

NEOGENOMICS INC  
Form 10KSB  
April 02, 2007

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20459**

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FORM 10-KSB

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Annual Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934.

**For the Year Ended December 31, 2006**

Transition Report Under 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.**

(Name of small business issuer)

**NEVADA**

**74-2897368**

(State or other jurisdiction of  
incorporation or organization)

(IRS Employer I.D. No.)

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

Address of Principal Executive Offices:

**(239) 768-0600**

Issuers telephone number

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

**NONE**

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

**NONE**

Check whether the issuer (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the past 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

Check 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 registrant's knowledge, in definitive proxy or information statements incorporated by referencing Part III of this Form 10-KSB or any amendment to this Form 10-KSB.

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

The issuer's revenues for the most recent fiscal year were approximately \$6,476,000.

The aggregate market value of the voting stock held by non-affiliates of the registrant at March 29, 2007 was approximately \$23,227,159 (Based on 14,889,205 shares held by non-affiliates and a closing share price of \$1.56/share on March 29, 2007). Shares of common stock held by each officer and director and by each person who owns more than 10% 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 purposes.

As of March 29, 2007, 27,695,984 shares of common stock were outstanding.

Transitional small business disclosure format.  Yes  No

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**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.

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## 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 cancer-focused testing laboratories that specifically target the rapidly growing genetic and molecular testing segment of the medical laboratory industry. Headquartered in Fort Myers, Florida, 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 genetic and molecular testing segment of the medical laboratory industry is the most rapidly growing niche of the market. Approximately six years ago, the World Health Organization reclassified cancers as genetic anomalies. This growing awareness of the genetic root behind most cancers combined with advances in technology and genetic research, including the complete sequencing of the human genome, have made possible a whole new set of tools to diagnose and treat diseases. This has opened up a vast opportunity for laboratory companies that are positioned to address this growing market segment.

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. This type of testing yields relatively low average revenue per test. 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. The higher complexity AP tests typically involve more labor and are more technology intensive than clinical lab tests. Thus AP tests generally result in higher average revenue per test than clinical lab tests.

Genetic and molecular testing typically involves analyzing chromosomes, genes or base pairs of DNA or RNA for abnormalities. Genetic and molecular testing have become important and highly accurate diagnostic tools over the last five years. 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 following chart shows the differences between the genetic and molecular niche and other segments of the medical laboratory industry. Up until approximately five years ago, the genetic and molecular testing niche was considered to be part of the Anatomic Pathology segment, but given its rapid growth, it is now more routinely broken out and accounted for as its own segment.

**COMPARISON OF THE MEDICAL LABORATORY MARKET SEGMENTS (1)**

<b>Attributes</b>	<b>Clinical</b>	<b>A n a t o m i c Pathology</b>	<b>Genetic/Molecular</b>
Testing Performed On	Blood, Urine	Tissue/Cells	Chromosomes/Genes/DNA
Testing Volume	High	Low	Low
Physician Involvement	Low	High - Pathologist	Low - Medium
Malpractice Ins. Required	Low	High	Low
Other Professionals Req.	None	None	Cyto/Molecular geneticist
Level of Automation	High	Low-Moderate	Moderate
Diagnostic in Nature	Usually Not	Yes	Yes
Types of Diseases Tested	Many Possible	Primarily to Rule out Cancer	Rapidly Growing
Typical per Price/Test	\$5 - \$35/Test	\$25 - \$500/Test	\$200 - \$1,000/Test
Estimated Size of Market	\$25 - \$30 Billion	\$10 - \$12 Billion	\$4 - \$5 Billion (2)
Estimated Annual Growth Rate	4% -5%	6% - 7%	25+%
Established Competitors	Quest Diagnostics LabCorp Bio Reference Labs DSI Laboratories Hospital Labs Regional Labs	Quest Diagnostics LabCorp Genzyme Genetics Ameripath Local Pathologists	Genzyme Genetics Quest Diagnostics LabCorp Major Universities

(1) Derived from industry analyst reports

(2) Includes flow cytometry testing, which historically has been classified under anatomic pathology.

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 liquid 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 intend to 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.

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 31, 2007, NeoGenomics' sales organization totaled 9 individuals. Recent, key hires included our Vice President of Sales & Marketing, and various sales managers and representatives in the Northeastern, Southeastern, and Western states. We intend to continue adding sales representatives on a quarterly basis throughout the year As more sales representatives are added, 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. 2006 saw the introduction of our Genetic Pathology Solutions (GPS) product that provides summary interpretation of multiple testing platforms all in one consolidated report. Response from clients has been very favorable and provides another option for those customers that require a higher degree of customized service.

Another important service was initiated in December 2006 when we became the first laboratory to offer technical-component only (tech-only) FISH testing to the key community-based pathologist market segment. NeoFISH has been enthusiastically received and has provided our sales team with another differentiating product to meet the needs of our target community-based pathologists. With NeoFISH these customers are able to retain a portion of the overall testing revenue from such FISH specimens themselves, which serves to much better align their interests with those of NeoGenomics than what might otherwise be possible with larger laboratory competitors.

We believe NeoGenomics average 3-5 day turn-around time for our cytogenetics services remains an industry-leading benchmark. 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 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 2006 we began an aggressive campaign to form new laboratories around the country that will allow us to regionalize our operations 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 2006, NeoGenomics achieved the milestone of opening two other laboratories to complement our headquarters in Fort Myers, Florida. NeoGenomics facilities in Nashville, Tennessee and Irvine, California received the appropriate state and CLIA licensure and are now receiving live 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.

2006 also saw the initial establishment of 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.

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 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.

Historically, the above approach has borne out well for the Company. For most of FY 2004, the Company only performed one type of test in-house, cytogenetics, which resulted in only one test being performed per customer requisition for most of the year and an average revenue per requisition of approximately \$490. With the subsequent addition of FISH testing in FY 2005 and flow cytometry to our pre-existing cytogenetics testing in FY 2006, our average revenue/requisition increased by 35.6% in FY 2005 to approximately \$632 and a further 7% in FY 2006 to approximately \$677/requisition. We believe with focused sales and marketing efforts and the recent launch of GPS reporting, NeoFISH tech-only FISH services, and the future addition of additional testing platforms, the Company can continue to increase our average revenue per customer requisition.

	<b>FY 2006</b>	<b>FY 2005</b>	<b>% Inc (Dec)</b>
Customer Requisitions Rec'd (Cases)	9,563	2,982	220.7%
Number of Tests Performed	12,838	4,082	214.5%
Average Number of Tests/Requisition	1.34	1.37	(2.1%)
Total Testing Revenue	\$ 6,475,996	\$ 1,885,324	243.5%
Average Revenue/Requisition	\$ 677.19	\$ 632.23	7.1%
Average Revenue/Test	\$ 504.44	\$ 461.86	9.2%



We believe this bundled approach to testing represents a clinically sound practice. In addition, as the average number of tests performed per requisition increases, this should drive large increases in our revenue and afford the Company significant synergies and efficiencies in our operations and sales and marketing activities. For instance, initial testing for many hematologic cancers may yield total revenue ranging from approximately \$1,800 - \$3,600/requisition and is generally comprised of a combination of some or all of the following tests: cytogenetics, fluorescence in-situ hybridization (FISH), flow cytometry and, per client request, morphology testing. Whereas in FY 2004, we only addressed approximately \$500 of this potential revenue per requisition; in FY 2005 we addressed approximately \$1,200 - \$1,900 of this potential revenue per requisition; and in FY 2006, we could address this revenue stream (see below), dependent on medical necessity criteria and guidelines:

	<b>Average Revenue/Test</b>	
Cytogenetics	\$	400-\$500
Fluorescence In Situ Hybridization (FISH)		
- Technical component	\$	300-\$1000
- Professional component	\$	200-\$500
Flow cytometry		
- Technical component	\$	400-\$700
- Professional component	\$	100-\$200
Morphology	\$	400-\$700
Total	\$	1,800-\$3,600

## **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 the chromosomes of 20 different cells. Examples of cytogenetics testing include bone marrow aspirate or peripheral blood analysis to diagnose various types of leukemia and lymphoma, and amniocentesis testing of pregnant women to diagnose genetic anomalies such as Down syndrome in a fetus.

Cytogenetics testing by large national reference laboratories and other competitors has historically taken anywhere from 10-14 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. These turnaround times are among the best in the industry and we believe that, with further demonstration of our consistency in generating results, more physicians will incorporate cytogenetics testing into their diagnostic regimens and thus drive incremental growth in our business.

***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 types. 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 specific genes that are implicated in cancer. FISH was originally used as an additional staining methodology for metaphase analysis (cells in a divided state after they have been cultured), but the technique is now routinely applied to interphase analysis (non-dividing quiescent cells). During the past 5 years, FISH testing has begun to demonstrate 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 investigative and diagnostic tool.

***Molecular Testing.*** Molecular testing primarily involves the analysis of DNA to screen for and diagnose single gene disorders such as cystic fibrosis and Tay-Sachs disease as well as abnormalities in liquid and solid tumors. There are approximately 1.0 - 2.0 million base pairs of DNA in each of the estimated 25,000 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 its 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 during the next several years to 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 virtual 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 2006, we performed 12,838 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. In 2005, four customers accounted for 65% of our total revenue. For 2006, 3 customers represented 61% of our revenue with each party representing greater than 15% of such revenues. However, as a result of our rapid increase in revenues from other customers, these 3 customers only represented 41% of our monthly revenue in December 2006. Given the substantial increase in customers in the first quarter of 2007, we expect this percentage to continue to decline. In the event that we lost one of these customers, we would potentially lose a significant percentage of our revenues.

**Trademarks**

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

**Number of Employees**

As of December 31, 2006, we had 48 full-time employees. In addition, our Acting Principal Financial Officer and a pathologist serve as consultants to the Company on a part-time basis. On December 31, 2005, we had 23 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**

*Genetics and Molecular Testing.* The Company operates clinical laboratories in Fort Myers, FL, Nashville, TN, and Irvine, CA. All locations have obtained CLIA certification 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 genetics laboratories.

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. In addition, federal regulatory authorities require participation in a proficiency testing program approved by HHS for many of the specialties and subspecialties for which a clinical laboratory seeks approval from Medicare or Medicaid and certification under CLIA ‘88. 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.

A final rule implementing CLIA '88, published by HHS on February 28, 1992, became effective September 1, 1992. This rule has been revised on several occasions and further revision is expected. The CLIA '88 rule applies to virtually all clinical laboratories in the United States, including our clinical laboratory locations. We have reviewed our operations as they relate to CLIA '88, including, among other things, the CLIA '88 rule's requirements regarding clinical laboratory administration, participation in proficiency testing, patient test management, quality control, quality assurance and personnel for the types of testing we undertake, and believe that all of our clinical laboratory locations are in compliance with these requirements. Our clinical laboratory locations may not pass inspections conducted to ensure compliance with CLIA '88 or with any other applicable licensure or certification laws. The sanctions for failure to comply with CLIA '88 or state licensure requirements might include the inability to perform services for compensation or the suspension, revocation or limitation of any clinical laboratory locations, CLIA '88 certificate or state license, as well as civil and/or criminal penalties.

*Regulation of Genetic Testing.* In 2000, the Secretary of Health and Human Services Advisory Committee on Genetic Testing published recommendations for increased oversight by the Centers for Disease Control and the FDA for all genetic testing. This committee continues to meet and discuss potential regulatory changes, but final recommendations have not been issued.

With respect to genetic therapies, which may become part of our business in the future, in addition to FDA requirements, the National Institutes of Health ("NIH") has established guidelines providing that transfers of recombinant DNA into human subjects at NIH laboratories or with NIH funds must be approved by the NIH Director. The NIH has established the Recombinant DNA Advisory Committee to review gene therapy protocols. Although we do not currently offer any gene therapy services, if we decide to enter this business in the future, we would expect that all of our gene therapy protocols will be subject to review by the Recombinant DNA Advisory Committee.

#### **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* enacted in 1864, 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.

### **Food and Drug Administration**

In January 1998, the FDA issued a revised draft Compliance Policy Guide ("CPG") that sets forth FDA's intent to undertake a heightened enforcement effort with respect to the improper Commercialization of In Vitro Diagnostic Devices prior to receipt of FDA premarket clearance or approval. September, 2006, the FDA issued the Draft Guidance for Industry, Clinical Laboratories, and FDA Staff on *In Vitro* Diagnostic Multivariate Index Assays (IVDMIAs) as a current initiative of the FDA to regulate test systems that employ data, derived in part from one or more in vitro assays, and an algorithm that usually, but not necessarily, runs on software to generate a result that diagnoses a disease or condition or is used in the cure, mitigation, treatment, or prevention of disease. In the future, we plan to perform some testing services using test kits purchased from manufacturers for which FDA premarket clearance or approval for commercial distribution in the United States has not been obtained by the manufacturers ("investigational test kits"). Under current FDA regulations and policies, such investigational test kits may be sold by manufacturers for investigational use only if certain requirements are met to prevent commercial distribution. The manufacturers of these investigational test kits are responsible for marketing them under conditions meeting applicable FDA requirements. That draft CPG as well as the current Draft Guidance on IVDMIAs is not presently in effect but, if implemented as written, would place greater restrictions on the distribution of such investigational test kits or devices. If we were to be substantially limited in or prevented from purchasing investigational test kits or devices by reason of the FDA finalizing these guidelines, there could be an adverse effect on our ability to access new technology, which could have a material adverse effect on our business.

We also perform some testing services using reagents, known as analyte specific reagents ("ASRs"), purchased from companies in bulk rather than as part of a test kit. In November 1997, the FDA issued a new regulation placing restrictions on the sale, distribution, labeling and use of ASRs. Most ASRs are treated by the FDA as low risk devices, requiring the manufacturer to register with the agency, its ASRs (and any other devices), conform to good manufacturing practice requirements, and comply with medical device reporting of adverse events.

### **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.

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**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**

The Company may seek to exploit business opportunities that require more capital than what is currently planned. The Company may not be able to raise such capital on favorable terms or at all. If the Company is unable to obtain such additional capital, the Company may be required to reduce the scope of its anticipated expansion, which could adversely affect the Company's business, financial condition and results of operations.

**Our Net Revenue will be Diminished If Payers do not Adequately Cover or Reimburse our Services.**

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the coverage and reimbursement status of new applications or services. Third party payers, including governmental payers such as Medicare and private payers, are scrutinizing new medical products and services and may not cover or may limit coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payers. Any pricing pressure exerted by these third party payers on our customers may, in turn, be exerted by our customers on us. If government and other third party payers do not provide adequate coverage and reimbursement for our assays, 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 payer is the party that pays for the tests, and the two are not always the same. Depending on the billing arrangement and applicable law, we need to bill various payers, such as patients, insurance companies, Medicare, Medicaid, doctors and employer groups, 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. This adds further complexity to the billing process.



Among many other factors complicating billing are:

- pricing differences between our fee schedules and the reimbursement rates of the payers;
- disputes with payers as to which party is responsible for payment; and
- disparity in coverage and information requirements among various carriers.

We incur significant additional costs as a result of our participation in the Medicare and Medicaid programs, as billing and reimbursement for clinical laboratory testing are subject to considerable and complex federal and state regulations. The additional costs we expect to incur include those related to: (1) complexity added to our billing processes; (2) training and education of our employees and customers; (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, as a large number of laboratories have been forced by the federal and state governments, as well as by private payers, to enter into substantial settlements under these laws. In particular, if an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$5,500 to \$11,000 for each separate false claim. There are many potential bases for liability under the federal False Claims Act. Liability arises, primarily, when an entity 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 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 providers and suppliers. Those provisions allow a private individual to bring actions 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 to become the primary prosecutor. If it declines to do so, the individual may choose to 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. Written "corporate compliance" programs to actively monitor compliance with fraud laws and other regulatory requirements are recommended by the Department of Health and Human Services' Office of the Inspector General.

### **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, the Company is subject to extensive state and federal regulatory oversight. Our laboratory locations may not pass inspections conducted to ensure compliance with CLIA '88 or with any other applicable licensure or certification laws. The sanctions for failure to comply with CLIA '88 or state licensure requirements might include the inability to perform services for compensation or the suspension, revocation or limitation of the a laboratory location's CLIA '88 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 will seek to structure our arrangements with physicians and other customers 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, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and other state laws contains 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.

### **We Are Subject to Security Risks Which Could Harm Our Operations**

Despite the implementation of various security measures by the Company, the Company's infrastructure is vulnerable to computer viruses, break-ins and similar disruptive problems caused by its customers or others. Computer viruses, break-ins or other security problems could lead to interruption, delays or cessation in service to the Company's customers. Further, such break-ins whether electronic or physical could also potentially jeopardize the security of confidential information stored in the computer systems of the Company's customers and other parties connected through the Company, which may deter potential customers and give rise to uncertain liability to parties whose security or privacy has been infringed. A significant security breach could result in loss of customers, damage to the Company's 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 the Company's business, results of operations and financial condition.

**The Company Is Controlled by Existing Shareholders And Therefore Other Shareholders Will Not Be Able to Direct The Company**

The majority of the Company's shares and thus voting control of the Company is held by a relatively small group of shareholders. Because of such ownership, those shareholders will effectively retain control of the Company's Board of Directors and determine all of the Company's corporate actions. In addition, the Company and shareholders owning 13,106,579 shares, or approximately 47.3% of the Company's voting shares outstanding as of March 29, 2007 have executed a Shareholders' Agreement that, among other provisions, gives Aspen Select Healthcare, LP, our largest shareholder, the right to elect three out of the seven directors authorized for our Board, and nominate one mutually acceptable independent director. Accordingly, it is anticipated that Aspen Select Healthcare, LP and other parties to the Shareholders' Agreement will continue to have the ability to elect a controlling number of the members of the Company's Board of Directors and the minority shareholders of the Company may not be able to elect a representative to the Company's 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**

The Company does not anticipate paying dividends on its common shares in the foreseeable future. Rather, the Company plans to retain earnings, if any, for the operation and expansion of Company business.

**There Is No Guarantee of Registration Exemption for Sales of Unregistered Stock, Which Could Result in the Liquidation of the Company**

From time to time, the Company sells shares of unregistered stock in various private placements to accredited investors. These sales are generally made in reliance upon the "private placement" exemption from registration provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated pursuant thereto. Reliance on this exemption does not, however, constitute a representation or guarantee that such exemption is indeed available.

If for any reason any future sales of unregistered stock are deemed to be a public offering of the Company's shares (and if no other exemption from registration is available), the sale of the offered shares would be deemed to have been made in violation of the applicable laws requiring registration of the offered shares and the delivery of a prospectus. As a remedy in the event of such violation, each purchaser of the offered shares would have the right to rescind his or her purchase of the offered shares and to have his or her purchase price returned. If such a purchaser requests a return of his or her purchase price, funds might not be available for that purpose. In that event, liquidation of the Company might be required. Any refunds made would reduce funds available for the Company's working capital needs. A significant number of requests for rescission would probably cause the Company to be without funds sufficient to respond to such requests or to proceed with the Company's activities successfully.

**ITEM 2. DESCRIPTION OF PROPERTY**

In August 2003, we entered into a three year lease for 5,200 square feet at our laboratory facility in Fort Myers, Florida. On June 29, 2006 we signed an amendment to the original lease which extended the lease through June 30, 2011. The amendment included the rental of an additional 4,400 square feet adjacent to our current facility. This space will allow for future expansion of our business. The lease was further amended on January 17, 2007 but this amendment did not materially alter the terms of the lease, which has total payments of approximately \$653,000 over the remaining life of the lease, including annual increases of rental payments of 3% per year. Such amount excludes estimated operating and maintenance expenses and property taxes.

As part of the acquisition of The Center for CytoGenetics, Inc. by the Company on April 18, 2006, we assumed the lease of an 850 square foot facility in Nashville, Tennessee. The lease expires on August 31, 2008. The average monthly rental expense is approximately \$1,350 per month. This space was not adequate for our future plans and the Company is currently not using the facility and is actively trying to sublease this facility. On June 15, 2006, we entered into a lease for a new facility totaling 5,386 square feet of laboratory space in Nashville, Tennessee. This space will be adequate to accommodate our current plans for the Tennessee laboratory. As part of the lease, we have the right of first refusal on an additional 2,420 square feet, if needed, directly adjacent to the facility. The lease is a five year lease and results in total payments by us of approximately \$340,000.

On August 1, 2006, the Company entered into a lease for 1,800 square feet of laboratory space in Irvine, California. The lease is a nine month lease and results in total payments by the Company of approximately \$23,000. This lease will expire on April 30, 2007. We are currently in negotiations on a new larger facility, which can accommodate our future growth.

### **ITEM 3. LEGAL PROCEEDINGS**

On October 26, 2006, Accupath Diagnostics Laboratories, Inc. d/b/a US Labs, a California corporation (“US Labs”) filed a complaint in the Superior Court of the State of California for the County of Los Angeles (the “Court”) against the Company and Robert Gasparini, as an individual, and certain other employees and non-employees of NeoGenomics with respect to claims arising from discussions with current and former employees of US Labs. US Labs alleges, among other things, that NeoGenomics engaged in “unfair competition” by having access to certain salary information of four recently hired sales personnel prior to the time we hired such individuals. We believe that US Labs’ claims against NeoGenomics lack any merit and that there are well-established laws that affirm the rights of employees to seek employment with any company they desire and employers to offer such employment to anyone they desire. US Labs seeks unspecified monetary relief. As part of the complaint, US Labs also sought preliminary injunctive relief against NeoGenomics and requested that the Court bar NeoGenomics from, among other things: a) inducing any further US Labs’ employees to resign employment with US Labs, b) soliciting, interviewing or employing US Labs’ employees for employment, c) directly or indirectly soliciting US Labs’ customers with whom four new employees of NeoGenomics did business while employed at US Labs; and d) soliciting, initiating and/or maintaining economic relationships with US Labs’ customers that are under contract with US Labs.

On November 15, 2006, the Court heard arguments on US Labs request for a preliminary injunction and denied the majority of US Labs’ requests for such injunction on the grounds that US Labs was not likely to prevail at trial. The Court did, however, issue a much narrower preliminary injunction which prevents NeoGenomics from “soliciting” the US Labs’ customers of such new sales personnel until such time as a full trial could be held. This preliminary injunction is limited only to the “solicitation” of the US Labs’ customers of the sales personnel in question and does not in any way prohibit NeoGenomics from doing business with any such customers to the extent they have sought or seek a business relationship with NeoGenomics on their own initiative. Furthermore, NeoGenomics is not in any way prohibited from recruiting any additional personnel from US Labs through any lawful means. We believe that none of US Labs’ claims will be affirmed at trial; however, even if they were, NeoGenomics does not believe such claims would result in a material impact to our business. NeoGenomics further believes that this lawsuit is nothing more than a blatant attempt by a large corporation to impede the progress of a smaller and more nimble competitor, and we intend to vigorously defend ourselves.

Discovery commenced in December 2006. While the Company received unsolicited and inaccurate salary information for three individuals that were ultimately hired, no evidence of misappropriation of trade secrets has been discovered by either side. As such, the Company is currently contemplating filing motions to narrow or end the litigation, and expects to ultimately prevail at trial.

The Company is also a defendant in one lawsuit from a former employee relating to compensation related claims. The Company does not believe this lawsuit is material to its operations or financial results and intends to vigorously

pursue its defense of the matter.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

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

Our common stock is quoted on the OTC Bulletin Board. 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
4 <sup>th</sup> Quarter 2006	\$ 2.05	\$ 0.94
3 <sup>rd</sup> Quarter 2006	\$ 1.25	\$ 0.60
2 <sup>nd</sup> Quarter 2006	\$ 0.78	\$ 0.45
1 <sup>st</sup> Quarter 2006	\$ 0.72	\$ 0.12
4 <sup>th</sup> Quarter 2005	\$ 0.35	\$ 0.18
3 <sup>rd</sup> Quarter 2005	\$ 0.59	\$ 0.24
2 <sup>nd</sup> Quarter 2005	\$ 0.60	\$ 0.26
1 <sup>st</sup> Quarter 2005	\$ 0.70	\$ 0.25

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 represent actual transactions. All historical data was obtained from the [www.BigCharts.com](http://www.BigCharts.com) web site.

As of March 29, 2007 there were 388 stockholders of record of our common stock, excluding shareholders who hold their shares in brokerage accounts in "street name". 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.

**Sales of Unregistered Securities**

Except as otherwise noted, all of the following shares were issued and options and warrants granted pursuant to the exemption provided for under Section 4(2) of the Securities Act of 1933, as amended, as a "transaction not involving a public offering." No commissions were paid, and no underwriter participated, in connection with any of these transactions. Each such issuance was made pursuant to individual contracts which are discrete from one another and are made only with persons who were sophisticated in such transactions and who had knowledge of and access to sufficient information about the Company to make an informed investment decision. Among this information was the fact that the securities were restricted securities.

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During 2004, we sold 3,040,000 shares of our common stock in a series of private placements at \$0.25/share to unaffiliated third party investors. These transactions generated net proceeds to the Company of approximately \$740,000 after deducting certain transaction expenses. These transactions involved the issuance of unregistered stock to accredited investors in transactions that we believed were exempt from registration under Rule 506 promulgated under the Securities Act of 1933. All of these shares were subsequently registered on a SB-2 Registration Statement, which was declared effective by the SEC on August 1, 2005.

During the period January 1, 2005 to May 31, 2005, we sold 450,953 shares of our common stock in a series of private placements at \$0.30 - \$0.35/share to unaffiliated third party investors. These transactions generated net proceeds to the Company of approximately \$146,000. These transactions involved the issuance of unregistered stock to accredited investors in transactions that we believed were exempt from registration under Rule 506 promulgated under the Securities Act of 1933. All of these shares were subsequently registered on a SB-2 Registration Statement, which was declared effective by the SEC on August 1, 2005.

On March 23, 2005, the Company entered into a Loan Agreement with Aspen Select Healthcare, LP ("Aspen") to provide up to \$1.5 million of indebtedness pursuant to a credit facility (the "Credit Facility"). As part of the Credit Facility transaction, the Company also issued to Aspen a five year Warrant to purchase up to 2,500,000 shares of its common stock at an original exercise price of \$0.50/share. Steven C. Jones, our Acting Principal Financial Officer and a Director of the Company, and is a general partner of Aspen.

On June 6, 2005, we entered into a Standby Equity Distribution Agreement ("SEDA") with Cornell Capital Partners, LP ("Cornell"). Pursuant to the Standby Equity Distribution Agreement, the Company may, at its discretion, periodically sell to Cornell shares of common stock for a total purchase price of up to \$5.0 million. Upon execution of the Standby Equity Distribution Agreement, Cornell received 381,888 shares of the Company's common stock as a commitment fee under the Standby Equity Distribution Agreement. The Company also issued 27,278 shares of the Company's common stock to Spartan Securities Group, Ltd. under a placement agent agreement relating to the Standby Equity Distribution Agreement.

On January 18, 2006, the Company entered into a binding letter agreement (the "Aspen Agreement") with Aspen Select Healthcare, LP, which provided, among other things, that:

(a) Aspen waived certain pre-emptive rights in connection with the sale of \$400,000 of common stock at a purchase price of \$0.20/share and the granting of 900,000 warrants with an exercise price of \$0.26/share to SKL Limited Partnership, LP ("SKL" as more fully described below) in exchange for five year warrants to purchase 150,000 shares at an exercise price of \$0.26/share (the "Waiver Warrants").

(b) Aspen had the right, up to April 30, 2006, to purchase up to \$200,000 of restricted shares of the Company's common stock at a purchase price per share of \$0.20/share (1,000,000 shares) and receive a five year warrant to purchase 450,000 shares of the Company's common stock at an exercise price of \$0.26/share in connection with such purchase (the "Equity Purchase Rights"). On March 14, 2006, Aspen exercised its Equity Purchase Rights.

(c) Aspen and the Company amended the Loan Agreement, dated March 23, 2005 (the "Loan Agreement") between the parties to extend the maturity date until September 30, 2007 and to modify certain covenants (such Loan Agreement as amended, the "Credit Facility Amendment").

(d) Aspen had the right, until April 30, 2006, to provide up to \$200,000 of additional secured indebtedness to the Company under the Credit Facility Amendment and to receive a five year warrant to purchase up to 450,000 shares of the Company's common stock with an exercise price of \$0.26/share (the "New Debt Rights"). On March 30, 2006, Aspen exercised its New Debt Rights and entered into the definitive transaction documentation for the Credit Facility Amendment and other such documents required under the Aspen Agreement.

(e) The Company agreed to amend and restate the warrant agreement, dated March 23, 2005, to provide that all 2,500,000 warrant shares (the "Existing Warrants") were vested and the exercise price per share was reset to \$0.31 per share.

(f) The Company agreed to amend the Registration Rights Agreement, dated March 23, 2005 (the "Registration Rights Agreement"), between the parties to incorporate the Existing Warrants, the Waiver Warrants and any new shares or warrants issued to Aspen in connection with the Equity Purchase Rights or the New Debt Rights.