## NEOGENOMICS INC Form SB-2 July 28, 2006

As filed with the U.S. Securities and Exchange Commission on July 28, 2006

Registration No. 333-\_\_\_\_

#### UNITED STATES

#### SECURITIES AND EXCHANGE COMMISSION

#### WASHINGTON, D.C. 20549

#### FORM SB-2

#### **REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

<u>Nevada</u> (State or Other Jurisdiction of Incorporation or Organization)

Robert P. Gasparini <u>12701 Commonwealth Drive, Suite 9</u> <u>Fort Myers, Florida 33913</u>

(239) 768-0600 (Address and telephone number of Principal Executive Offices and Principal Place of Business)

With a copy to: Clayton E. Parker, Esq. Kirkpatrick & Lockhart Nicholson Graham LLP 201 S. Biscayne Boulevard, Suite 2000 Miami, Florida 33131 Telephone: (305) 539-3300 Telecopier: (305) 358-7095 74-2897368 (I.R.S. Employer Identification No.)

Steven C. Jones <u>12701 Commonwealth Drive, Suite 9</u> Fort Myers, Florida 33913 (239) 768-0600 (Name, address and telephone number

of agent for service)

With a copy to: Alina S. Pastiu, Esq. Kirkpatrick & Lockhart Nicholson Graham LLP 201 S. Biscayne Boulevard, Suite 2000 Miami, Florida 33131 Telephone: (305) 539-3300 Telecopier: (305) 358-7095

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

NeoGenomics, Inc.

(Primary Standard Industrial

Classification Code Number)

<u>873</u>1

(Name of Registrant in Our Charter)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. /X/

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act of 1933, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.  $/_/$ 

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act of 1933, check the following box and list the Securities Act of 1933 registration statement number of the earlier effective registration statement for the same offering. /\_/

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. /\_/

#### CALCULATION OF REGISTRATION FEE

**Proposed Maximum** 

F		<b>Proposed Maximum</b>	1	
Title Of Each Class	Amount	Offering Price	Aggregate	Amount
Of Securities To Be Registered	To Be Registered	Per Share <sup>(1)</sup>	Offering Price <sup>(1)</sup>	Of Registration Fee
Common Stock, par value \$0.001 per share	1,800,000 shares	\$0.66	\$1,188,000	\$127.12
TOTAL	1,800,000 shares	\$0.66	\$1,188,000	\$127.12

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933. For the purposes of this table, we have used the average of the closing bid and asked prices as of a recent date.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

## PROSPECTUS

## NEOGENOMICS, INC.

### 1,800,000 shares of Common Stock

This prospectus relates to the sale of up to 1,800,000 shares of NeoGenomics, Inc. (referred to individually as the <u>Parent Company</u> or, collectively with all of its subsidiaries, as the <u>Company</u> or <u>NeoGenomics</u>) common stock by certain persons who are stockholders of the Company. The selling stockholders consist of:

Dr. Michael Dent, our Chairman of the Board of Directors (the <u>Board</u>), who intends to sell up to 123,523 shares of common stock previously issued to him;

Steven C. Jones, a member of our Board, who intends to sell up to 600,798 shares of common stock previously issued to him pursuant to a private placement conducted in 2003;

George G. O Leary, a member of our Board, who intends to sell up to 100,000 shares of common stock previously issued to him, pursuant to an Assignment Agreement, dated May 26, 2006;

Aspen Select Healthcare, LP, which intends to sell up to 175,679 shares of common stock previously issued to it pursuant to a private placement conducted in 2003; and

Other selling stockholders, which intend to sell up to 800,000 shares of common stock issued to them in May 2006 pursuant to an exercise of options by such stockholders under that certain Stock Options Agreement, dated July 9, 2004.

Please refer to Selling Stockholders beginning on page 12.

We are not selling any shares of common stock in this offering and therefore will not receive any proceeds from this offering. Fifty percent of the costs associated with the registration of the 1,800,000 shares on behalf of the selling stockholders will be borne by us, and fifty percent of the costs will be borne by the selling stockholders which are parties to the Stock Options Agreement, dated July 9, 2004.

The shares of common stock are being offered for sale by the selling stockholders at prices established on the Over-the-Counter Bulletin Board (the <u>OTCBB</u>) during the term of this offering. Our common stock is quoted on OTCBB under the symbol NGMN.OB. On July 26, 2006, the last reported sale price of our common stock was \$0.66 per share. These prices will fluctuate based on the demand for the shares of common stock.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

These securities are speculative and involve a high degree of risk. Please refer to Risk Factors beginning on page 5.

The information in this prospectus is not complete and may be changed. We and the selling stockholders may not sell these securities until the registration statement filed with the U.S. Securities and Exchange Commission (the <u>SEC</u>) is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

No other underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. This offering will terminate twenty-four months after the accompanying registration statement is declared effective by the SEC. None of the proceeds from the sale of stock by the selling stockholders will be placed in escrow, trust or any similar account.

The SEC and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July \_\_\_\_, 2006

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### PROSPECTUS SUMMARY

The following is only a summary of the information, financial statements and the notes included in this prospectus. You should read the entire prospectus carefully, including Risk Factors and our Financial Statements and the notes to the Financial Statements before making any investment decision.

#### **Our Company**

#### General

NeoGenomics operates a cancer genetics laboratory that is targeting the rapidly growing genetic and molecular testing segment of the medical laboratory market. We operate in two laboratory locations: the first location is in Fort Myers, Florida and the second is in Nashville, Tennessee. We currently offer the following types of testing services to oncologists, pathologists, urologists, hospitals, and other laboratories that do not perform genetic testing throughout the United States: a) cytogenetics testing, which analyzes human chromosomes, b) Fluorescence In-Situ Hybridization (FISH) testing which analyzes abnormalities at the gene level, c) flow cytometry testing services, which analyzes clusters of differentiation on cell surfaces and d) molecular testing which involves testing DNA and other molecular structures to screen for and diagnose single gene disorders. All of these testing services are widely used in the diagnosis of various types of cancer. Our common stock is listed on the NASDAQ Over-the-Counter Bulletin Board (the OTCBB ) under the symbol NGNM.OB

We believe the genetic and molecular testing segment of the medical laboratory industry is the most rapidly growing segment of the market. Approximately five years ago, the World Health Organization reclassified cancers as being 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/molecular testing.

Clinical labs typically are engaged in high volume, high automation tests on 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 known AP tests are Pap smears, skin biopsies, and tissue biopsies. AP tests are typically more labor and technology intensive than clinical lab tests and thus typically have higher average revenue per test than clinical lab tests.

Genetic/molecular testing typically involves analyzing chromosomes, genes or base pairs of DNA for disorders. Whereas anatomic pathology testing is focused from the cell surface outward, genetic and molecular testing is focused from the cell surface inward. Both genetic and molecular testing have become important and highly-accurate diagnostic tools over the last five years. New tests are being developed rapidly, thus this market segment is expanding rapidly. Genetic/molecular testing requires very specialized equipment and credentialed individuals (typically MD or PhD level) to certify the results and typically yields the highest average revenue per test of the three market segments. The following chart shows the differences between the genetic/molecular segment and other segments of the medical laboratory industry. Up until about five years ago, the genetic/molecular segment was considered to be part of the Anatomic Pathology segment, but given its rapid growth, many industry veterans now break genetic/molecular testing out into its own segment.

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

<u>Attributes</u>	<u>Clinical</u>	Anatomic Pathology	Genetic/Molecular	
Testing Performed On Testing Volume Physician Involvement	Blood, Urine High Low	Tissue/Cells Low High - Pathologist	- Chromosomes/Genes/DNA Low Low - Medium	
Malpractice Ins. Required	Low	High	Low	
Other Professionals Req.	None	None	Cyto/Molecular geneticist	
Level of Automation Diagnostic in Nature	High Usually Not	Low-Moderate Yes	Moderate Yes	
Types of Diseases Tested	Many Possible	Typically Cancer \$25 - \$500/Test	Rapidly Growing	
Typical Revenue Per Test	\$5 - \$35/Test	\$10.0 - \$12.0 Billion	\$200 - \$1,000/Test	
Estimated Size of Market Estimated Growth Rate	\$25 - \$30 Billion 4.0 -5.0%	6.0 7.0% Annually	\$3.0 - \$4.0 Billion (2) 25.0+% Annually	
Established Competitors	Quest Diagnostics	Quest Diagnostics	Genzyme Genetics	
	LabCorp	LabCorp	Quest Diagnostics	
	Bio Reference Labs	Genzyme Genetics	LabCorp	
	DSI Laboratories	Ameripath	Major Universities	
	Hospital Labs	Local Pathologists		
	Regional Labs			

(1) Derived from industry analyst reports and Company estimates.

(2) Includes flow cytometry testing, which historically has been classified under Anatomic Pathology testing.

Our primary focus is on the oncology market. We target oncologists that perform bone marrow sampling and treat patients with leukemia, lymphoma and other forms of cancer as well as urologists that treat patients with bladder cancer. Historically, our clients were predominantly located in Florida. Beginning in January 2005, we began targeting large institutional clients throughout the United States. This was successful and we landed several clients outside of the State of Florida. During the third quarter of 2005, we began testing for cervical, breast and bladder cancer. Our bladder cancer program focused around the UroVysion test has grown significantly since it started in the third quarter of 2005. As

we grow, 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.

We compete in the marketplace based on the quality and accuracy of our test results, our turn-around times and our ability to provide after-test support to those physicians requesting consultation. We believe our average 3 - 5 day turn-around time on oncology-related cytogenetics tests is helping to increase the usage patterns of cytogenetics tests by our referring oncologists and hematopathologists. Based on empirical data, we believe that cytogenetics labs typically 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.

We have an opportunity to add additional types of tests to our product offering. We believe that by doing so we may 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 bundle our testing services more appropriately to the needs of the market. Until December 2004, we only performed one type of test, cytogenetics, in-house, which resulted in only one test being performed per customer requisition for most of FY 2004 and average revenue per requisition of approximately \$490 in FY 2004. In December 2004, we added FISH testing to our product offering, and in February 2005, we began offering flow cytometry testing services. With the addition of these two new testing platforms, our average revenue/requisition increased by 35.6% in FY 2005 to approximately \$632/requisition. This trend continued into the first half of FY 2006 with average revenue/requisition increasing to \$704 per requisition. We believe that we can continue to increase our average revenue per customer requisition with the addition of additional testing platforms and more focused marketing.

	For the Six Months Ended	For the Six Months Ended		For the ThreeFor the ThreeMonths EndedMonths Ended		
	June 30, 2006	June 30, 2005	% Inc (Dec)	June 30, 2006	June 30, 2005	% Inc (Dec)
Requisitions Received (Cases)	4,420	970	355.7%	2,472	593	316.9%
Number of Tests Performed	6,139	1,235	397.1%	3,475	768	352.5%
Avg. # of Tests/Requisition	1.389	1.273	9.4%	1.406	1.295	8.5%
Total Testing Revenue	\$3,111,292	\$ 575,080	441.1%	\$1,767,492	\$344,888	412.5%
Avg. Revenue/Requisition	\$ 703.91	\$ 592.86	18.7%	\$ 715.00	\$581.60	22.9%
Avg. Revenue/Test	\$ 506.81	\$ 465.65	8.8%	\$ 508.63	\$ 449.07	13.3%

We believe our strategy of bundling complementary types of tests together to better service the needs of our clients will continue to drive 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 most hematological cancers may yield total revenue ranging from approximately \$1,700 to \$2,800 per case and is generally comprised of one or more of the following tests: cytogenetics, FISH, flow cytometry, and morphology testing. Whereas in the fiscal year ended 2004, we only addressed approximately \$500 of this potential revenue per case, we now address approximately \$1,200 to \$1,900 of this potential revenue per case.

Avg. Rev/Test
\$400-\$600
\$400-\$600
\$400-\$700
\$100-\$200
\$400-\$700
\$1,700-\$2,800

#### About Us

Our principal executive offices are located at 12701 Commonwealth Drive, Suite 9, Fort Myers, Florida 33913. Our telephone number is (239) 768-0600. Our website can be accessed at www.neogenomics.org.

This offering relates to the sale of common stock by certain persons who are, or will become, our stockholders. The selling stockholders consist

#### THE OFFERING

of:

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Dr. Michael Dent, our Chairman of the Board, who intends to sell up to 123,523 shares of common stock previously issued to him; Steven C. Jones, a member of our Board, who intends to sell up to 600,798 shares of common stock previously issued to him pursuant to a private placement conducted in 2003; George G. O Leary, a member of our Board, who intends to sell up to 100,000 shares of common stock previously issued to him, pursuant to an Assignment Agreement, dated May 26,2006; Aspen Select Healthcare, LP, which intends to sell up to 175,679 shares of common stock previously issued to it pursuant to a private placement conducted in 2003; and Other selling stockholders, which intend to sell up to 800,000 shares of common stock issued to them in May 2006 pursuant to an exercise of options by such stockholders under that certain Stock Options Agreement, dated July 9, 2004. **Common Stock Offered** 1,800,000 shares by selling stockholders **Offering Price** Market price **Common Stock Outstanding Before the Offering** 26,328,365 shares as of July 26, 2006 **Use of Proceeds** We will not receive any proceeds of the shares offered by the selling stockholders. See Use of Proceeds. **Risk Factors** The securities offered hereby involve a high degree of risk and immediate substantial dilution. See Risk Factors and Dilution.

NGNM.OB

**Over-the-Counter Bulletin Board Symbol** 

## SUMMARY CONSOLIDATED FINANCIAL INFORMATION

The Summary Consolidated Financial Information set forth below is **unaudited** and was excerpted from the Company s Quarterly Reports on Form 10-QSB for the periods ended June 30, 2006 and 2005, as filed with the SEC.

	For the Six-Mont 2006	hs Ended June 30, 2005
Statement of Operations Data: Revenue Cost of Revenue Gross Profit	\$ 3,111,292 1,302,614 1,808,678	\$ 575,080 347,005 228,075
Total other operating expenses Net Income (Loss)	1,540,090 \$ 267,688	624,606 \$ (396,531)
Net Income (Loss) Per Share - Basic and DilutedWeighted Average Number of Shares OutstandingBasicWeighted Average Number of Shares OutstandingDiluted	\$ 0.01 25,531,132 27,951,298	\$ (0.02) 21,952,046 21,952,046
	As of June 30, 2006	
Balance Sheet Data: Assets:		
Cash and cash equivalents Accounts receivable (net of allowance for doubtful accounts of \$51,555 and \$13,137 respectiverly) Inventory Other current assets Total current assets	274,353 1,032,674 76,299 81,665 1,464,991	
Property and Equipment (net of accumulated depreciation of \$354,939 as of June 30, 2006 and \$193,001 as of June 30, 2006 Other Assets Total assets	839,225 19,186 \$ 2,323,402	
Liabilities & Stockholders Deficit: Total current liabilities Long term portion of equipment leases Line of Credit Total liabilities	\$ 788,077 106,065 1,533,772 2,427,914	
Common Stock, \$.001 par value, 100,000,000 shares authorized; 26,328,365 as of June 30, 2006; 22,498,252 shares issued and outstanding as of June 30, 2005 Additional paid in capital Deferred Stock Compensation Accumulated Deficit	26,328 10,700,948 (79,078) (10,752,710)	
Total stockholders deficit	(104,512)	
Total Liabilities and Stockholders Deficit	\$ 2,323,402	

### **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.

#### **Risks Related To Our Business**

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

We commenced revenue operations in 2002 and are just beginning to generate meaningful revenue. Accordingly, we have a limited operating history upon which an evaluation of us and our prospects can be based. We and our 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, we must, among other things, respond to competitive developments, attract, retain and motivate qualified personnel, implement and successfully execute our sales strategy, develop and market additional services, and upgrade our technological and physical infrastructure in order to scale our revenues. We may not be successful in addressing such risks. Our limited operating history makes the prediction of future results of operations difficult or impossible.

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

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

## We May Be Unsuccessful In Managing Our Growth Which Could Prevent the Company From Being Profitable

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

Part of our business strategy may be to acquire assets or other companies that will complement our business. At this time, we are unable to predict whether or when any material transaction will be completed should negotiations commence. If we proceed with any such transaction, we may not effectively integrate the acquired operations with our own operations. We may also seek to finance any such acquisition by debt financings or issuances of equity securities and such financing may not be available on acceptable terms or at all.

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

We used reasonable efforts to assess and predict the expenses necessary to pursue our business plan. However, implementing our business plan may require more employees, capital equipment, supplies or other expenditure items than management has predicted. Similarly, the cost of compensating additional management, employees and consultants or other operating costs may be more than we estimate, which could result in 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 our limited operating history and the relatively limited information available on our competitors, we may not have sufficient internal or industry-based historical financial data upon which to calculate anticipated operating expenses. Management expects that our results of operations may also fluctuate significantly in the future as a result of a variety of factors, including, but not limited to, (i) the continued rate of growth, usage and acceptance of our products and services; (ii) demand for our products and services; (iii) the introduction and acceptance of new or enhanced products or services by us or by competitors; (iv) our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; (v) our ability to attract, retain and motivate qualified personnel; (vi) the initiation, renewal or expiration of significant contracts with our major clients; (vii) pricing changes by us, our suppliers or our competitors; (viii) seasonality; and (ix) general economic conditions and other factors.

Accordingly, future sales and operating results are difficult to forecast. Our expenses are based in part on our expectations as to future revenues and to a significant extent are relatively fixed, at least in the short-term. We may not be able to adjust spending in a timely manner to compensate for any unexpected revenue shortfall. Accordingly, any significant shortfall in relation to our expectations would have an immediate adverse impact on our business, results of operations and financial condition. In addition, we may determine from time to time to make certain pricing or marketing decisions or acquisitions that could have a short-term material adverse affect on the our business, results of operations and financial condition. In Florida, currently our primary referral market for lab tests, a meaningful percentage of the population returns to homes in the Northern U.S. for the spring and summer months. This results in seasonality in our business. We estimate that our operating results during the second and third quarter of each year will be somewhat impacted by these seasonality factors until such time as we can generate more clients from outside of Florida. Because of all of the foregoing factors, our 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

We are a clinical medical laboratory that provides medical testing services to doctors, hospitals and other laboratories on patient specimens that are sent to us. In the case of most specimen referrals that are received from patients that are not in-patients at a hospital or institution or otherwise sent by another reference laboratory, we generally have to bill the patient s insurance company or a government program for our services. As such, we rely 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 our clients. Wherever possible, the amount of such third party payments is governed by contractual relationships in cases where we are a participating provider for a specified insurance company or by established government reimbursement rates in cases where we are an approved provider for a government program such as Medicare. However, we do not have a contractual relationship with many of the insurance companies with whom we deal, nor are we necessarily able to become an approved provider for all government programs. In such cases, we are deemed to be a non-participating provider and there is no contractual assurance that we are able to collect the amounts billed to such insurance companies or government programs. Currently, we are not a participating provider with the majority of the insurance companies we bill for our services. Until such time as we become a participating provider with such insurance companies, there can be no contractual assurance that we will be paid for the services we bill 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 our ash flow or results of operations.

## Our Business Is Subject To Rapid Scientific Change, Which Could Have A Material Adverse Affect On Our Operations

The market for genetic and molecular biology testing products and services is characterized by rapid scientific developments, evolving industry standards and customer demands, and frequent new product introductions and enhancements.

Our future success will depend in significant part on our ability to continually improve our offerings in response to both evolving demands of the marketplace and competitive product offerings, and we may be unsuccessful in doing so.

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

The market for genetic and molecular biology testing services is highly competitive and competition is expected to continue to increase. We compete with other commercial medical laboratories in addition to the in-house laboratories of many major hospitals. Many of our existing competitors have significantly greater financial, human, technical and marketing resources than we do. Our competitors may develop products and services that are superior to ours or that achieve greater market acceptance than our offerings. We may not be able to compete successfully against current and future sources of competition and competitive pressures faced by us may have a material adverse affect on our business, results of operations and financial condition.

#### Our Failure to Manage Potential Growth May Impair Our Ability To Become Profitable

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

Any failure to handle higher volume of requests for our products and services could lead to the loss of established customers and have a material adverse affect on our 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 severally harm our operations. In addition, based on the importance of the subject matter of our tests, inaccurate results could result in improper treatment of patients, and potential liability for us.

# We May Fail to Deliver Timely Results to Customers, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

Our operations are dependent in part upon our ability to protect our laboratory operations against physical damage from fire, floods, hurricanes, earthquakes, power loss, telecommunications failures, break-ins and similar events. We do not presently have redundant, multiple site capacity in the event of any such occurrence, nor do we have an emergency back-up generator in place at our main laboratory location that can mitigate 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 affect on our business, results of operations and financial condition.

# The Steps Taken By Us To Protect Our Proprietary Rights May Not Be Adequate, Which Could Have A Material Adverse Affect On Our Business, Results Of Operations And Financial Condition

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

similar proprietary rights, which could have a material adverse affect on our business, results of operations and financial condition. In addition, other parties may assert infringement claims against us.

#### We are Dependent on Key Personnel and Need to Hire Additional Qualified Personnel

Our performance is substantially dependent on the performance of our senior management and key technical personnel. In particular, our success depends substantially on the continued efforts of our senior management team. We do not carry key person life insurance on any of our senior management personnel. The loss of the services of any of our executive officers, our laboratory director or other key employees could have a material adverse affect on the business, results of operations and our financial condition. Our future success also depends on our continuing ability to attract and retain highly qualified technical and managerial personnel. Competition for such personnel is intense and we may not be able to retain our key managerial and technical employees or that it will 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 affect upon our business, results of operations and financial condition.

# The Failure to Obtain Necessary Additional Capital to Finance Growth and Capital Requirements, Could Adversely Affect Our Business, Financial Condition and Results of Operations

We may seek to exploit business opportunities that require more capital than what is currently planned. We may not be able to raise such capital on favorable terms or at all. If we are unable to obtain such additional capital, we may be required to reduce the scope of our anticipated expansion, which could adversely affect our business, financial condition and results of operations. The failure to comply with significant government regulation and laboratory operations procedures may subject us to liability, penalties or limitation of operations.

# The Failure to Comply With Significant Government Regulation and Laboratory Operations May Subject Us to Liability, Penalties or Limitation of Operations

We are subject to extensive state and federal regulatory oversight. Our laboratory may not pass inspections conducted to ensure compliance with the Clinical Laboratories Improvement Act of 1967, as amended by the Clinical Laboratory Improvement Amendments of 1988 (collectively, <u>CLIA`88</u>) 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 labs 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 do not anticipate could have a material adverse affect on our business, results of operations and financial condition.

In addition, 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, when necessary. 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 (<u>HIPAA</u>) and other state laws contain provisions that affect the handling of claims and other patient information that are, or have been, transmitted electronically and regulate the general disclosure of patient records and patient health information. These provisions, which address security and confidentiality of patient information as well as the administrative aspects of claims handling, have very broad applicability and they specifically apply to healthcare providers, which include physicians and clinical laboratories. While 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 affect on our 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 us, our infrastructure is vulnerable to computer viruses, break-ins and similar disruptive problems caused by our customers or others. Computer viruses, break-ins or other security problems could lead to interruption, delays or cessation in service to our customers. Further, such break-ins whether electronic or physical could also potentially jeopardize the security of confidential information stored in our computer systems of our customers and other parties connected through us, 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 our reputation, direct damages, costs of repair and detection, and other expenses. The occurrence of any of the foregoing events could have a material adverse affect on our business, results of operations and financial condition.

## We Are Controlled by Existing Shareholders And Therefore Other Shareholders Will Not Be Able to Direct Our Company

The majority of our 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 our Board of Directors and determine all of our corporate actions. In addition, the Company and shareholders owning 14,281,345 shares as of July 26, 2006, or approximately 54% of our common shares outstanding as of such date have executed a Shareholders Agreement, that, among other provisions, gives Aspen Select Healthcare, LP<u>(Aspen Select Healthcare)</u>, 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 and other parties to the Shareholders of the Company may not be able to elect a representative to our Board of Directors. Such concentration of ownership may also have the effect of delaying or preventing a change in control.

### No Foreseeable Dividends

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

## **Risks Related To This Offering**

### Future Sales By Our Stockholders May Adversely Affect Our Stock Price And Our Ability To Raise Funds In New Stock Offerings

Sales of our common stock in the public market following this offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Of the 26,328,365 shares of common stock outstanding as of July 26, 2006, 9,481,141 shares are freely tradable without restriction, unless held by our affiliates. The remaining 16,847,224 shares of common stock which are held by existing stockholders, including the officers and directors, are restricted securities and may be resold in the public market only if registered or pursuant to an exemption from registration. Some of these shares may be resold under Rule 144.

# The Selling Stockholders Intend To Sell Their Shares Of Common Stock In The Market, Which Sales May Cause Our Stock Price To Decline

The selling stockholders intend to sell in the public market up to 1,800,000 shares of common stock being registered in this offering. That means that up to 1,800,000 shares, or 7% of our outstanding shares, may be sold pursuant to this registration statement. Such sales may cause our stock price to decline. Our officers and directors and those shareholders who are significant shareholders as defined by the SEC will continue to be subject to the provisions of various insider trading and rule 144 regulations.

# The Price You Pay In This Offering Will Fluctuate And May Be Higher Or Lower Than The Prices Paid By Other People Participating In This Offering

The price in this offering will fluctuate based on the prevailing market price of the common stock on the OTCBB. Accordingly, the price you pay in this offering may be higher or lower than the prices paid by other people participating in this offering.

# Our Common Stock Is Deemed To Be Penny Stock, Which May Make It More Difficult For Investors To Sell Their Shares Due To Suitability Requirements

Our common stock is deemed to be penny stock as that term is defined in Rule 3a51-1 promulgated under the Securities Exchange Act of 1934, as amended (the <u>1934 Act</u>). Penny stocks are stocks:

With a price of less than \$5.00 per share;

That are not traded on a recognized national exchange;

Whose prices are not quoted on the Nasdaq automated quotation system;

Nasdaq stocks that trade below \$5.00 per share are deemed a penny stock for purposes of Section 15(b)(6) of the 1934 Act;

In issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation for less than three years), or with average revenues of less than \$6.0 million for the last three years.

Broker/dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stocks. Moreover, broker/dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor. These requirements may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to sell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline.

## FORWARD-LOOKING STATEMENTS

Information included or incorporated by reference in this prospectus may contain forward-looking statements. This information may involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by any forward-looking statements. Forward-looking statements, which involve assumptions and describe our future plans, strategies and expectations, are generally identifiable by use of the words may, should, expect, anticipate, estimate, believe, intend or project or the negative of these words or other variations on these word comparable terminology.

This prospectus contains forward-looking statements, including statements regarding, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) our future financing plans and (e) our anticipated needs for working capital. These statements may be found under Management s Discussion and Analysis or Plan of Operations and Description of Business, as well as in this prospectus generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under Risk Factors and matters described in this prospectus generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this prospectus will in fact occur.

### SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders. The selling shareholders are the entities who have assisted in or provided financing to the Company. A description of each selling shareholder s relationship to the Company and how each selling shareholder acquired the shares to be sold in this offering is detailed in the information immediately following this table.

	Shares Beneficial	Percentage of Outstanding lyShares Beneficiall	v	Percentage of Outstanding Shares Beneficially
	Owned Before	Owned Before		Owned After The
Selling Stockholder	Offering <sup>(1)</sup>	Offering <sup>(1)</sup>	In The Offering	Offering
Dr. Michael T. Dent	2,857,992	10.66%	123,523	10.25%
Steven C. Jones <sup>(4)</sup>	14,755,172	49.34%	600,798	47.99%
George G. O Leary	100,000	1.13%	100,000	*
Aspen Select Healthcare, LP	13,553,279	45.36%	175,679	45.04%
The Craigmore Corporation Defined Benefit Pension Plan <sup>(5)</sup>	360,350	1.37%	300,000	1.54%
National Investor Services Corp. FBO Lynn N. Edelman				
IRA Account <sup>(6)</sup>	400,000	1.52%	200,000	*
Stillman Limited Partnership <sup>(7)</sup>	239,200	*	200,000	*
White Financial Money Purchase Plan <sup>(8)</sup>	200,000	*	100,000	*
Total	19,112,714		1,800,000	61.45%

Less than 1%.

(1) Applicable percentage of ownership is based on 26,328,365 shares of common stock outstanding as of July 26, 2006 together with securities exercisable or convertible into shares of common stock within 60 days of July 26, 2006, for each stockholder. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of common stock are deemed to be beneficially owned by the person holding such securities for the purpose of computing the percentage of ownership of such person, but are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Note that affiliates are subject to Rule 144 and Insider trading regulations. Percentage computation is for form purposes only.

The following information contains a description of each selling shareholder s relationship to the Company and how each selling shareholder acquired the shares to be sold in this offering is detailed below. None of the selling stockholders have held a position or office, or had any other material relationship, with the Company, except as follows:

#### Shares Acquired By The Selling Shareholders In Transactions With The Company

**Dr. Michael T. Dent**. In June 2001, we issued 2,385,000 founders shares to Dr. Dent, a director of the Company, in connection with his formation of the Company. Dr. Dent is the Chairman of our Board. We are registering 123,523 of such founder s shares in this offering.

**Steven C. Jones**. In April 2003, we conducted a private placement to Aspen Select Healthcare and its affiliates in which we received net proceeds of \$114,271 (after deducting certain transaction expenses) through the issuance of 13,927,062 shares of common stock. Mr. Steven Jones acts as Managing Member of Medical Venture Partners, LLC, which is the general partner of Aspen Select Healthcare. In the April 2003 transaction, Mr. Jones purchased 1,541,261 shares in his own name, of which 366,666 were subsequently transferred to other entities. We are registering 600,798 shares of Mr. Jones remaining shares in this offering.

**George O Leary**. Mr. O Leary received the options to purchase 100,000 options of our common share pursuant to an Assignment Agreement, dated May 26, 2006, by and between Mr. O Leary and The Craigmore Corporation Defined Benefit Pension Plan (the <u>Craigmore Corporation</u>). The Craigmore

Corporation acquired options to purchase 400,000 shares of our common stock pursuant to that certain Stock Option Agreement, dated July 9, 2004 (the <u>2004 Stock Option Agreement</u>), by and among the MVP 3 LP, a Delaware limited partnership (the predecessor to Aspen Select Healthcare) and certain entities, including The Craigmore Corporation (collectively, the <u>Option Holders</u>).

**Aspen Select Healthcare LP**. In April 2003, we conducted a private placement to Aspen Select Healthcare, LP and its affiliates in which we received net proceeds of \$114,271 (after deducting certain transaction expenses) through the issuance of 13,927,062 shares of common stock. In the April 2003 transaction, Aspen Select Healthcare purchased 9,303,279 shares, of which 1,300,000 were subsequently transferred to other entities, including 900,000 shares transferred pursuant to the 2004 Stock Option Agreement. All investment decisions of Aspen Select Healthcare are made by Mr. Steven Jones, a Director of the Board. We are registering 175,679 shares in this offering.

The Craigmore Corporation Defined Benefit Pension Plan. The Craigmore Corporation received options to purchase 400,000 shares of our common stock pursuant to the 2004 Stock Option Agreement. Pursuant to that certain Assignment Agreement, dated May 26, 2006, the Craigmore Corporation assigned options to purchase 100,000 of its option shares to Mr. George O Leary, a member of our Board of Directors. Pursuant to that certain Registration Right Agreement, dated July 9, 2004 (the <u>2004 Registration Rights Agreement</u>), by and between us and the Option Holders, we are obligated to register these shares provided that a demand for registration has been made after December 31, 2005, by at least fifty-percent of the holders. The Craigmore Corporation, along with the other Option Holders, exercised their demand rights in May 2006. All investment decisions of The Craigmore Corporation are made by its Trustee, Gary L. Shapiro. We are registering 300,000 shares in this offering.

**National Investor Services Corp.** National Investor Services Corp received options to purchase 200,000 shares of our common stock pursuant to the 2004 Stock Option Agreement. Pursuant to the 2004 Registration Right Agreement, we are obligated to register these shares provided that a demand for registration has been made after December 31, 2005, by at least fifty-percent of the holders. National Investor Services Corp., along with the other Option Holders, exercised their demand rights in May 2006. All investment decisions of National Investor Services Corp. with respect to this account are made by Lynn N. Edelman. We are registering 200,000 shares in this offering.

**Stillman Limited Partnership**. Stillman Limited Partnership received options to purchase 200,000 shares of our common stock pursuant to the 2004 Stock Option Agreement. Pursuant to the 2004 Registration Right Agreement, we are obligated to register these shares provided that a demand for registration has been made after December 31, 2005, by at least fifty-percent of the holders. Stillman Limited Partnership, along with the other Option Holders, exercised their demand rights in May 2006. All investment decisions of Stillman Limited Partnership are made by its General Partner, Andrew Stillman. We are registering 200,000 shares in this offering.

White Financial Money Purchase Plan. White Financial Money Purchase Plan received options to purchase 100,000 shares of our common stock pursuant to the 2004 Stock Option Agreement. Pursuant to the 2004 Registration Right Agreement, we are obligated to register these shares provided that a demand for registration has been made after December 31, 2005, by at least fifty-percent of the holders. White Financial Money Purchase Plan, along with the other Option Holders, exercised their demand rights in May 2006. All investment decisions of White Financial Money Purchase Plan are made by its Trustee, Kevin White. We are registering 100,000 shares in this offering.

With respect to the sale of unregistered securities referenced above, all transactions were exempt from registration pursuant to Section 4(2) of the 1933 Act and Regulation D promulgated under the 1933 Act. In each instance, the purchaser had access to sufficient information regarding the Company so as to make an informed investment decision. More specifically, we had a reasonable basis to believe that each purchaser was an accredited investor as defined in Regulation D of the 1933 Act and otherwise had the requisite sophistication to make an investment in our securities.

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## **USE OF PROCEEDS**

This prospectus relates to shares of our common stock that may be offered and sold from time to time by certain selling stockholders. There will be no proceeds to us from the sale of shares of common stock in this offering.

### PLAN OF DISTRIBUTION

The selling stockholders have advised us that the sale or distribution of Our common stock owned by the selling stockholders may be effected directly to purchasers by the selling stockholders or by pledgees, transferees or other successors in interest, as principals or through one or more underwriters, brokers, dealers or agents from time to time in one or more transactions (which may involve crosses or block transactions) (i) on the over-the-counter market or in any other market on which the price of our shares of common stock are quoted or (ii) in transactions otherwise than on the over-the-counter market or in any other market on which the price of our shares of common stock are quoted. Any transferees and pledges will be identified by a post-effective amendment to the accompanying registration statement. Any of such transactions may be effected at market prices prevailing at the time of sale, at prices related to such prevailing market prices, at varying prices determined at the time of sale or at negotiated or fixed prices, in each case as determined by a selling stockholder or by agreement between a selling stockholder and underwriters, brokers, dealers or agents, or purchasers. If the selling stockholders of agents may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of common stock for whom they may act as agent (which discounts, concessions or commissions as to particular underwriters, brokers, dealers or agents may be in excess of those customary in the types of transactions involved). Any brokers, dealers or agents that participate in the distribution of the common stock may be deemed to be underwriters, brokers, dealers or agents may be deemed to be underwriters, brokers, dealers or agents may be deemed to be underwriters, brokers, dealers or agents may be deemed to be underwriters, brokers, dealers or agents may be deemed to be underwriters, brokers, dealers or agents may be deemed to be underwriters, brokers, dea

Under the securities laws of certain states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. The selling stockholders are advised to ensure that any underwriters, brokers, dealers or agents effecting transactions on behalf of the selling stockholders are registered to sell securities in all fifty states. In addition, in certain states the shares of common stock may not be sold unless the shares have been registered or qualified for sale in such state or have been deemed exemptive securities pursuant to an exemption from registration or qualification under the laws of such state.

Our common stock is deemed to be penny stock as that term is defined in Rule 3a51-1 promulgated under the 1934 Act. Penny stocks are stock: (i) with a price of less than \$5.00 per share; (ii) that are not traded on a recognized national exchange; (iii) whose prices are not quoted on the NASDAQ automated quotation system (NASDAQ listed stock must still have a price of not less than \$5.00 per share); or (iv) in issuers with net tangible assets less than \$2.0 million (if the issuer has been in continuous operation for at least three years) or \$5.0 million (if in continuous operation for the last three years), or with average revenues of less than \$6.0 million for the last three years.

Broker/dealers dealing in penny stocks are required to provide potential investors with a document disclosing the risks of penny stocks. Moreover, broker/dealers are required to determine whether an investment in a penny stock is a suitable investment for a prospective investor. These requirements may reduce the potential market for our common stock by reducing the number of potential investors. This may make it more difficult for investors in our common stock to sell shares to third parties or to otherwise dispose of them. This could cause our stock price to decline.

We will pay fifty percent of the expenses incident to the registration, offering and sale of the shares of common stock to the public hereunder other than commissions, fees and discounts of underwriters, brokers, dealers and agents. The remaining fifty percent of the costs will be borne by the selling stockholders which are parties to the Stock Options Agreement, dated July 9, 2004. We estimate that the expenses of the offering to be borne by us will be approximately \$35,000. The estimated offering expenses consist of: a SEC registration fee of \$200, printing expenses of \$1,000, accounting fees of \$30,000 and miscellaneous expenses of \$800. We will not receive any proceeds from the sale of any of the shares of common stock by the selling stockholders.

The selling stockholders are subject to applicable provisions of the 1934 Act, as amended, and its regulations, including, Regulation M. Under Regulation M, the selling stockholders or their agents may not bid for, purchase, or attempt to induce any person to bid for or purchase, shares of our common stock while such selling stockholders are distributing shares covered by this prospectus. Pursuant to the requirements of Item 512 of Regulation S-B and as stated in Part II of this Registration Statement, we must file a post-effective amendment to the accompanying Registration Statement once informed of a material change from the information set forth with respect to the Plan of Distribution.

## MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

The following discussion of the financial condition and results of operations should be read in conjunction with the consolidated financial statements and related notes thereto. The following discussion contains certain forward-looking statements that involve risk and uncertainties. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include, but are not limited to, risks and uncertainties related to the need for additional funds, the rapid growth of the operations and our ability to operate profitably after the initial growth period is completed. We undertake no obligation to publicly release the results of any revisions to those forward-looking statements that may be made to reflect any future events or circumstances.

## **Critical Accounting Policies And Estimates**

The preparation of financial statements in conformity with United States generally accepted accounting principles requires our management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Our management routinely makes judgments and estimates about the effects of matters that are inherently uncertain.

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

**Revenue Recognition** 

Accounts Receivable

#### **Revenue Recognition**

Net revenues are recognized in the period when tests are performed and consist primarily of net patient revenues that are recorded based on established billing rates less estimated discounts for contractual allowances principally for patients covered by Medicare, Medicaid and managed care and other health plans. These revenues also are subject to review and possible audit by the payers. We believe that adequate provision has been made for any adjustments that may result from final determination of amounts earned under all the above arrangements. There are no known material claims, disputes or unsettled matters with any payers that are not adequately provided for in the accompanying consolidated financial statements.

#### **Accounts Receivable**

We record accounts receivable net of estimated and contractual discounts. We provide for accounts receivable that could become uncollectible in the future by establishing an allowance to reduce the carrying value of such receivables to their estimated net realizable value. We estimate this allowance based on the aging of our accounts receivable and our historical collection experience for each type of payer. Bad debts are charged off to the allowance account at the time they are deemed uncollectible.

### **Recent Accounting Pronouncements**

### SFAS 123(R) Share-Based Payments

In December 2004, the Financial Accounting Standards Board (<u>FASB</u>) issued Statement Number 123 (FAS 123(R)), Share-Based Payments, which is effective for the reporting period beginning on January 1, 2006. The statement will require us to recognize compensation expense in an amount equal to the fair value of share-based payments such as stock options granted to employees. We have the option to either apply FAS 123 (R) on a modified prospective method or to restate previously issued financial statements, and chose to utilize the modified prospective method. Under this method, we are required to record compensation expense (as previous awards continue to vest) for the unvested portion of previously granted awards that remain outstanding at the date of adoption. The impact of adopting this statement is expected to increase our expense by approximately 30,000 in 2006.

## SFAS 155 Accounting For Certain Hybrid Financial Instruments An Amendment Of FASB Statements M& And 140

In February 2006, the FASB issued this Statement, which amends FASB Statements No. 133, Accounting for Derivative Instruments and Hedging Activities, and No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities. This Statement resolves issues addressed in Statement 133 Implementation Issue No. D1, Application of Statement 133 to Beneficial Interests in Securitized Financial Assets.

This Statement:

a. Permits fair value remeasurement for any hybrid financial instrument that contains an embedded derivative that otherwise would require bifurcation.

b. Clarifies which interest-only strips and principal-only strips are not subject to the requirements of Statement 133.

c. Establishes a requirement to evaluate interests in securitized financial assets to identify interests that are freestanding derivatives or that are hybrid financial instruments that contain an embedded derivative requiring bifurcation.

d. Clarifies that concentrations of credit risk in the form of subordination are not embedded derivatives.
e. Amends Statement 140 to eliminate the prohibition on a qualifying special-purpose entity from holding a derivative financial instrument that pertains to a beneficial interest other than another derivative financial instrument.

This Statement is effective for all financial instruments acquired or issued after the beginning of our first fiscal year that begins after September 15, 2006.

The fair value election provided for in paragraph 4(c) of this Statement may also be applied upon adoption of this Statement for hybrid financial instruments that had been bifurcated under paragraph 12 of Statement 133 prior to the adoption of this Statement. Earlier adoption is permitted as of the beginning of our fiscal year, provided we have not yet issued financial statements, including financial statements for any interim period, for that fiscal year. Provisions of this Statement may be applied to instruments that we hold at the date of adoption on an instrument-by-instrument basis.

We are currently reviewing the effects of adoption of this statement but it is not expected to have a material impact on our financial statements.

#### SFAS 154 Accounting Changes And Error Corrections--A Replacement Of APB Opinion No20 And FASB Statement No. 3

In May 2005, the FASB issued Statement No. 154. This Statement replaces APB Opinion No. 20, Accounting Changes, and FASB Statement No. 3, Reporting Accounting Changes in Interim Financial Statements, and changes the requirements for the accounting for, and reporting of, a change in accounting principle. This Statement applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. When a pronouncement includes specific transition provisions, those provisions should be followed.

SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. It will only affect our financial statements if we change any of our accounting principles. At this time, no such changes are contemplated or anticipated.

#### SFAS 153 Exchanges Of Nonmonetary Assets An Amendment Of APB Opinion No29

In December 2004, FASB Statement No. 153 was issued amending APB Opinion No. 29 to eliminate the exception allowing nonmonetary exchanges of similar productive assets to be measured based on the carrying value of the assets exchanged as opposed to being measured at their fair values. This exception was replaced with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The provisions

of this statement are effective for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of this statement did not have a material impact on our financial statements.

#### SFAS 151 Inventory Costs--An Amendment Of ARB No43, Chapter 4

Issued by the FASB in November 2004, this Statement amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ... under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges.... This Statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of so abnormal. In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities.

The provisions of this statement are effective for inventory costs incurred during fiscal periods beginning after June 15, 2005. The adoption of this statement did not have a material impact on our financial statements.

In December 2004, the FASB issued Statement Number 123 (FAS 123(R)), Share-Based Payments, which is effective for the reporting period beginning on January 1, 2006. The statement will require us to recognize compensation expense in an amount equal to the fair value of share-based payments such as stock options granted to employees. We have the option to either apply FAS 123(R) on a modified prospective method or to restate previously issued financial statements, and chose to utilize the modified prospective method. Under this method, we are required to record compensation expense (as previous awards continue to vest) for the unvested portion of previously granted awards that remain outstanding at the date of adoption. The impact of adopting this statement is 30,156 in 2006.

#### FIN 47 Accounting For Conditional Asset Retirement Obligations An Interpretation Of FASB Statement Nb43

FASB Interpretation No. 47, issued in March 2005, clarifies that the term conditional asset retirement obligation as used in FASB Statement No. 143, Accounting for Asset Retirement Obligations, refers to a legal condition to perform an asset retirement activity in which the timing and (or) method of settlement are conditional on a future event that may or may not be within the control of the entity. The obligation to perform the asset retirement activity is unconditional even though uncertainty exists about the timing and (or) method of settlement. Thus, the timing and (or) method of settlement may be conditional on a future event. Accordingly, an entity is required to recognize a liability for the fair value of a conditional asset retirement obligation if the fair value of the liability can be reasonably estimated.

This Interpretation is effective no later than the end of fiscal years ending after December 15, 2005 (our fiscal year ended December 31, 2005). Adoption of this Interpretation did not have any material impact on our financial statements.

FIN 46(R) Consolidation Of Variabldnterest Entities--An Interpretation Of ARB No. 51

In December 2003, FASB Interpretation No. 46(R) was issued. This Interpretation of Accounting Research Bulletin No. 51, Consolidated Financial Statements, which replaces FIN 46, Consolidation of Variable Interest Entities, addresses consolidation by business enterprises of variable interest entities, which have one or more of the following characteristics:

1. The equity investment at risk is not sufficient to permit the entity to finance its activities without additional subordinated financial support provided by any parties, including the equity holders.

2. The equity investors lack one or more of the following essential characteristics of a controlling financial interest:

a. The direct or indirect ability to make decisions about the entity s activities through voting rights or similar rights.

- b. The obligation to absorb the expected losses of the entity.
- c. The right to receive the expected residual returns of the entity.

3. The equity investors have voting rights that are not proportionate to their economic interests, and the activities of the entity involve or are conducted on behalf of an investor with a disproportionately small voting interest.

The adoption of FIN 46(R) had no effect on our financial statements.

#### **Results of Operations**

#### Results Of Operations For The Three And Six Months Ended June 30, 2006 Compared To The Three And Six Months Ended June 30, 2005

#### Revenue

For the three months ended June 30, 2006 our revenues increased 413% to approximately \$1,767,500 from approximately \$344,900 in 2005. This was the result of a 353% increase in testing volume and a 13% increase in average revenue per test. For the six months ended June 30, 2006 our revenues increased 441% to approximately \$3,111,300 from approximately \$575,100 in 2005. This was the result of an increase in testing volume of 397% and a 9% increase in revenue per test. This volume increase is the result of wide acceptance of our bundled testing product offering and our industry leading turnaround times resulting in new customers. This increase in revenue per test is a direct result of restructuring arrangements with lower revenue per test and pricing policies with new customers.

### Cost of Revenue

For the three months ended June 30, 2006 our cost of revenue increased 298% to approximately \$725,800 from approximately \$182,400 in 2005. This was the result of the 353% increase in testing volume and is explained primarily as follows:

Increase of approximately 279% in employee and contract labor related costs

Increase of approximately 282% in supply costs; and

Increase of approximately 312% in postage and delivery costs

For the six months ended June 30, 2006 our cost of revenue increased 275% to approximately \$1,302,600 from approximately \$347,000 in 2005. This was the result of the 397% increase in testing volume and is explained primarily as follows:

Increase of approximately 226% in employee and contract labor related costs

Increase of approximately 414% in supply costs; and

Increase of approximately 323% in postage and delivery costs

#### Gross Profit

As a result of the revenue and cost of revenue our gross profit percentage for the three months ended June 30, 2006 increased to 59% from 47% for the three months ended June 30, 2005. The gross profit percentage for the six months ended June 30, 2006 increased to approximately 58% from approximately 40% for the six months ended June 30, 2005.

#### Selling, General and Administrative Expenses

During the three months ended June 30, 2006, our selling, general and administrative expenses increased by approximately 175% to approximately \$802,100 from approximately \$291,800 in the three months ended June 30, 2005. For the six months ended June 30, 2006, our selling, general and administrative expenses increased by approximately 155% to approximately \$1,392,800 from approximately \$545,400 in the three months ended June 30, 2005. This increase was primarily as a result of higher personnel and personnel-related expenses associated with increased levels of volumes as described above and a 157% increase in headcount. Selling, general and administrative expenses include all of our overhead and technology expenses as well as the cost of our management and sales personnel.

### Interest Expense

Interest expense for the three months ended June 30, 2006 increased approximately 51% to approximately \$78,300 from approximately \$52,000 for the three months ended June 30, 2005. Interest expense for the six months ended June 30, 2006 increased approximately 87% to approximately \$148,200 from approximately \$79,200 for the six months ended June 30, 2005. Interest expense is mainly comprised of interest payable on advances under our Credit Facility from Aspen, which have increased as a result of our increased borrowing to fund operations.

### Net Income

As a result of the foregoing, our net income for the three months-ended June 30, 2006 increased approximately \$342,600 to approximately \$161,300 from a loss of approximately \$181,400 during the three months-ended June 30, 2005. For the six months-ended June 30, 2006 net increased approximately \$664,200 to approximately \$267,700 from a loss of approximately \$396,500 during the six months-ended June 30, 2005.

### Results Of Operations For The Year Ended December 31, 2005 Compared To The Year Ended December 31, 2004

During the fiscal year ended December 31, 2005, our revenues increased by \$1,327,000 (approximately 238%) to \$1,885,000 from \$558,000 during the fiscal year ended December 31, 2004, primarily as a result of attracting new customers to our services and increasing the volume of services sold to existing customers. During 2005, our cost of revenue increased approximately 106% to \$1,188,000 from \$577,000 in 2004, primarily as a result of additional costs associated with hiring more laboratory personnel to support our increased testing volumes as well as increased costs from opening new lines of business. This resulted in a gross margin of approximately \$697,000 in 2005 versus a gross margin (deficit) of approximately \$19,000 for 2004. In percentage terms, our gross margin deficit increased from negative 3% of revenue in 2004 to 37% of revenue in 2005. This increase in gross margin was largely a result of completing an additional 2,197 tests in 2005 and the economies of scales related to such higher volumes.

During 2005, our general and administrative expenses increased by \$786,000 (approximately 110%) to \$1,497,000 from approximately \$711,000 in 2004, primarily as a result of higher personnel related expenses associated with increased levels of staffing (an increase of 16 people from December 31, 2004) including the hiring of our senior management team. The increase for 2005 also included one-time expenses of \$50,000 for an impairment of asset charge related to a write down of a mass spectrometer, approximately \$47,000 for the recruiting fees associated with hiring our senior management team, and approximately \$26,000 for the implementation of our Laboratory Information System (LIS). General and administrative expenses include all of our overhead and technology expenses as well as the cost of our management and sales personnel.

Interest expense increased approximately 121% during 2005 to \$197,000 from \$89,000 in 2004. Interest expense is mainly comprised of interest payable on advances from our credit facility from Aspen Select Healthcare, which increased in 2005 to fund our operating losses and working capital needs. During 2005 approximately \$40,500 of such interest expense was non-cash as it resulted from the amortization of the Credit Facility discount, which resulted from the allocation of part of the proceeds received to the warrants issued in conjunction with the Aspen Credit Facility.

As a result of the foregoing, our net loss increased by approximately 22% or \$178,000 to \$997,000 in 2005 from \$819,000 in 2004.

During the year ended December 31, 2005, our average revenue per customer requisition increased by approximately 29% to \$632 from \$489 in 2004, primarily as a result of performing more tests per customer requisition in 2005 than we did in 2004. Our average revenue per test decreased by approximately 5% to \$461 from \$484 in 2004 primarily as a result of an increase in the percentage of lower priced tests into our overall testing mix. Revenues per test are a function of both the nature of the test and the payer (Medicare, Medicaid, third party insurer, institutional client etc.). Our policy is to record as revenue the amounts that we expect to collect based on published or contracted amounts and/or prior experience with the payer. We have established a reserve for uncollectible amounts based on estimates of what we will collect from a) co-payments directly from patients, and b) those procedures that are not covered by insurance or other third party payers. On December 31, 2005, our Allowance for Doubtful Accounts was approximately \$37,800.

### Liquidity And Capital Resources

### 2005

During the fiscal year ended December 31, 2005, our operating activities used approximately \$902,000 in cash compared to \$658,000 used in 2004. This amount primarily represented cash used to pay the expenses associated with our operations as well as fund our working capital needs. We also spent approximately \$118,000 and \$86,000 on new equipment in 2005 and 2004, respectively. We were able to finance operations and equipment purchases primarily through net advances on our Aspen Credit Facility and through sales of our common stock. This resulted in net cash from financing activities of approximately \$918,000 and \$832,000 in 2005 and 2004, respectively. At December 31, 2005 we had cash or cash equivalents of approximately \$11,000.

On January 3, 2005, we issued 27,288 shares of common stock under the Company s 2003 Equity Incentive Plan to two of our employees in satisfaction of \$6,822 of accrued, but unpaid vacation.

During the period from January 1, 2005 to May 31, 2005, we sold 522,382 shares of our common stock in a series of private placements at \$0.30 per share and \$0.35 per share to unaffiliated third party investors. These transactions generated net proceeds to us of approximately \$171,000.

On March 23, 2005, we entered into an agreement with Aspen Select Healthcare to refinance our existing indebtedness of \$740,000 and provide for additional liquidity of up to \$760,000 to the Company. Under the terms of the agreement, Aspen Select Healthcare, made available up to \$1.5 million of debt financing in the form of a revolving credit facility (the <u>Aspen Credit Facility</u>) with an initial maturity of March 31, 2007. Aspen Select Healthcare is managed by its General Partner, Medical Venture Partners, LLC, which is controlled by a Steven C. Jones, a member of our Board of Directors. As part of this transaction, we issued a five year warrant to Aspen to purchase up to 2,500,000 shares of common stock at an initial exercise price of \$0.50 per share, all of which are currently vested. Steven C. Jones, our Acting Principal Financial Officer and a Director, is the general partner of Aspen Select Healthcare.

On June 6, 2005, we entered into a Standby Equity Distribution Agreement with Cornell Capital Partners. Pursuant to the Standby Equity Distribution Agreement, we may, at its discretion, periodically sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$5.0 million. For each share of common stock purchased under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay us 98% of the lowest volume weighted average price of our common stock as quoted by Bloomberg, LP on the OTCBB or other principal market on which our common stock is traded for the five days immediately following the notice date. The total number of shares issued to Cornell Capital Partners under each advance request will be equal to the total dollar amount of the advance request divided by the purchase price determined during the five day pricing period. Cornell Capital Partners will also retain 5% of each advance under the Standby Equity Distribution Agreement as a transaction fee. Cornell Capital Partners obligation to purchase shares of the Company s common stock under the Standby Equity Distribution Agreement is subject to certain conditions, including us maintaining an effective registration statement for shares of common stock sold under the Standby Equity Distribution Agreement are at our discretion and we are not obligated to issue and sell any securities to Cornell Capital Partners, unless and until it decides to do so. Upon execution of the Standby Equity Distribution Agreement, Cornell Capital Partners received 381,888 shares of our common stock as a commitment fee under the Standby Equity Distribution Agreement. We also issued 27,278 shares of our common stock to Spartan Securities under a placement agent agreement relating to the Standby Equity Distribution Agreement.

On July 1, 2005, we issued 14,947 shares of our common stock under the Company s 2003 Equity Incentive Plan to two employees of the Company in satisfaction of \$4,933 of accrued, but unpaid vacation.

On August 29, 2005, we requested a \$25,000 advance on our Standby Equity Distribution Agreement with Cornell Capital Partners. The advance was completed on September 8, 2005 and resulted in the sale of 63,776 shares of common stock. Our net proceeds were \$23,250 after deducting \$1,250 in fees to Cornell Capital Partners and a \$500 escrow agent fee to Yorkville Advisors.

On December 10, 2005, we requested a \$50,000 advance on our Standby Equity Distribution Agreement with Cornell Capital Partners. The advance was completed on December 18, 2005 and resulted in the sale of 241,779 shares of common stock. Our net proceeds were \$47,000 after deducting \$2,500 in fees to Cornell Capital Partners and a \$500 escrow agent fee to Yorkville Advisors.

### 2006

On January 18, 2006, we entered into the Aspen Agreement with Aspen Select Healthcare, which provided, among other things, that (a) Aspen Select Healthcare waived certain pre-emptive rights in connection with the sale of \$400,000 of common stock at a purchase price of \$0.20 per share and the granting of 900,000 warrants with an exercise price of \$0.26 per share to a SKL in exchange for five year warrants to purchase 150,000 shares at an exercise price of \$0.26 per share; (b) Aspen Select Healthcare would have the right, up to April 30, 2006, to purchase up to \$200,000 of restricted shares of our common stock at a purchase price per share of \$0.20 per share (1.0 million shares) and receive a five year warrant to purchase up to 450,000 shares of the our common stock at an exercise price of \$0.26 per share in connection with such purchase (the <u>Equity Purchase Rights</u>); (c) in the event that Aspen Select Healthcare did not exercise its Equity Purchase Rights in total, we had the right to sell the difference to SKL at terms no more favorable than Aspen Select Healthcare s Equity Purchase Rights; (d) Aspen Select Healthcare and we would amend the certain Loan Agreement between the parties to extend the maturity date until September 30, 2007 and enter into the Aspen Credit Facility Amendment; (e) Aspen Select Healthcare would have the right, until April 30, 2006, to provide up to \$200,000 of additional secured indebtedness to us under the Aspen Credit Facility Amendment and receive a five year warrant agreement, dated March 23, 2005 to provide that all 2,500,000 warrant shares were vested and the exercise price per share of such warrants was reset to \$0.31 per share; and (g) we agreed to amend the certain Registration Rights Agreement between the parties to incorporate the Existing Warrants and any new shares or warrants issued to Aspen Select Healthcare in connection with the Equity Purchase Rights or the New Debt Rights.

During the period from January 18 to January 21, 2006, we entered into agreements with four other shareholders who are parties to that certain Shareholders Agreement, dated March 23, 2005, to exchange five year warrants to purchase 150,000 shares of stock in the aggregate at an exercise price of \$0.26 per share for such shareholders waiver of their pre-emptive rights under the Shareholders Agreement.

On January 21, 2006 we entered into a subscription agreement (the <u>Subscription</u>) with SKL, whereby SKL purchased 2.0 million shares (the <u>Subscription Shares</u>) of our common stock at a purchase price of \$0.20 per share for \$400,000. Under the terms of the Subscription, the Subscription Shares are restricted for a period of 24 months and then carry piggyback registration rights to the extent that exemptions under Rule 144 are not available to SKL. In connection with the Subscription, we also issued a five year warrant to purchase 900,000 shares of the Company s common stock at an exercise price of \$0.26 per share. SKL has no previous affiliation with us.

On March 14, 2006, Aspen exercised its Equity Purchase Rights and we issued to Aspen 1,000,000 restricted shares of common stock at a purchase price of \$0.20 per share for \$200,000. In connection with this transaction, we also issued a five year warrant to purchase 450,000 shares of common stock at an exercise price of \$0.26 per share.

Also on March 30, 2006, Aspen Select Healthcare 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, dated January 18, 2006. As part of the Credit Facility Amendment, we have the right, but not the obligation, to borrow an additional \$200,000 from Aspen Select Healthcare. In connection with Aspen making such debt capital available to us, we issued a five year warrant to purchase 450,000 shares of common stock at an exercise price of \$0.26 per share.

During the six months ended June 30, 2006, our operating activities used approximately \$255,700 in cash. This amount primarily resulted from cash tied-up in receivables as a result of increased revenues and to a lesser extent cash used to pay the expenses associated with our operations as well as fund our working capital needs. We also spent approximately \$238,700 on new equipment. We were able to finance operations and equipment purchases primarily through the sale of equity securities which provided approximately \$613,600 and to a lessor extent with borrowings on the Aspen credit facility during the six months ended June 30, 2006. At June 30, 2006, we had cash and cash equivalents of approximately \$274,400.

At the present time, we anticipate that based on our current business plan, operations and the financing package we announced in January 2006 that we have sufficient cash to become profitable and further manage our business for at least the next 12 months. This estimate of our cash needs does not include any additional funding which may be required for growth in our business beyond that which is planned, strategic transactions or acquisitions. To the extent we need additional capital beyond our current cash resources, the amended Aspen Credit Facility allows us to draw an additional \$100,000 and we still have \$4,872,000 of availability under our Standby Equity Distribution Agreement with Cornell Capital Partners. In the event that we grow faster than we currently anticipate or we engage in strategic transactions or acquisitions and our cash on hand and availability under our Credit Facility and Standby Equity Distribution Agreements is not sufficient to meet our financing

needs, we may need to raise additional capital from other resources. In such event, we may not be able to obtain such funding on attractive terms or at all and we may be required to curtail its operations.

### **Capital Expenditures**

We currently forecast capital expenditures for the coming year in order to execute on our business plan. The amount and timing of such capital expenditures will be determined by the volume of business, but we currently anticipate that we will need to purchase approximately \$300,000 to \$500,000 of additional capital equipment during the next twelve months. We plan to fund these expenditures through borrowings under our Aspen Credit Facility and through traditional lease financing from equipment lessors. If we are unable to obtain such funding, we will be required to curtail our equipment purchases, which may have an impact on our ability to generate revenues.

### **DESCRIPTION OF BUSINESS**

NeoGenomics was founded by Dr. Michael T. Dent in June of 2001. Dr. Dent is the founder and primary physician of an OB/GYN practice in Southwest Florida. In November of 2001, we became a publicly-traded company by reverse merging into American Communications Enterprises, Inc, which was a shell corporation at the time. During 2002, we assembled our initial staff and began clinical testing operations. In 2003, we obtained new venture capital sponsorship through Medical Venture Partners, LLC, a related entity, and moved to a much larger, state-of-the art laboratory facility in Fort Myers, Florida. In January 2005, we hired our President, Robert Gasparini. Mr. Gasparini has considerable experience in building genetic and molecular laboratory companies.

We operate a cancer genetics laboratory that is targeting the rapidly growing genetic and molecular testing segment of the medical laboratory market. We operate in two laboratory locations: the first location is in Fort Myers, Florida and the second is in Nashville, Tennessee. We currently offer the following types of testing services to oncologists, pathologists, urologists, hospitals, and other laboratories that do not perform genetic testing throughout the United States: a) cytogenetics testing, which analyzes human chromosomes, b) Fluorescence In-Situ Hybridization (FISH) testing which analyzes abnormalities at the gene level, c) flow cytometry testing services, which analyzes clusters of differentiation on cell surfaces and d) molecular testing which involves testing DNA and other molecular structures to screen for and diagnose single gene disorders. All of these testing services are widely used in the diagnosis of various types of cancer. Our common stock is listed on the NASDAQ Over-the-Counter Bulletin Board (the OTCBB ) under the symbol NGNM.OB

We believe the genetic and molecular testing segment of the medical laboratory industry is the most rapidly growing segment of the market. Approximately five years ago, the World Health Organization reclassified cancers as being 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. We believe 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/molecular testing.

Clinical labs typically are engaged in high volume, high automation tests on 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. AP testing involves evaluation of tissue, as in surgical pathology, or cells as in cytopathology. The most widely known AP tests are Pap smears, skin biopsies, and tissue biopsies. AP tests are typically more labor and technology intensive than clinical lab tests and thus typically have higher average revenue per test than clinical lab tests.

Genetic/molecular testing typically involves analyzing chromosomes, genes or base pairs of DNA for disorders. Whereas anatomic pathology testing is focused from the cell surface outward, genetic and molecular testing is focused from the cell surface inward. Both genetic and molecular testing have become important and highly-accurate diagnostic tools over the last five years. New tests are being developed rapidly, thus this market segment is expanding rapidly. Genetic/molecular testing requires very specialized equipment and credentialed individuals (typically MD or PhD level) to certify the results and typically yields the highest average revenue per test of the three market segments. Up until about five years ago, the genetic/molecular segment was considered to be part of the AP segment, but given its rapid growth, many industry veterans now break genetic/molecular testing out into its own segment.

The following chart shows the differences between the genetic/molecular segment and other segments of the medical laboratory industry.

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

<u>Attributes</u>	<u>Clinical</u>	Anatomic Pathology	Genetic/Molecular			
Testing Performed On Testing Volume Physician Involvement	Blood, Urine High Low	Tissue/Cells Low High - Pathologist	- Chromosomes/Genes/DNA Low Low - Medium			
Malpractice Ins. Required	Low	High	Low			
Other Professionals Req.	None	None	Cyto/Molecular geneticist			
Level of Automation Diagnostic in Nature	High Usually Not	Low-Moderate Yes	Moderate Yes			
Types of Diseases Tested	Many Possible	Typically Cancer \$25 - \$500/Test	Rapidly Growing			
Typical Revenue Per Test	\$5 - \$35/Test	\$10.0 - \$12.0 Billion	\$200 - \$1,000/Test			
Estimated Size of Market Estimated Growth Rate	\$25 - \$30 Billion 4.0 -5.0%	6.0 7.0% Annually	\$3.0 - \$4.0 Billion (2) 25.0+% Annually			
Established Competitors	Quest Diagnostics	Quest Diagnostics	Genzyme Genetics			
	LabCorp	LabCorp	Quest Diagnostics			
	Bio Reference Labs	Genzyme Genetics	LabCorp			
	DSI Laboratories	Ameripath	Major Universities			
	Hospital Labs	Local Pathologists				
	Regional Labs					

<sup>(1)</sup> Derived from industry analyst reports and Company estimates.

<sup>(2)</sup> Includes flow cytometry testing, which historically has been classified under Anatomic Pathology testing.

Our primary focus is on the oncology market. We target oncologists that perform bone marrow sampling and treat patients with leukemia, lymphoma and other forms of cancer as well as urologists that treat patients with bladder cancer. Historically, our clients were predominantly

located in Florida. Beginning in January 2005, based on the experience of our new President, we began targeting large institutional clients throughout the United States. This was successful and we landed several clients outside of the State of Florida. During the third quarter of 2005 we began testing for cervical, breast and bladder cancer. Our bladder cancer program focused around the UroVysion test has grown significantly since it started in the third quarter of 2005. As we grow, 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.

We compete in the marketplace based on the quality and accuracy of our test results, our turn-around times and our ability to provide after-test support to those physicians requesting consultation. We believe our average 3 - 5 days turn-around time on oncology-related cytogenetics tests is helping to increase the usage patterns of cytogenetics tests by our referring oncologists and hematopathologists. Based on empirical data, we believe that cytogenetics labs typically have 7 - 14 days 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.

We have an opportunity to add additional types of tests to our product offering. We believe that by doing so we may 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 bundle our testing services more appropriately to the needs of the market. Until December 2004, we only performed one type of test, cytogenetics, in-house, which resulted in only one test being performed per customer requisition for most of fiscal year ended 2004 and average revenue per requisition of approximately \$490 in fiscal year ended 2004. In December 2004, we added FISH testing to our product offering, and in February 2005, we began offering flow cytometry testing services. With the addition of these two new testing platforms, our average revenue/requisition increased by 35.6% in fiscal year ended 2005 to approximately \$632/requisition. This trend continued into the first half of fiscal year

ended 2006 with average revenue/requisition increasing to \$704/requisition. We believe that we can continue to increase our average revenue per customer requisition with the addition of additional testing platforms and more focused marketing.

	For the Six Months Ended	For the Six Months Ended		For the Three Months Ended	For the Three Months Ended		
	June 30, 2006	June 30, 2005	% Inc (Dec)	June 30, 2006	June 30, 2005	% Inc (Dec)	
Requisitions Received (Cases)	4,420	970	355.7%	2,472	593	316.9%	
Number of Tests Performed	6,139	1,235	397.1%	3,475	768	352.5%	
Avg. # of Tests/Requisition	1.389	1.273	9.4%	1.406	1.295	8.5%	
Total Testing Revenue	\$3,111,292	\$ 575,080	441.1%	\$1,767,492	\$344,888	412.5%	
Avg. Revenue/Requisition	\$ 703.91	\$ 592.86	18.7%	\$ 715.00	\$581.60	22.9%	
Avg. Revenue/Test	\$ 506.81	\$ 465.65	8.8%	\$ 508.63	\$ 449.07	13.3%	

We believe our strategy of bundling complementary types of tests together to better service the needs of our clients will continue to drive 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 most hematological cancers may yield total revenue ranging from approximately \$1,700 to \$2,800 per case and is generally comprised of one or more of the following tests: cytogenetics, FISH, flow cytometry, and morphology testing. Whereas in the fiscal year ended 2004, we only addressed approximately \$500 of this potential revenue per case, we now address approximately \$1,200 to \$1,900 of this potential revenue per case.

	Avg. Rev./Test
Cytogenetics	\$400-\$600
Fluorescence In Situ Hybridization (FISH)	\$400-\$600
Flow Cytometry	
- Technical component	\$400-\$700
- Professional component	\$100-\$200
Morphology	\$400-\$700
Total	\$1,700-\$2,800

## **Business Of NeoGenomics**

#### Services

We currently offer four types of testing services: cytogenetics testing, flow cytometry testing, 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 cytogenetic testing include bone marrow testing 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. Currently, we offer the following types of cytogenetics tests, each of which is performed on different types of biological samples: bone marrow tests to assist in the diagnosis of leukemia and lymphoma, peripheral blood tests and various other specialty tests.

*Analogy*. Cytogenetics provides the equivalent of a detailed picture of a neighborhood with 46 houses from 1000 feet up. Each house is analogous to a human chromosome.

We believe that historically cytogenetics testing by large national laboratories and other competitors has taken anywhere from 10 to 14 days on average to obtain a complete diagnostic report. We believe that as a result of this, many practitioners have refrained from ordering such tests because the results traditionally were not returned within an acceptable

diagnostic window. We have designed our business operations in order to complete our cytogenetics tests for most types of biological samples and produce a complete diagnostic report and make it available electronically within 3 to 5 days. We believe these turnaround times are among the best in the industry. Furthermore, we believe that as we continue to demonstrate these turnaround times to customers and the awareness of the benefits of cytogenetics testing continues to increase, more and more practitioners will incorporate cytogenetics testing into their diagnostic regimes and thus drive incremental growth in our business.

**Flow Cytometry Testing**. Flow cytometry testing analyzes clusters of differentiation on cell surfaces. Most cancers have by-products which create clusters of differentiation on the cell surfaces that can then be traced back to a specific type of cancer. Flow cytometry is a method of separating blood into its different cell types. This methodology is used to determine what cell types within the blood of leukemia and cancer patients is abnormal. Flow cytometry is important in developing an accurate diagnosis and defining what treatment options are best for specific patients. 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 findings from one test to complement the findings of the other test, which leads to an even more accurate diagnosis.

Analogy. Flow cytometry provides a snapshot of the shrubbery, walkways and trim around a single house from 500 feet up. The trim around the house is analogous to the cell surface markers.

**FISH Testing**. As an adjunct to traditional chromosome analysis, we offer FISH testing to expand the capabilities of routine chromosome analysis in cancer. FISH testing permits preliminary identification of the most frequently occurring numerical chromosomal abnormalities in a relatively rapid manner by looking at specific genes that are implicated in cancer. There are approximately 25,000 genes spread across the chromosomes in the nucleus of each cell. FISH testing allows us to look more closely at the functioning of approximately 2-10 of the specific genes associated with various types of cancers. FISH testing is typically performed on 100-200 cells. FISH was originally used as an additional staining method (the colorization of genes to highlight markers and abnormalities) for metaphase analysis (cells in a divided state after they are cultured), but is now being applied to interphase analysis (non, single 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.

*Analogy*. FISH provides a close-up view of the doors and windows from one house on one street in that neighborhood. The doors and windows are analogous to a gene located on a chromosome. FISH allows us to see if a door is open (i.e., the gene is up-regulated) and it should be closed (i.e., the gene should be down-regulated).

*Molecular Testing*. Molecular testing involves testing DNA and other molecular structures to screen for and diagnose single gene disorders such as cystic fibrosis and Tay-Sachs disease as well as hematological cancers. There are approximately 1.0 2.0 million base pairs of DNA in each of the 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 only to research laboratories and are only offered on a limited basis to family members of someone who has been diagnosed with a genetic condition. About 50 molecular tests are more widely available for clinical use. We currently provide these tests on an outsourced basis. We anticipate in the near future performing some of these tests within our facility as the number of requests we receive for these types of tests continues to increase and we expand our clinical staff. Molecular testing is a growing market with many new diagnostic tests being developed every year. We are committed to providing the latest and most accurate testing to its clients, where demand warrants it.

*Analogy*. Molecular testing provides the equivalent of a close-up view of the serial number on the lock of the front door of one house in the neighborhood as viewed under a magnifying glass. The serial number is analogous to a DNA sequence.

### **Target Markets And Customers**

We initially targeted oncologists, pathologists and hospitals in southern and central Florida that perform bone marrow sampling. During 2005, we took steps to establish a national presence and also began marketing our services to urologists and other laboratories that did not offer our types of testing services. These strategies have allowed us to gain customers from around the country. We intend to continue to increase our testing volumes from customers around the U.S. in addition to continuing to grow our volumes from within the State of Florida. We market our services primarily through our direct salesforce. We plan to continue to increase the numbers of salespeople and the geographies in which we cover. We

estimate our current and total potential market for Florida, the Southeastern United States and the entire United States as follows:

					Tot	al
	Flori	da	Sout	theast U.S.	U.S	•
Total Oncology Testing Market						
Population over 55 years old (millions) (1)(2)	4.6		11.5		60.6	5
Total Cancer Testing Market (\$, MMs) (3)	\$	583.7	\$	1,588.2	\$	8,208.2
Approx % of Market NGNM Currently Addresses (4)	45%		45%		45%	6
NGNM Current Addressable Market (\$, MMs)	\$	262.7	\$	714.7	\$	3,693.7

(1) US Census Bureau estimates for 2002.

(2) 76% of all new cancers are reported in people age 55 or older. Source: American Cancer Society.

(3) Company estimate.

(4) NeoGenomics intends to increase the % of the overall market it can address by offering more types of tests.

#### **Distribution Methods**

We currently perform all of its genetic testing at our clinical laboratory facility located in Fort Myers, Florida, and then produce a report for the requesting practitioner. We currently out-source all of the molecular testing to third parties, but expects to begin bringing some of this testing in-house during the next few years.

### **Recent Developments**

On April 18, 2006, our Operating Subsidiary entered into a certain Merger Agreement (the <u>Merger Agreement</u>), by and among Center for Cytogenetics, a Tennessee corporation (the <u>CFC</u>), and certain individuals who were the shareholders of CFC, pursuant to which Operating Subsidiary acquired CFC. CFC operates in Nashville, Tennessee. Through this acquisition, we consolidated our position in the private genetics industry, added to our acquiring capacity and faster growth potential, and we secured a second site to facilitate us mitigate the risk of weather-related phenomena common to Southwest Florida.

#### Competition

We are engaged in segments of the medical testing laboratory industry that are 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, many of which offer both types of testing. Of this total group, 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 faster turnaround times and high-quality test reports and post test consultation services. In addition, we have a fully integrated and interactive virtual Lab Information System ( $\underline{LIS}$ ) that enables us to report real time results to customers in a secure environment.

### Suppliers

We order our laboratory and research supplies from large national laboratory supply companies such as Fisher Scientific, Inc., Invitrogen and Beckman Coulter and do not believe any disruption from any one of these supplier would

have a material effect on its business. We order the majority of our FISH probes from Abbott/Vysis 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/Vysis patent protection limits other vendors from supplying these probes.

### **Dependence On Major Customers**

We currently market our services to other laboratories, major hospitals and doctor s practices nationwide. During 2005, we performed 4,082 individual tests. Four customers represented approximately 65% of our volume with each party representing greater than 10% of our volume. In the event that we lost one of these customers we would potentially lose a significant percentage of our revenues. In 2004, one customer made up approximately 16% of our total volume.

### Trademarks

Our NeoGenomics logo has been trademarked with the United States Patent and Trademark Office.

### Number Of Employees

As of July 26, 2006, we had 43 employees, all of which were full-time employees. In addition, our principal financial officer and our pathologist serve as our consultants on a part-time basis. None of our employees are represented by unions.

### **Government Regulation**

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

### Laboratory Operations

*Cytogenetics and, Molecular Testing.* Our laboratory is located in the state of Florida. Our laboratory has obtained certification under the federal Medicare program, the Clinical Laboratories Improvement Act of 1967, as amended by the CLIA 88 and the respective clinical laboratory licensure laws of the state of Florida, where such licensure is required. The Clinical Laboratories Improvement Act provides for the regulation of clinical laboratories by the U.S. Department of Health and Human Services. Regulations promulgated under the federal Medicare guidelines, the CLIA and the clinical laboratory licensure laws of the state of Florida affect our genetics laboratory.

The federal and state certification and licensure programs establish standards for the operation of medical 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 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 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 laboratory. We have reviewed our operations as they relate to CLIA `88, including, among other things, the CLIA `88 rule s requirements regarding laboratory administration, participation in proficiency testing, patient test management, quality control, quality assurance and personnel for the types of testing we undertake, and believe we are in compliance with these requirements. Our laboratory 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 labs 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 no additional formal recommendations have 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 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 Medicare and Medicaid, 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 (<u>OIG</u>) 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 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. Some states also have laws similar to the Stark law.

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 could become subject to scrutiny thereunder.

In February 1997, the OIG released a model compliance plan (later revised in August 1998) 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 have adopted aspects of the model plan that we deem appropriate to the conduct of our business. This adoption may have an impact on the utilization of our services.

### Confidentiality

The HIPAA contains provisions that affect the handling of claims and other patient information that are, or have been, transmitted electronically. 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. Rules implementing various aspects of HIPAA are continuing to be developed. National standards for electronic healthcare transactions were published by HHS on August 17, 2000. The regulations establish standard data content and formats for submitting electronic claims and other administrative health transactions. All healthcare providers will be able to use the electronic format to bill for their services and all health plans and providers will be required to accept standard electronic claims, referrals, authorizations, and other transactions. Under the regulation, all electronic claims transactions must follow a single standardized format. All health plans, providers and clearinghouses had to comply with the standards by October 2003. Failure to comply with this rule could result in significant civil and/or criminal penalties. Despite the initial costs, the use of uniform standards for all electronic transactions is leading to greater efficiency in processing claims and in handling health care information.

On December 28, 2000, HHS published rules governing the use of individually identifiable health information. The regulation protects certain health information (<u>PHI</u>) transmitted or maintained in any form or medium, and requires specific patient consent for the use of PHI for purposes of treatment, payment or health care operations. For most other uses or disclosures of PHI, the rule requires that covered entities (healthcare plans, providers and clearinghouses) obtain a valid patient authorization. For purposes of the criminal and civil penalties imposed under Title XI of the Social Security Act, the current date for compliance is 2003. Complying with the Standards, Security and Privacy rules under HIPAA requires significant effort and expense for virtually all entities that conduct healthcare transactions electronically and handle patient health information. We believe we are in compliance with applicable HIPAA regulations regarding the confidentiality of protected health information.

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 applicable state law regarding the confidentiality of health information.

## Food And Drug Administration

The FDA does not currently regulate laboratory testing services, which is our principal business. However, we plan to perform some testing services using test kits purchased from manufacturers for which FDA pre-market clearance or approval for commercial distribution in the United States has not been obtained by the manufacturers (<u>investigational test kits</u>). 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. In January 1998, the FDA issued a revised draft Compliance Policy Guide (<u>CPG</u>) that sets forth FDA is intent to undertake a heightened enforcement effort with respect to investigational test kits improperly commercialized prior to receipt of FDA pre-market clearance or approval. That draft CPG is not presently in effect but, if implemented as written, would place greater restrictions on the distribution of investigational test kits. If we were to be substantially limited in or prevented from purchasing investigational test kits by reason of the FDA finalizing the new draft CPG, 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 may perform some testing services using reagents, known as analyte specific reagents (<u>ASR</u>s), 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, list it s ASRs (and any other devices), conform to good manufacturing practice requirements, and comply with medical device reporting of adverse events.

A smaller group of ASRs, primarily those used in blood banking and/or screening for fatal contagious diseases (e.g., HIV/AIDS), are treated as higher risk devices requiring pre-market clearance or approval from the FDA before commercial distribution is permitted. The imposition of this regulatory framework on ASR sellers may reduce the availability or raise the price of ASRs purchased by laboratories like ours. In addition, when we perform a test developed in-house, using reagents rather than a test kit cleared or approved by the FDA, we are required to disclose those facts in the test report. However, by clearly declining to impose any requirement for FDA pre-market approval or clearance for most ASRs, the rule removes one barrier to reimbursement for tests performed using these ASRs. We have no plans to perform testing in these high risk areas.

### Other

Our operations currently are, or may be in the future, subject to various federal, state and local laws, regulations and recommendations relating to data protection, safe working conditions, laboratory and manufacturing practices and the purchase, storage, movement, use and disposal of hazardous or potentially hazardous substances used in connection with our

research work and manufacturing operations, including radioactive compounds and infectious disease agents. Although we believe that our safety procedures comply with the standards prescribed by federal, state and local regulations, the risk of contamination, injury or other accidental harm cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result and any liabilities could exceed our resources. Failure to comply with such laws could subject an entity covered by these laws to fines, criminal penalties and/or other enforcement actions.

Pursuant to the Occupational Safety and Health Act, laboratories have a general duty to provide a work place to their employees that is safe from hazard. Over the past few years, the Occupational Safety and Health Administration (OSHA) has issued rules relevant to certain hazards that are found in the laboratory. In addition, OSHA has promulgated regulations containing requirements healthcare providers must follow to protect workers from blood borne pathogens. Failure to comply with these regulations, other applicable OSHA rules or with the general duty to provide a safe work place could subject employers, including a laboratory employer such as the Company, to substantial fines and penalties.

### Properties

Our Florida laboratory and executive offices are located in a 10,000 square foot facility at 12701 Commonwealth Drive, Suite 9, Fort Myers, FL 33913. We lease this space from an unaffiliated third party under a three year lease agreement at a cost of approximately \$11,400/month. We also lease two laboratory facilities in Nashville, TN. The first is a 760 square foot facility with a lease cost of \$1,170/month. The second is a 5,300 square foot facility with a lease cost of \$5,160/month. We believe that the above properties are suitable for our current and projected needs.

## Legal Proceedings

We are currently a defendant in one lawsuit from a former employee relating to compensation related claims. We do not believe the resolution of this lawsuit will be material to our operations or financial results and intends to vigorously pursue our defense of the matter.

In June 2006, we received a legal letter from Ciphergen Biosystems related to a research and license agreement stating that we were in breach of the contract and demanding financial restitution. We do not believe that this matter is material to our financial results and plans to vigorously pursue its defense of the matter.

## MANAGEMENT

### **Officers And Directors**

The following table sets forth the names, ages, and titles of each of our directors and executive officers and employees expected to make a significant contribution to the Company.

Name	Age	Position
Board of Directors:		
Robert P. Gasparini	51	President and Chief Science Officer, Board Member
Steven C. Jones	43	Acting Principal Financial Officer, Board Member
Michael T. Dent	41	Chairman of the Board
Thomas D. Conrad	75	Board Member
George G. O Leary	43	Board Member
Peter M. Peterson	49	Board Member
Other Executives:		
Jimmy W. Bryan	36	Director of Sales
Jerome J. Dvonch	37	Director of Finance
Thomas J. Schofield	27	Director of Operations

### **Family Relationships**

There are no family relationships between or among the members of the Board of Directors or other executives. With the exception of Mr. Peterson, the directors and other executives of the Company are not directors or executive officers of any company that files reports with the SEC. Mr. Peterson also serves as Chairman of the Board of Innovative Software Technologies, Inc. (OTCBB: INIV.OB).

### Legal Proceedings

None of the members of the Board of Directors or other executives has been involved in any bankruptcy proceedings, criminal proceedings, any proceeding involving any possibility of enjoining or suspending members of our Board of Directors or other executives from engaging in any business, securities or banking activities, and have not been found to have violated, nor been accused of having violated, any federal or state securities or commodities laws.

#### Elections

Members of our Board of Directors are elected at the annual meeting of stockholders and hold office until their successors are elected. Our officers are appointed by the Board of Directors and serve at the pleasure of the Board and are subject to employment agreements, if any, approved and ratified by the Board.

### Robert P. Gasparini, M.S. President and Chief Science Officer, Board Member

Mr. Gasparini is the President and Chief Science Officer of NeoGenomics. Prior to assuming the role of President and Chief Science Officer, Mr. Gasparini was a consultant to the Company since May 2004. Prior to NeoGenomics, Mr. Gasparini was the Director of the Genetics Division for US Pathology Labs, Inc. (<u>US Labs</u>) from January 2001 to December 2004. During this period, Mr. Gasparini started the Genetics Division for US Labs and grew annual revenues of this division to \$30 million over a 30 month period. Prior to US Labs, Mr. Gasparini was the Molecular Marketing Manager for Ventana Medical Systems from 1999 to 2001. Prior to Ventana, Mr. Gasparini was the Assistant Director of the Cytogenetics Laboratory for the Prenatal Diagnostic Center from 1993 to 1998 an affiliate of Mass General Hospital and part of Harvard University. While at the Prenatal Diagnostic Center, Mr. Gasparini was also an Adjunct Professor at Harvard University. Mr. Gasparini is a licensed Clinical Laboratory Director and an accomplished author in the field of Cytogenetics. He received his BS degree from The University of Connecticut in Biological Sciences and his Master of Health Science degree from Quinnipiac University in Laboratory Administration.

### Steven C. Jones Acting Principal Financial Officer, Board Member

Mr. Jones has served as a director since October 2003. He is a Managing Director in Medical Venture Partners, LLC, a venture capital firm established in 2003 for the purpose of making investments in the healthcare industry. Mr. Jones is also the co-founder and Chairman of the Aspen Capital Group and has been President and Managing Director of Aspen Capital Advisors since January 2001. Prior to that Mr. Jones was a chief financial officer at various public and private companies and was a Vice President in the Investment Banking Group at Merrill Lynch & Co. Mr. Jones received his B.S. degree in Computer Engineering from the University of Michigan in 1985 and his MBA from the Wharton School of the University of Pennsylvania in 1991. He is also Chairman of the Board of Quantum Health Systems, LLC and T3 Communications, LLC.

### Michael T. Dent M.D. Chairman of the Board

Dr. Dent is our founder and Chairman of the Board. Dr. Dent was our President and Chief Executive Officer from June 2001, when he founded NeoGenomics, to April 2004. From April 2004 until April 2005, Dr. Dent served as our President and Chief Medical Officer. Dr. Dent founded the Naples Women s Center in 1996 and continues his practice to this day. He received his training in Obstetrics and Gynecology at the University of Texas in Galveston. He received his M.D. degree from the University of South Carolina in Charleston, S.C. in 1992 and a B.S. degree from Davidson College in Davidson, N.C. in 1986. He is a member of the American Association of Cancer Researchers and a Diplomat and fellow of the American College of Obstetricians and Gynecologists. He sits on the Board of the Florida Life science Biotech Initiative.

### Thomas D. Conrad, PhD. Board Member

Dr. Conrad is a Director of NeoGenomics. During his 50-year professional career, he has been involved in starting and operating numerous businesses. He is currently and for the last five years has been the President of Financial Management Corporation, which acts as the General Partner for Competitive Capital Partners, LP, a Naples, Florida-based hedge fund. Prior to his involvement in the fund management business, Dr. Conrad was involved with, among others The Military Benefit Association and The Government Employees Association, both large life insurance companies. Dr. Conrad has taught at five universities, been a cattleman, an Army pilot and a restaurateur. Before coming to Florida he was a member of the Reagan Administration as an Assistant Secretary of the United States Air Force. Dr. Conrad has a BS and an MBA from the University of Maryland and received his PhD. in Business from the American University.

#### George G. O Leary Board Member

Mr. O Leary is a Director of NeoGenomics and is currently the President of US Medical Consultants, LLC. Prior to assuming his duties with US Medical, he was a consultant to the company and acting Chief Operating Officer. Prior to NeoGenomics, Mr. O Leary was the President and CFO of Jet Partners, LLC from 2002 to 2004. During that time he grew annual revenues from \$12 million to \$17.5 million. Prior to Jet Partners, Mr. O Leary was CEO and President of Communication Resources Incorporated (CRI) from 1996 to 2000. During that time he grew annual revenues from \$5 million to \$40 million. Prior to CRI, Mr. O Leary held various positions including VP of Operations for Cablevision Industries from 1987 to 1996. Mr. O Leary was a CPA with Peat Marwick Mitchell from 1984 to 1987. He received his BBA in Accounting from Siena College in Albany, New York.

#### Peter M. Peterson Board Member

Mr. Peterson is a Director of NeoGenomics and is the founder of Aspen Capital Partners, LLC which specializes in capital formation, mergers & acquisitions, divestitures, and new business start-ups. Mr. Peterson is also the Chairman and Founder of CleanFuel USA and the Chairman of Innovative Software Technologies (OTCBB: INIV). Prior to forming Aspen Capital Partners, Mr. Peterson was Managing Director of Investment Banking with H. C. Wainwright & Co. Prior to Wainwright, Mr. Peterson was president of First American Holdings and Managing Director of Investment Banking. Previous to First American, he served in various investment banking roles and was the co-founder of ARM Financial Corporation. Mr. Peterson was one of the key individuals responsible for taking ARM Financial public on the OTC market and the American Stock Exchange. Under Mr. Peterson s financial leadership, ARM Financial Corporation was transformed from a diversified holding company into a national clinical laboratory company with more than 14 clinical laboratories and ancillary services with over \$100 million in assets. He has also served as an officer or director for a variety of other companies, both public and private. Mr. Peterson earned a Bachelor of Science degree in Business Administration from the University of Florida.