary to our current test offerings. At no time do we expect to intentionally compete with fee-for-service pathologists for services of this type and Company sales efforts will operate under a strict "right of first refusal" philosophy that supports rather than undercuts the practice of community-based pathology. We believe that by adding additional types of tests to our product offering we will be able to capture increases in our testing volumes through our existing customer base as well as more easily attract new customers via the ability to package our testing services more appropriately to the needs of the market.

The above market strategy continues to bear fruit for the Company, resulting in strong year over year growth of 78% in FY 2007 versus FY 2006. Our average revenue/requisition FY 2006 was approximately \$677/requisition. FY 2007 saw a slight erosion of average tests per requisition due to the overwhelming success of our UroVysion (bladder cancer) product line, which tends to be a singly ordered test request. New sales hires and a new focus on global workups with interpretation and our integrated GPS product line should allow us to increase our average revenue per customer requisition in 2008.

	FY 2007	FY 2006	% Inc (Dec)
Customer Requisitions Rec'd (Cases)	16,385	9,563	71.3%
Number of Tests Performed	20,998	12,838	63.6%
Average Number of Tests/Requisition	1.28	1.34	(4.5)%
Total Testing Revenue	\$ 11,504,725	\$ 6,475,996	77.7%
Average Revenue/Requisition	702.15	\$ 677.19	3.7%
Average Revenue/Test	547.90	\$ 504.44	8.6%

We believe this bundled approach to testing represents a clinically sound practice that is medically valid. Within the subspecialty field of hematopathology, such a bundled approach to the diagnosis and prognosis of blood and lymph node diseases has become the standard of care throughout the country. In addition, as the average number of tests performed per requisition increases, we believe this should drive large increases in our revenue and afford the Company significant synergies and efficiencies in our operations and sales and marketing activities.

Business of NeoGenomics

Services

We currently offer four primary types of testing services: cytogenetics, flow cytometry, FISH testing and molecular testing.

Cytogenetics Testing. Cytogenetics testing involves analyzing chromosomes taken from the nucleus of cells and looking for abnormalities in a process called karyotyping. A karyotype evaluates the entire 46 human chromosomes by number and banding patterns to identify abnormalities associated with disease. In cytogenetics testing, we typically analyze chromosomes from 20 different cells. Examples of cytogenetics testing at NeoGenomics include bone marrow aspirate or peripheral blood analysis to diagnose various types of leukemias and lymphomas.

Cytogenetics testing by large national reference laboratories and other competitors has historically taken anywhere from 7-14 days on average to obtain a complete diagnostic report. We believe that as a result of this timeframe, many practitioners have refrained to some degree from ordering such tests because the results traditionally were not returned within an acceptable diagnostic window. NeoGenomics has designed our laboratory operations in order to complete cytogenetics tests for most types of biological samples, produce a final diagnostic report and make it available via fax or online viewing within 3-5 days. We have consistently delivered these turnaround times over the last three years without taking shortcuts that can undermine the quality of the delivered result. These turnaround times are among the best in the industry and we believe that more physicians are incorporating cytogenetics testing into their diagnostic regimens, thus affording NeoGenomics the opportunity to drive the incremental growth of our business via this product line for the foreseeable future.

Flow Cytometry Testing. Flow cytometry testing analyzes clusters of differentiation on cell surfaces. Gene expression of many cancers creates protein-based clusters of differentiation on the cell surfaces that can then be traced back to a specific lineage or type of cancer. Flow cytometry is a method of separating liquid specimens or disaggregated tissue into different constituent cell populations. This methodology is used to determine which of these cell types is abnormal in a patient specific manner. Flow cytometry is important in developing an accurate diagnosis, defining the patient's prognosis, and clarifying what treatment options may be optimal. Flow cytometry testing is performed using sophisticated lasers and will typically analyze over 100,000 individual cells in an automated fashion. Flow cytometry testing is highly complementary with cytogenetics and the combination of these two testing methodologies allows the results from one test to complement the findings of the other methodology, which can lead to a more accurate snapshot of a patient's disease state.

FISH Testing. As an adjunct to traditional chromosome analysis, we offer Fluorescence In Situ Hybridization (FISH) testing to extend our capabilities beyond routine cytogenetics. FISH testing permits identification of the most frequently occurring numerical chromosomal abnormalities in a rapid manner by looking at centromeres or specific genes that are implicated in cancer. During the past 5 years, FISH testing has demonstrated its considerable diagnostic potential. The development of molecular probes by using DNA sequences of differing sizes, complexity, and specificity, coupled with technological enhancements (direct labeling, multicolor probes, computerized signal amplification, and image analysis) make FISH a powerful and diagnostic and prognostic tool.

Molecular Testing. Molecular testing primarily involves the analysis of DNA to diagnose DNA & RNA abnormalities in liquid and solid tumors. There are approximately 1.0 – 2.0 million base pairs of DNA in each of the estimated 20,000 genes located across the 46 chromosomes in the nucleus of every cell. Molecular testing allows us to look for variations in this DNA that are associated with specific types of diseases. Today there are molecular tests for about 500 genetic diseases. However, the majority of these tests remain available under the limited research use only designation and are only offered on a restricted basis to family members of someone who has been diagnosed with a genetic condition. About 50 molecular tests are now available for the diagnosis, prognosis or monitoring of various types of cancers and physicians are becoming more comfortable ordering such adjunctive tests. We currently provide these tests on an outsourced basis. We anticipate in the near future performing some of the more popular tests within our facilities as the number of requests continues to increase. Although reimbursement rates for these new molecular tests still need to improve, we believe that molecular testing is an important and growing market segment with many new diagnostic tests being developed every year. We are committed to providing the latest and most accurate testing to clients and we will invest accordingly when market demand warrants.

Distribution Methods

The Company currently performs testing services at each of its' three main clinical laboratory locations: Fort Myers, FL, Nashville, TN and Irvine, CA, and then produces a report for the requesting physician. The Company currently out sources all of its molecular testing to third parties, but expects to validate some of this testing in-house in FY 2008 and offer it to customers to best meet client demand.

Competition

We are engaged in segments of the medical testing laboratory industry that are highly competitive. Competitive factors in the genetic and molecular testing business generally include reputation of the laboratory, range of services offered, pricing, convenience of sample collection and pick-up, quality of analysis and reporting and timeliness of delivery of completed reports.

Our competitors in the United States are numerous and include major medical testing laboratories and biotechnology research companies. 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 genetics and molecular testing is divided among approximately 300 laboratories. However, approximately 80% of these laboratories are attached to academic institutions and only provide clinical services to their affiliate university hospitals. We further believe that less than 20 laboratories market their services nationally. We believe that the industry as a whole is still quite fragmented, with the top 20 laboratories accounting for approximately 50% of market revenues.

We intend to continue to gain market share by offering industry leading turnaround times, a broad service menu, high-quality test reports, and enhanced post-test consultation services. In addition, we have a fully integrated and interactive internet-enabled Laboratory Information System that enables us to report real time results to customers in a secure environment.

Suppliers

The Company orders its laboratory and research supplies from large national laboratory supply companies such as Fisher Scientific, Inc., Invitrogen and Beckman Coulter and does not believe any disruption from any one of these suppliers would have a material effect on its 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 they were to have a disruption and 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 Customers

We currently market our services to pathologists, oncologists, urologists, hospitals and other clinical laboratories. During 2007, we performed 20,998 individual tests. Ongoing sales efforts have decreased dependence on any given source of revenue. Notwithstanding this fact, several key customers still account for a disproportionately large case volume and revenues. Accordingly, for the year ended December 31, 2007, one customer accounted for 25% of total revenue and all others were less than 10% of total revenue individually. During the year ended December 31, 2006, three customers accounted for 26%, 18% and 17% of total revenue, respectively. In the event

that we lost one of these customers, we would potentially lose a significant percentage of our revenues. For the year ended December 31, 2007, Medicare and one commercial insurance provider accounted for 44% and 10% of the Company's total accounts receivable balance, respectively.

Trademarks

The “NeoGenomics” name and logo has been trademarked with the United States Patent and Trademark Office.

Number of Employees

As of December 31, 2007, we had 92 full-time employees. In addition, our Acting Principal Financial Officer and two pathologists serve as consultants to the Company on a part-time basis. On December 31, 2006, we had 48 employees. Our employees are not represented by any union and we believe our employee relations are good.

Government Regulation

Our business is subject to government regulation at the federal, state and local levels, some of which regulations are described under "Clinical Laboratory Operations," "Anti-Fraud and Abuse Laws," "The False Claims Act," "Confidentiality of Health Information," and "Food and Drug Administration" below.

Clinical Laboratory Operations

Licensure and Accreditation

The Company operates clinical laboratories in Fort Myers, FL, Nashville, TN, and Irvine, CA. All locations have obtained CLIA licensure under the federal Medicare program, the Clinical Laboratories Improvement Act of 1967 and the Clinical Laboratory Amendments of 1988 (collectively “CLIA ‘88”) as well as state licensure as required in FL, TN, and CA. CLIA ‘88 provides for the regulation of clinical laboratories by the U.S. Department of Health and Human Services (“HHS”). Regulations promulgated under the federal Medicare guidelines, CLIA ‘88 and the clinical laboratory licensure laws of the various states affect our testing laboratories. All locations are also accredited by the College of American Pathologists and actively participate in CAP’s proficiency testing programs and educational challenges for all tests offered by the Company. Proficiency testing programs involve actual testing of specimens that have been prepared by an entity running an approved program for testing by a clinical laboratory.

The federal and state certification and licensure programs establish standards for the operation of clinical laboratories, including, but not limited to, personnel and quality control. Compliance with such standards is verified by periodic inspections by inspectors employed by federal or state regulatory agencies as well as routine internal inspections conducted by the Company’s Quality Assurance team which is comprised of representatives of all departments of the Company.

Quality of Care

The quality of care provided by the Company to its customers is of paramount importance to the Company and a distinct differentiator from many of our competitors. As such, all 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. All employees are responsible for the Company’s commitment to quality and immediately communicating activities that do not support quality.

Compliance Program

The healthcare industry is one of the most highly regulated industries with respect to federal and state oversight of Fraud, Waste, and Abuse. As such the Company has implemented a Compliance Program that is overseen by the senior management of the Company (collectively the "Compliance Committee") to assure compliance with the vast regulations and governmental guidance. Our program consists of training / education of the employees and monitoring / audits of Company practices. The Company actively discusses with the Board of Directors any Compliance related findings as well as any Compliance related issues that may have material effect on the Company.

Hotline

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 Company does not allow any retaliation against an employee who reports a compliance related issue in good faith.

Anti-Fraud and Abuse Laws

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. One provision of these laws, known as the "anti-kickback law," contains extremely broad proscriptions. Violation of this provision may result in criminal penalties, exclusion from participation in Medicare and Medicaid programs, and significant civil monetary penalties.

In January 1990, following a study of pricing practices in the clinical laboratory industry, the Office of the Inspector General ("OIG") of HHS issued a report addressing how these pricing practices relate to Medicare and Medicaid. The OIG reviewed the industry's use of one fee schedule for physicians and other professional accounts and another fee schedule for patients/third-party payers, including Medicare, in billing for testing services, and focused specifically on the pricing differential when profiles (or established groups of tests) are ordered.

Existing federal law authorizes the Secretary of HHS to exclude providers from participation in the Medicare and Medicaid programs if they charge state Medicaid programs or Medicare fees "substantially in excess" of their "usual and customary charges." On September 2, 1998, the OIG issued a final rule in which it indicated that this provision has limited applicability to services for which Medicare pays under a Prospective Payment System or a fee schedule, such as anatomic pathology services and clinical laboratory services. 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 a 1999 Advisory Opinion 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 Medicaid laws in some states also have prohibitions related to discriminatory pricing.

Under another federal law, known as the "Stark" law or "self-referral prohibition," physicians who have an investment or compensation relationship with an entity furnishing clinical laboratory services (including anatomic pathology and clinical chemistry services) may not, subject to certain exceptions, refer clinical laboratory testing for Medicare patients to that entity. Similarly, laboratories may not bill Medicare or Medicaid or any other party for services furnished pursuant to a prohibited referral. Violation of these provisions may result in disallowance of Medicare and Medicaid claims for the affected testing services, as well as the imposition of civil monetary penalties and application of False Claims submissions penalties. Some states also have laws similar to the Stark law.

The False Claims Act

The Civil False Claims Act pertains to any federally funded program and defines "Fraudulent" as: knowingly submitting a false claim, i.e. actual knowledge of the falsity of the claim, reckless disregard or deliberate ignorance of the falsity of the claim. These are the claims to which criminal penalties are applied. Penalties include permissive exclusion in federally funded programs by Center for Medicare Services ("CMS") as well as \$11,500 plus treble damages per false claim submitted, and can include imprisonment. High risk areas include but are not limited to accurate use and selection of CPT codes, ICD-9 codes provided by the ordering physician, billing calculations, performance and billing of reported testing, use of reflex testing, and accuracy of charges at fair market value.

We will seek to structure our arrangements with physicians and other customers to be in compliance with the Anti-Kickback Statute, Stark Law, State laws, and the Civil False Claims Act 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 could become subject to scrutiny there under.

In February 1997 (as revised in August 1998), the OIG released a model compliance plan for laboratories that is based largely on corporate integrity agreements negotiated with laboratories that had settled enforcement action brought by the federal government related to allegations of submitting false claims. We believe that we comply with the aspects of the model plan that we deem appropriate to the conduct of our business.

Confidentiality of Health Information

The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") contains provisions that affect the handling of claims and other patient information that are, or have been used or disclosed by healthcare providers. These provisions, which address security and confidentiality of PHI (Protected Health Information or "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. Rules implementing various aspects of HIPAA are continuing to be developed. The HIPAA Rules include the following components which have already been implemented at our locations and industry wide: The Privacy Rule which granted patients rights regarding their information also pertains to the proper uses and disclosures of PHI by healthcare providers in written and verbal formats required implementation no later than April 14, 2003 for all covered entities except small health plans which had another year for implementation. The Electronic Health Care Transactions and Code Sets Standards which established standard data content and formats for submitting electronic claims and other administrative healthcare transactions required implementation no later than October 16, 2003 for all covered entities. On April 20, 2005, CMS required compliance with the Security Standards which established standards for electronic uses and disclosures of PHI for all covered entities except small health plans who had an additional year to meet compliance. Currently, the industry, including all of our locations, is working to comply with the National Provider Identification number to replace all previously issued provider (organizational and individual) identification numbers. This number is being issued by CMS and must be used on all covered transactions no later than May 23, 2007 by all covered entities except small health plans which have an additional year to meet compliance with this rule.

In addition to the HIPAA rules described above, we are subject to state laws regarding the handling and disclosure of patient records and patient health information. These laws vary widely, and many states are passing new laws in this area. Penalties for violation include sanctions against a laboratory's licensure as well as civil or criminal penalties. We believe we are in compliance with current state law regarding the confidentiality of health information and continue to keep abreast of new or changing state laws as they become available.

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 Have A Limited Operating History Upon Which You Can Evaluate Our Business

The Company commenced revenue operations in 2002 and is just beginning to generate meaningful revenue. Accordingly, the Company has a limited operating history upon which an evaluation of the Company and its prospects can be based. The Company and its prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in the rapidly evolving market for healthcare and medical laboratory services. To address these risks, the Company must, among other things, respond to competitive developments, attract, retain and motivate qualified personnel, implement and successfully execute its sales strategy, develop and market additional services, and upgrade its technological and physical infrastructure in order to scale its revenues. The Company may not be successful in addressing such risks. The limited operating history of the Company makes the prediction of future results of operations difficult or impossible.

We May Not Be Able To Implement The Company's Business Strategies Which Could Impair Our Ability To Continue Operations

Implementation of the Company's business strategies will depend in large part on the Company's ability to (i) attract and maintain a significant number of customers; (ii) effectively provide acceptable products and services to the Company's customers; (iii) obtain adequate financing on favorable terms to fund the Company's business strategies; (iv) maintain appropriate procedures, policies, and systems; (v) hire, train, and retain skilled employees; (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 payers. The Company's inability to obtain or maintain any or all these factors could impair its ability to implement its business strategies successfully, which could have material adverse effects on its results of operations and financial condition.

We May Be Unsuccessful In Managing Our Growth Which Could Prevent The Company From Becoming Profitable

The Company's recent growth has placed, and is expected to continue to place, a significant strain on its managerial, operational and financial resources. To manage its potential growth, the Company must continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The Company may not be able to effectively manage the expansion of its operations and the Company's systems, procedures or controls may not be adequate to support the Company's operations. The Company's management may not be able to achieve the rapid execution necessary to fully exploit the market opportunity for the Company's products and services. Any inability to manage growth could have a material adverse effect on the Company's business, results of operations, potential profitability and financial condition.

Part of the Company's business strategy may be to acquire assets or other companies that will complement the Company's existing business. The Company is unable to predict whether or when any material transaction will be completed should negotiations commence. If the Company proceeds with any such transaction, the Company may not effectively integrate the acquired operations with the Company's own operations. The Company 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

The Company used reasonable efforts to assess and predict the expenses necessary to pursue its business plan. However, implementing the Company's 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 the Company estimates, which could result in sustained losses.

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

As a result of the Company's limited operating history and the relatively limited information available on the Company's competitors, the Company may not have sufficient internal or industry-based historical financial data upon which to calculate anticipated operating expenses. Management expects that the Company's 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 the Company's products and services; (ii) demand for the Company's products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) the Company's ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) the Company's ability to attract, retain and motivate qualified personnel; (vi) the initiation, renewal or expiration of significant contracts with the Company's 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. The Company's expenses are based in part on the Company's expectations as to future revenues and to a significant extent are relatively fixed, at least in the short-term. The Company 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 the Company's expectations would have an immediate adverse impact on the Company's business, results of operations and financial condition. In addition, the Company may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short-term material adverse effect on the Company's business, results of operations and financial condition and may not result in the long-term benefits intended. Furthermore, in Florida, currently a primary referral market for our lab testing services, a meaningful percentage of the population returns to homes in the Northern U.S. to avoid the hot summer months. This may result in seasonality in our business. Because of all of the foregoing factors, the Company's operating results could be less than the expectations of investors in future periods.

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

The Company is a clinical medical laboratory that provides medical testing services to doctors, hospitals, and other laboratories on patient specimens that are sent to the Company. In the case of most specimen referrals that are received for patients that are not in-patients at a hospital or institution or otherwise sent by another reference laboratory, the Company generally has to bill the patient's insurance company or a government program for its services. As such it relies on the cooperation of numerous third party payers, including but not limited to Medicare, Medicaid and various insurance companies, in order to get paid for performing services on behalf of the Company's clients. Wherever possible, the amount of such third party payments is governed by contractual relationships in cases where the Company is a participating provider for a specified insurance company or by established government reimbursement rates in cases where the Company is an approved provider for a government program such as Medicare. However, the Company does not have a contractual relationship with 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 affect 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. The Company's future success will depend in significant part on its ability to continually improve its offerings in response to both evolving demands of the marketplace and competitive service offerings, and the Company 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. The Company competes with other commercial medical laboratories in addition to the in-house laboratories of many major hospitals. Many of the Company's existing competitors have significantly greater financial, human, technical and marketing resources than the Company. The Company's competitors may develop products and services that are superior to those of the Company or that achieve greater market acceptance than the Company's offerings. The Company 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 the Company's 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 customers 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 customers and cases increases, the Company's products, services, and infrastructure may not be able to scale accordingly. Any failure to handle higher volume of requests for the Company's products and services could lead to the loss of established customers and have a material adverse effect on the Company's business, results of operations and financial condition.

If we produce inaccurate test results, our customers 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 the Company.

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, power loss, telecommunications failures, break-ins and similar events. The Company does not presently have an emergency back-up generator in place at its Fort Myers, FL, Nashville, TN and Irvine, CA 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 Customers, which could have a material adverse effect on the Company's business, results of operations and financial condition.

The Steps Taken By The Company To Protect Its Proprietary Rights May Not Be Adequate

The Company regards its copyrights, trademarks, trade secrets and similar intellectual property as critical to its success, and the Company relies upon trademark and copyright law, trade secret protection and confidentiality and/or license agreements with its employees, customers, partners and others to protect its proprietary rights. The steps taken by the Company to protect its proprietary rights may not be adequate or third parties may infringe or misappropriate the Company's copyrights, trademarks, trade secrets and similar proprietary rights. In addition, other parties may assert infringement claims against the Company.

We Are Dependent On Key Personnel And Need To Hire Additional Qualified Personnel

The Company's performance is substantially dependent on the performance of its senior management and key technical personnel. In particular, the Company's success depends substantially on the continued efforts of its senior management team, which currently is composed of a small number of individuals. The loss of the services of any of its executive officers, its laboratory director or other key employees could have a material adverse effect on the business, results of operations and financial condition of the Company.

The Company's future success also depends on its continuing ability to attract and retain highly qualified technical and managerial personnel. Competition for such personnel is intense and the Company may not be able to retain its 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 the Company's business, results of operations and financial condition.

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