BIO REFERENCE LABORATORIES INC
Form 10-K
January 14, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[Mark One]

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE

SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended October 31, 2008

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 159d) OF THE SEUCIRITES

EXHANGE ACT OF 1934

For the transition period from to

Commission file number 0-15266

BIO-REFERENCE LABORATORIES, INC.

New Jersey	**22-2405059**
(State of incorporation)	(I.R.S. Employer Identification No.)

481 Edward H. Ross Drive, Elmwood Park, New Jersey 07407

(Address of principal executive offices)

Registrant s telephone number **201-791-2600**

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

Securities registered pursuant to Section 12(g) of the Act:	**Name of Exchange on Which Registered**
Common Stock, $.01 par value	NASDAQ Global Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x.

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No x.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o.

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer. accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer x Non-Accelerated filer o Smaller reporting company o

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

The aggregate market value of the voting stock of Bio-Reference Laboratories, Inc. (consisting of Common Stock, $.01 par value) held by non-affiliates of the registrant was approximately $297,400,000 based upon the last sale price for the Common Stock on April 30, 2008, the last trading date of the registrant s most recently completed second quarter, as reported on the NASDAQ Global Market System.

On January 5, 2009, there were 13,788,343 shares of Common Stock issued and outstanding

PART I

Item. 1. - Business

Overview

We believe that we are the largest independent regional clinical laboratory servicing the greater New York metropolitan area. We offer a comprehensive list of laboratory testing services utilized by healthcare providers in the detection, diagnosis, evaluation, monitoring and treatment of diseases.

We currently process nearly 4.1 million requisitions each year. A requisition form accompanies a patient specimen. It indicates the tests to be performed and the party to be invoiced for the tests. Our clients include doctors, employers, clinics and governmental units. We have a network of over 50 patient service centers for collection of patient specimens.

In 2006 we acquired GeneDx, a diagnostic genetic testing laboratory providing services to national and international customers. GeneDx specializes in testing for rare and complex genetic conditions through the use of DNA sequencing. In 2007 we introduced the first commercially available genome-wide oligonucleotide microarray analysis testing useful for the diagnosis of, among other conditions, developmental disorders, which has significantly grown GeneDx s business. The success and growth of GeneDx can be attributed to both the unique nature of our testing and the highly experienced clinicians and researchers who run the business.

In addition to our clinical testing operations, we operate a clinical knowledge management service through our PSIMedica business unit. This system uses customer data from laboratory results, pharmaceutical data, claims data and other data sources to provide administrative and clinical decision support systems which enable our customers to provide quality and efficient healthcare to their populations.

We also operate a web-based connectivity portal solution for laboratories and physicians through our CareEvolve subsidiary. We use this portal ourselves to provide laboratory ordering and results to our physician customers. We are also marketing this connectivity solution to other laboratories throughout the country.

We are a New Jersey corporation. We may at times refer to ourselves and our subsidiaries as the Company. We are the successor to Med-Mobile, Inc., a New Jersey corporation that was organized in 1981. Our executive offices are located at 481 Edward H. Ross Drive, Elmwood Park, NJ 07407, telephone number: 201-791-2600.

The Clinical Laboratory Testing Market in the United States

We believe that the U.S. market for clinical laboratory testing generates approximately $52 billion in annual revenue. Nearly all laboratory tests are performed by one of three types of laboratories: hospital laboratories, physician office laboratories or independent clinical laboratories. We believe approximately 55% of the clinical laboratory tests done in the United States are currently performed in a hospital laboratory, approximately 40% performed by an independent clinical laboratory and the balance in a physician office or other laboratory.

During the last few years, the economic fundamentals of the industry have been improving. In the cost containment era of the 1990s, the industry was negatively impacted by the rapid growth of managed care, stringent government regulation and investigations into fraud and abuse. These factors led to revenue and profit declines and industry consolidations, especially among commercial clinical laboratories. As a result, fewer but larger clinical laboratories have emerged with greater economies of scale, more effective compliance with government billing regulation and other laws and a better approach to pricing their services. These changes resulted in improved profitability. In addition, new and emerging technologies continue to provide greater testing opportunities for clinical laboratories.

We believe the industry will continue to experience growth in testing volume due to the following:

Aging of the population of the United States;

Awareness by patients of the value of laboratory tests;

Decrease in the cost of tests;

Decrease in the influence of managed care organizations on the ordering patterns of their physicians;

Development of sophisticated and specialized tests for early detection of disease and disease management;

Diagnosis and monitoring of infectious diseases such as AIDS and Hepatitis C;

Early detection and prevention as a means of reducing healthcare costs;

Employer sponsored wellness programs;

Research and development in genomics.

Business Strategy

We are a regional clinical laboratory with subspecialty testing capabilities. As a regional laboratory, we service the New York metropolitan area, and currently conduct business in most New York State counties, as well as in most of New Jersey and some parts of Pennsylvania and Connecticut. We primarily offer laboratory services to physician offices in these areas with an infrastructure that includes a comprehensive logistical department, extensive phlebotomy services and phlebotomy draw stations scattered around our geographic area. We have also developed expertise in certain testing areas with specific emphasis in cancer pathology and diagnostics as well as molecular diagnostics. These services are marketed as a business unit, called GenPath, which services customers outside of routine physician office testing. Through the acquisition of the operating assets of GeneDx, we have acquired expertise and credibility in the area of genetic diagnostic testing and we intend to leverage that resource in the development of expanded genetic diagnostic testing. We have developed certain specialized markets, such as in the areas of correctional health, substance abuse testing, fertility testing and molecular diagnostics. Testing in these areas also may be supported outside of physician offices.

We have one of the largest regional marketing staffs of any laboratory in the country, some of whom are trained specifically in Oncology and call on Oncology practices and hospitals.

We believe that our large marketing staff and strong infrastructure within our designated area can be leveraged to bring new technologies to physicians and healthcare providers. Over the past year, our volume of testing in the area of molecular diagnostics has increased. We believe that laboratory data has great value in managing the healthcare of a population, but can only be properly utilized when combined with medical claims and pharmacy data. Our medical information unit, PSIMedica, seeks to combine laboratory data with these other data elements in order to provide information analytics that will help to improve the quality and efficiency of healthcare. We seek to continue our strong growth not only through our marketing organization, new technologies and superior service, but by providing value added analytics in conjunction with laboratory results.

Our mission is to be recognized by our clients as the best provider of clinical laboratory testing, information and related services. The principal components of our strategy to achieve our mission are as follows:

Capitalize on our position within the clinical market

Lead in the providing of medical information

Provide the highest quality service

Pursue strategic growth opportunities

Services

The clinical laboratory testing business consists of routine testing and esoteric testing. Routine testing generates approximately 50% and esoteric testing generates approximately 50% of our net revenues. The net revenue generated by our GeneDx and our CareEvolve subsidiaries were 3.94% and .82% in fiscal 2007, respectively and 5.7% and .74% in fiscal 2008, respectively as a percentage of total revenue.

Routine Testing

Routine tests measure various health parameters such as the functions of the heart, kidney, liver, thyroid and other organs. Below is an abbreviated list of some commonly ordered tests:

Blood Cell Counts

Cholesterol levels

HIV-related tests

Pap Smears

Pregnancy

Substance Abuse

Urinalysis

We perform these tests at our main processing facility in Elmwood Park, New Jersey.

We operate 24 hours a day, 365 days a year. We perform and report most routine tests within 24 hours. Tests results are delivered via driver or electronically.

Esoteric Tests

We also perform esoteric tests that require sophisticated equipment and materials, highly skilled personnel, professional attention and which are ordered less frequently than routine tests. These tests are generally priced higher than routine tests. Esoteric tests are usually in these medical fields:

Endocrinology (the study of glands and their hormone secretions)

Genetics (the study of chromosomes, genes and their protein products)

Immunology (the study of the immune system)

Microbiology (the study of microscopic forms of life)

Oncology (the study of abnormal cell growth)

Serology (the study of body fluids)

Toxicology (the study of chemicals and drugs and their effects on the body)

We perform cancer cytogenetic testing at our leased facilities in Elmwood Park, NJ and Milford, Massachusetts and genetic testing at our GeneDx leased facilities in Gaithersburg, Maryland.

Medical Information

Our PSIMedica business unit is based on a Clinical Knowledge Management (CKM) System that uses data derived from various disparate sources to provide both administrative and clinical analysis of a population. The source data consists of enrollment (demographic) data, claims data, pharmacy data, laboratory results data, and any other data that may be available. The system uses sophisticated algorithms to cleanse and configure the data so that analysis can be comprehensive and meaningful. The data is maintained on multiple levels of analysis enabling review of data from the global level to the granular transactional detail. The system includes a base set of queries that provide basic functionality and allows on-line real-time ad hoc query capability enabling the user to customize analysis to the best needs of the organization using the system. In addition to the basic queries provided by the system, PSIMedica Quality Indicators (PQI) provide comprehensive, disease state oriented queries that disclose the quality and efficiency of the care and service. These indicators have been designed to provide the customer with standards and outcome predictors based on a medical standards basis. We are using PSIMedica to market value-added clinical laboratory services to bulk purchasers of clinical laboratory solutions, as well as marketing our PSIMedica programs to businesses such as Health Plans, Integrated Delivery Networks, Disease Management Companies, Insurers, Clinical Trial Companies and other healthcare providers that most benefit from the ability of the system to combine both clinical and administrative analysis.

Other Products

CareEvolve, our wholly owned subsidiary, is a physician-based connectivity portal. This system provides a complex, sophisticated system for ordering laboratory services and delivering laboratory results. The system is designed to be physician-centric and to provide a highly flexible, scalable, comprehensive desktop solution for physicians to manage their day-to-day practice and personal needs, as well as to handle their clinical laboratory ordering and reporting. This product has been designed to work as a platform with plug and play capability that can easily be used by other laboratories that also need a web-based solution for their physician customers.

Payors and Clients

We provide laboratory services to a range of healthcare providers. A payor is the party who pays for the tests while the client is the party that refers the tests to us. We may consider an organization that has a contract with us, such as a clinic or governmental agency, both a payor and a

client. Some states, such as New York and New Jersey, prohibit us from billing physician clients. During fiscal year 2008, no single client accounted for more than 10% of our net revenues.

The following table reflects the current estimates of the breakdown of net revenue by payor for the twelve months ended October 31, 2006, 2007, and 2008.

	October 31		
	2008	**2007**	**2006**
Direct Patient Billing	4%	3%	4%
Commercial Insurance	47%	46%	44%
Professional Billing	23%	25%	24%
Medicare	24%	24%	26%
Medicaid	2%	2%	2%
	100%	100%	100%

Clients

Physicians who order clinical tests for their patients represent one of the primary sources of our testing volume. Fees invoiced to patients and third parties are based on our fee schedule, which may be subject to limitations on fees imposed by third-party payors. Medicare and Medicaid reimbursements are based on fee schedules set by governmental authorities.

Employers, Governmental Agencies

We provide laboratory services to governmental agencies and large employer groups. We believe that we are the largest regional laboratory providing laboratory testing services to correctional facilities in the Northeastern United States. All of these clients are charged on a contractual basis.

Sales and Marketing

We employ full and part-time sales and marketing representatives. All of our sales and marketing personnel operate in a dual capacity, as both marketing and client support representatives. This ensures that all of our salespersons are intimately involved with the client. We believe that this is unique in the industry and is extremely helpful in client retention, since it provides a strong connection between the physician and our staff.

Client Service Coordinators

We utilize the services of full and part-time client service coordinators at our Elmwood Park, Clarksburg and Gaithersburg facilities, all of whom are trained in medical and laboratory terminology. This staff is used as an interface with physicians and nurses and augments the client support provided by our sales force. They also report highly abnormal and life threatening results to the ordering physician immediately via telephone in order to provide speedy medical resolution to any patient problem.

Logistical Support

We employ full and part-time couriers. They pick up patient specimens from and deliver printed reports to physician offices, nursing homes, clinics and correctional facilities.

Strategic Growth Opportunities

Over the last several years, we have experienced substantial growth and have expanded our operational capabilities. In September 2006, we acquired certain assets and liabilities of two Maryland laboratories, a pathology laboratory and a genetics laboratory for $1,500,000 and $10,000,000, respectively. The genetics laboratory purchase agreement contains certain operational targets, which, if achieved in the four years following the closing, could result in an increase in the purchase price from $10,000,000 to a maximum $17,000,000. During the recently completed fiscal year ended October 31, 2008 as well as for the fiscal year ended October 31, 2007, the genetics laboratory achieved certain of the targets, entitling the prior owners to receive $1,917,000 in cash and an additional 11,548 shares of our Common Stock with respect to each such year. These amounts have been accrued and are reflected in our financial statements. We retained the staffs of these laboratories and continue to operate at the same locations. We intend to develop further and expand both our core laboratory business and other products. This growth and expansion has placed, and will continue to place, a significant strain on our resources. We cannot assure that we will be able to successfully manage a continuation of the rate of growth similar to that which we have experienced in the past, should such growth occur.

Billing

Billing for laboratory services is extremely complicated. We must bill various payors, such as patients, Medicare, Medicaid, insurance companies and employer groups, all of which have different billing requirements. Compliance with applicable laws and regulations as well as internal compliance procedures adds complexity to this process.

Our bad debt expense is the result of issues that are not credit-related as is the case in most industries. It is due in most part to missing or incorrect billing information on our requisitions; this occurs because we depend on the healthcare provider to supply us with the information. We perform the tests and report the test results as requested on the requisition regardless of whether the demographic information is correct or even missing altogether. We then attempt to obtain any missing information and correct the billing information received from the healthcare provider. This adds to the complexity, slows the invoicing process, and generally increases the aging of our accounts receivable. When all issues are not resolved in a timely manner, the item is written-off to bad debt expense through the allowance for doubtful accounts. Other items such as pricing differences and payor disputes also complicate billing. Adjustments to receivables as a result of these types of matters are accounted for as revenue adjustments and are not written-off to bad debt expense.

Competition

We compete with three types of providers in a highly fragmented and competitive industry: hospital laboratories, physician-office laboratories and other independent clinical laboratories. Our major competitors in the New York metropolitan area are Quest Diagnostics and Laboratory Corporation of America. Although we are much smaller than these national laboratories, we believe that we compete successfully with them in our region because of the following factors:

Fewer layers of staff

A more responsive business atmosphere

Customized service

We believe our responses to medical consultation are faster and more personalized than those of the national laboratories. Our client service staff only deals with basic technical questions and those that have medical or scientific significance are referred directly to our senior scientists and medical staff.

Quality Assurance

Medical testing is essentially a process of communication and data transfer. In order to provide accurate and precise information to the physician, it is essential that we maintain a well structured and vigorous quality assurance program. Our goal is to continually improve this process. We hold the required Federal and State licenses necessary to permit our operation of a clinical laboratory at our facilities in New Jersey, New York, Maryland and Massachusetts. We submit to vigorous proficiency tests (or surveys) in all tests that we perform. We are also subject to unannounced inspections from the various state licensing agencies.

Our laboratories are accredited by the College of American Pathologists (CAP). This accreditation includes on-site inspections and participation in the CAP proficiency testing program or an equivalent. CAP is an independent organization of board certified pathologists approved by the Center for Medicare and Medicaid Services (CMS) to inspect clinical laboratories in order to determine compliance with the standards required by the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88).

Our Quality Assurance Committee, headed by a Quality Assurance Coordinator and composed of supervisors from all departments, meets daily to assess and evaluate the laboratory s quality. Based on the information received from the Committee, recommendations are made to correct conditions which have led to errors. Management, department supervisors and members of the Committee continually monitor the laboratory s quality.

Depending on the test, two or three levels of Quality Control materials are run in each analytical assay to assure precision and accuracy. Patient population statistics are evaluated each day. Testing of highly abnormal samples is repeated to assure accuracy.

We believe that all of these procedures are necessary, not only in assuring a quality product, but also in maintaining Federal and state licensing. These high standards of quality are an important factor in what we regard as our excellent rate of client retention.

Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact included in this Report, including without limitation, statements regarding our financial position, business strategy, products, products under development, markets, budgets and plans and objectives of management for future operations, are forward-looking statements. Although we believe that the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to have been correct. Important factors that could cause actual results to differ materially from our expectations are disclosed in statements set forth under the caption Risk Factors herein and elsewhere in this Report, including, without limitation, in conjunction with the forward-looking statements included in this Report. All subsequent written and oral forward-looking statements attributable to us, or persons on our behalf, are expressly qualified in their entirety by the enumerated Risk Factors and such other statements.

Item 1A. Risk Factors

Because of the following factors, as well as of the factors affecting our operating results and financial condition, financial performance should not be considered to be a reliable indicator of future performance. Investors should not use historical trends to anticipate results in future periods. See also Special Note Regarding Forward Looking Statements .

Regulation of Clinical Laboratory Operations

The clinical laboratory industry is highly regulated and subjected to significant Federal and state regulation. This includes inspections and audits by governmental agencies. These agencies may impose fines, criminal penalties, or other enforcement actions to enforce laws and regulations. These penalties can include revocation of a clinical laboratory s license. Changes in regulations may increase the cost of testing or processing claims.

Waste management is subject to Federal and state regulations governing the transportation and disposal of medical waste including bodily fluids. Federal regulations require licensure of interstate transporters of medical waste. In New Jersey, we are subject to the Comprehensive Medical Waste Management Act, (CMWMA), which requires us to register as a generator of special medical waste. All of our medical waste is disposed of by a licensed interstate hauler. The hauler provides a manifest of the disposition of the waste products as well as a certificate of incineration which is retained by us. These records are audited by the State of New Jersey on a yearly basis. We are also subject to Federal requirements. The Federal Hazardous materials transportation law, 49 U.S.C. 5101 et seq., and the Hazardous Materials Regulations (HMR), 49 CFR parts 171-180. The Federal government has classified hazardous medical waste as hazardous materials for the purpose of regulation. These regulations preempt State regulation which must be substantively the same, the non-Federal requirement must conform in every significant

respect to the Federal requirement. Editorial and other similar de minimis changes are permitted. 49 CFR 107.202(d). The amendments to provisions in 49 U.S.C., 5125 reaffirmed the need to achieve greater uniformity and to promote the public health, welfare, and safety at all levels, Federal standards for regulating the transportation of hazardous materials in intrastate, interstate, and foreign commerce are necessary and desirable. We believe we are in compliance with all Federal and State medical waste regulations.

Regulation of Reimbursement for Laboratory Services

Containment of health-care costs, including reimbursement for clinical laboratory services, has been a focus of ongoing governmental activity. Omnibus budget reconciliation legislation, designed to reconcile existing laws with reductions and reimbursements required by enactment of a Congressional budget can adversely affect clinical laboratories by reducing Medicare reimbursement for laboratory services. For most of the tests performed for Medicare beneficiaries or Medicaid recipients, laboratories are required to bill Medicare or Medicaid directly, and to accept Medicare or Medicaid reimbursement as payment in full.

The current administration, Congress and various Federal agencies have examined the rapid growth of Federal expenditures for clinical laboratory services, and the use by the major clinical laboratories of dual fee schedules (client fees charged to physicians, hospitals, institutions and companies with whom a laboratory deals on a bulk basis and which involve relatively low administrative costs, and patient fees charged to individual patients and third party payors, including Medicare, who generally require separate bills or claims for each patient encounter and which involve relatively high administrative costs). The permitted Medicare reimbursement rate for clinical laboratory services has been reduced by the Federal government in a number of instances over the past several years to a present level equal to 74% of the national median of laboratory charges. Calendar year 2008 marked the final year of a five-year freeze on Laboratory fee updates, as required by the Medicare Modernization Act of 2003. A number of proposals for legislation or regulation are under discussion which could have the effect of substantially reducing Medicare reimbursements to clinical laboratories through reduction of the present allowable percentage or through other means. In addition, the structure and nature of Medicare reimbursement for laboratory services is also under discussion and we are unable to predict the outcome of these discussions. Depending upon the nature of congressional and/or regulatory action, if any, which is taken and the content of legislation, if any, which is adopted, we could experience a significant decrease in revenues from Medicare and Medicaid, which could have a material adverse effect on us. For the first time in five years, as of January 1, 2009, laboratories will receive a 4.5% across the board increase in reimbursements.

CLIA-88

CLIA-88 extended Federal licensing requirements to all clinical laboratories (regardless of the location, size or type of laboratory), including those operated by physicians in their offices, based on the complexity of the tests they perform. The legislation also substantially increased regulation of cytology screening, most notably by requiring the Secretary of Health and Human Services, (HHS) to implement regulations placing a limit on the number of slides that a cytotechnologist may review in a twenty-four hour period. CLIA-88 also established a more stringent proficiency testing program for laboratories and increased the range and severity of sanctions for violating Federal licensing requirements. A number of these provisions, including those that imposed stricter cytology standards and increased proficiency testing, have been implemented by regulations applicable only to laboratories subject to Medicare certification. On February 28, 1992, HHS published three sets of regulations implementing CLIA-88, including quality standard regulations establishing Federal quality standards for all clinical laboratories; application and user fee regulations applicable to most laboratories in the United States which became effective on March 30 1993; and enforcement procedure regulations applicable to laboratories that are found not to meet CLIA-88 requirements. The quality standard regulations establish varying levels of regulatory scrutiny depending upon the complexity of testing performed. Under these regulations, a laboratory that performs only one or more of seventy eight routine waived tests may apply for a waiver from most requirements of CLIA-88. We believe that most tests performed by physician office laboratories will fall into either the waived or the moderately complex category. The latter category applies to simple or automated tests and generally permits existing personnel in physicians offices to continue to perform testing under the implementation of systems that insure the integrity and accurate reporting of results, establishment of quality control systems, proficiency testing by approved agencies, and biannual inspection. Our testing is often much more complex and as a result, we are subject to full compliance with CLIA-88. The quality standard and enforcement procedure regulations became effective on September 1, 1992, most personnel, quality control and proficiency testing requirements have been implemented; the remainder will be phased in over a number of years. Our laboratory completed its first CLIA inspection under CLIA-88 guidelines and received its certificate of compliance effective February 7, 1996. It has been reinspected since on a bi-annual basis and found to be in compliance.

5

Compliance Program

The Office of Inspector General has published a Model Compliance Program for the clinical laboratory industry. This is a voluntary program for laboratories to demonstrate to the Federal government that they are responsible providers. We have implemented a voluntary compliance program adhering to the standards set forth in the Model Compliance Program.

Confidentiality of Health Information

Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), on December 28, 2000, the Secretary of HHS issued final regulations that would establish comprehensive federal standards with respect to the use and disclosure of protected health information by a health plan, healthcare provider or healthcare data clearinghouse. The regulations establish a regulatory framework on various subject matter, including:

The circumstances under which disclosures and uses of protected health information require the patient s consent, or authorization or no patient consent or authorization.

The content of notices of privacy practices for protected health data.

Patients rights to access, amend and receive an accounting of the disclosures and uses of protected health information.

Administrative, technical and physical safeguards required for that use or for disclosure of protected health data.

These regulations establish a minimum and would default to more stringent state laws. Therefore, we are required to comply with both sets of standards. Laboratories were required to submit a compliance plan to HHS by October 16, 2003. We filed our application for a one year extension for compliance with the Transaction Data Set Regulations and filed our compliance plan during the extension period in accordance with the model form provided by HHS. HIPAA provides for significant fines as well as substantial criminal penalties for violations of the Act.

Laboratory Developed Tests (LDTs)

Complex laboratories such as BioReference frequently develop testing procedures to provide diagnostic results to customers for tests which are not available using Federal Drug Administration (FDA) approved methods. These tests have been traditionally offered by nearly all complex laboratories for the last few decades. The FDA has been considering changes in the way laboratories are allowed to offer these LDTs. While changes have been considered for some time now, the potential for FDA involvement appears greater now than in the past. Currently all such tests are conducted and offered under approval by CLIA and individual state licensing procedures; the FDA is considering requiring FDA approval on a portion of those currently non-FDA approved tests. There is an associated risk for BioReference that some of the tests that it currently offers might need to be subject to approval by the FDA; there are currently no formal definitions, procedures or FDA processes on how such approvals would be handled.

Fraud and Abuse Regulations

Medicare and Medicaid anti-kickback laws prohibit clinical laboratories from making payments or furnishing other benefits to influence the referral of tests billed to federal programs. Federal enforcement agencies (including both the Federal Bureau of Investigation and the Office of the Inspector General) liberally interpret and aggressively enforce statutory fraud and abuse provisions of these anti-kickback statutes. According to public statements made by the Department of Justice, healthcare fraud has become one of its highest priorities. Many of the anti-fraud statutes are vague or indefinite and have not been interpreted in the courts. We believe we operate lawfully within these statutes; however, we cannot predict if some of our practices may be interpreted as violating these statutes and regulations.

Intellectual Property

BioReference, primarily through its wholly-owned subsidiary, GeneDx, but additionally through its primary laboratory in Elmwood Park has in the past, and may in the future, have the need to deal with intellectual property issues, such as patent issues, trademark issues and copyright issues. BioReference diligently researches all matters that may give rise to an intellectual property issue and has taken substantial legal steps to make sure that all such matters are fully considered and understood. In certain instances the issues are not apparent and in some other cases, BioReference believes that the current intellectual property law may not be appropriate to current conditions or may be in a transitional state of change and BioReference may challenge the law in such instances. There is an associated risk with such challenges that could force BioReference to stop or change a testing procedure in certain instances or could possibly result in financial expense as a result of the Company s decision.

Insurance

We maintain professional liability insurance of $1,000,000 per occurrence, $3,000,000 in the aggregate. In addition, we maintain excess commercial insurance of $5,000,000 per occurrence and $5,000,000 in the aggregate. We believe that our present insurance coverage is sufficient to cover currently estimated exposures, but we cannot assure that we will not incur liabilities in excess of the policy limits. In addition, although we believe that we will be able to continue to obtain adequate insurance coverage, we cannot assure that we will be able to do so at acceptable cost.

Employees

At October 31, 2008, we had 1,484 full-time and 423 part-time employees serving in executive positions, as technicians and technologists (including physicians, pathologists and PhDs), in marketing and as drivers and in bookkeeping, clerical and administrative positions. None of our employees are represented by a labor union. We regard relations with our employees as satisfactory.

Risks Associated with Growth:

Over the last several years, we have experienced substantial growth and have expanded our operational capabilities. In September 2006, we acquired certain assets and liabilities of two Maryland laboratories, a pathology laboratory and a genetics laboratory for $1,500,000 and $10,000,000, respectively. The genetics laboratory purchase agreement contains certain operational targets, which, if achieved in the next four years could result in an increase in the purchase price from $10,000,000 to a maximum $17,000,000. During the recently

completed fiscal year ended October 31, 2008 as well as for the fiscal year ended October 31, 2007, the genetics laboratory achieved certain of the targets, entitling the prior owners to receive $1,917,000 in cash and an additional 11,548 shares of our Common Stock with respect to each such year. These amounts have been accrued and are reflected in our financial statements. We retained the staffs of these laboratories and continue to operate at the same locations. We intend to develop further and expand both our core laboratory business and other products. This growth and expansion has placed, and will continue to place, a significant strain on our resources. We cannot assure that we will be able to successfully manage a continuation of the rate of growth similar to that which we have experienced in the past, should such growth occur.

Fluctuations in Operating Results:

Our quarterly and annual operating results can be affected by a wide variety of factors, many of which are outside of our control and which have in the past and could in the future materially and adversely affect our operating results. These factors include the quantities and timing of specimens received, pricing pressures, reimbursement changes, availability and cost of diagnostic supplies, cost of logistic and delivery systems, changes in product mix, retention and expansion of our marketing staff, timing of payments from governmental agencies and third-party payors and the effect of adverse weather conditions. We rely principally upon our internal logistic group for pick-up and delivery of specimens. However, as we shift our product mix we have begun to rely on Federal Express, UPS and other such providers for this service. Any disruption in this service, as occurred on

September 11, 2001 when the National Airspace System (NAS) was shut down for a week, could have a material adverse effect on our operating results. As a result of these factors, our operating results may continue to fluctuate in the future.

Uncertainties Related to Government Regulation and Enforcement

We are a provider of healthcare services. As such, we are subject to extensive and rapidly changing federal, state and local laws and regulations governing licensure, billing practices, financial relationships, referrals, conduct of operations, purchase of existing businesses and other aspects of our business. We cannot predict the timing or impact of any changes in these laws and regulations or their interpretations by regulatory bodies, and we cannot assure that these changes will not have a material adverse effect on us.

Current federal laws governing federal healthcare programs, as well as some state laws, regulate certain aspects of the relationship between healthcare providers, including us, and their referral sources. The Federal Anti-Kickback Law and the Stark Law generally prohibit providers and others from soliciting, offering, receiving or paying, directly or indirectly, any monies in return for either making a referral for a service or item or purchasing, ordering or leasing a service or item, and prohibits physicians from making such referrals to entities in which they have an investment interest or with which they have a compensation arrangement. Exceptions to these laws are limited. Violations are punishable by disallowance of claims, civil monetary or criminal penalties and or exclusion from Medicare. Government authorities (both federal and state) have become more aggressive in examining laboratory billing practices, and in seeking repayments and even penalties based on how the services were billed, regardless of whether the carriers had furnished clear guidance.

In addition, our laboratory operations are required to be licensed or certified under CLIA-88, CMS (Medicare) and various State and local laws. We are also subject to federal and state laws relating to the handling and disposal of medical waste and radioactive materials, as well as the safety and health of laboratory employees. Although we seek to structure our practices to comply with these laws and regulations, no assurances can be given regarding compliance in any given situation. The possible sanctions for failure to comply with these laws and regulations may include the denial to conduct business, significant fines and criminal penalties. Any significant fine or criminal penalty could have a material adverse effect on our financial condition. Any exclusion or suspension from participation in a CMS program, any loss of licensure or accreditation or the inability to obtain the required license would have a material adverse effect on our business.

Uncertainties Related to Third-Party Payors

We typically bill third party payors such as Medicare, Medicaid, Governmental programs and private insurers for our services. Such third party payors are constantly negotiating prices with the goal of lowering their costs, which may result in lower profit margins for us. Reimbursement rates have been established for most, but not every service. We cannot collect from third party payors for services that these payors have not approved for reimbursement. As is common with all laboratories, there is a certain amount of variability with respect to reimbursement among third party payors. Furthermore, third party payors have, on occasion ceased reimbursements when certain tests are ordered for patients with certain diagnoses while maintaining reimbursement when those tests are ordered for other diagnoses deemed appropriate by the carrier. In addition, Medicare or Medicaid may retroactively audit its payments to us and may determine that certain payments must be returned.

Potential Healthcare Reform Including Decreasing Reimbursement Rates

The public and the federal government continue to focus attention on reforming the healthcare system in the United States. At the beginning of calendar year 2005, CMS announced significant cuts to Medicare reimbursement rates for flow cytometry testing. We benefited from a partial restoration of the former reimbursement rates in fiscal 2007. Furthermore, several legislative proposals have been introduced in Congress and state legislatures in recent years that would effect major reforms of the healthcare systems. In addition, CMS has made a number of proposals regarding the payment and coverage of laboratory services including the development of national coverage policies. Because of the uncertainties in regard to the nature, timing and extent of any such reimbursement changes, audits and reform initiatives, we are unable to predict the effect of these changes on us. For the first time in five years, as of January 1, 2009, laboratories will receive a 4.5% across the board increase in reimbursements.

Uncertainties Related to Accounts Receivable

All of our services are rendered based upon a fee for services list. We assume the financial risk related to collection of these receivables such as:

Delays attendant to reimbursement by third party payors

Difficulties in gathering complete and accurate billing information

Inability to collect accounts

Long collection cycles

There have been times when our accounts receivable have increased at a greater rate than revenue growth and, therefore, has adversely affected our cash flow from operations. We have taken steps to implement systems and processing changes intended to improve billing procedures and related collection results. We believe that we have made progress by reorganizing our accounts receivable and billing functions and that our allowance for doubtful accounts is adequate. However, we cannot assure that our ongoing assessment of accounts receivable will not result in the need for additional provisions. Such additional provisions, if implemented, could have a material adverse effect on our operating results.

Competition

We operate in a business which is characterized by intense competition. Our major competitors in the New York metropolitan area, Quest Diagnostics and Laboratory Corporation of America, are large national laboratories which possess greater name recognition, larger customer bases, significantly greater financial resources and employ substantially more personnel than we do. Many of our competitors have long established relationships. We cannot give assurances that we will be able to compete successfully with such entities in the future. Our ability to attract and retain sales representatives and management may also affect our ability to compete in this marketplace.

Dependence on Bank Financing

In May 2008, the Company entered into an amended revolving note payable loan agreement with PNC Bank, N.A. (the bank). The maximum amount of the credit line available to the Company pursuant to the loan agreement is the lesser of (i) $40,000,000 or (ii) 50% of the Company s qualified accounts receivable [as defined in the agreement]. The amendment to the Loan and Security Agreement provides for interest on advances to be subject to the bank s prime rate or the Eurodollar rate of interest plus, in certain instances, an additional interest percentage. The additional interest percentage charges on Eurodollar borrowings range from 1% to 4% and are determined based upon certain financial ratios achieved by the Company. At October 31, 2008, the Company had elected to have all of the total advances outstanding to be subject to the bank s prime rate of interest of 4.0%. The credit line is collateralized by substantially all of the Company s assets. The line of credit is available through October 2012 and may be extended for annual periods by mutual consent, thereafter. The terms of this agreement contain, among other provisions, requirements for maintaining defined levels of capital expenditures, fixed charge coverage, and the prohibition of the payment by the Company of cash dividends. As of October 31, 2008, the Company was utilizing $18,831,000 of the available credit under this revolving note payable loan agreement.

Effective as of October 31, 2007, we executed a fifth amendment to the loan agreement formalizing the repayment terms of a $5 million term loan from PNC Bank used by our wholly-owned subsidiary, BRLI No. 2 Acquisition Corp. to fund the $5 million acquisition Cash Payment in connection with the purchase of the operating assets of GeneDx. The term loan is evidenced by a secured promissory note payable over a six year term in equal monthly principal payments of $69,000, plus interest at an annual rate of 6.85%. The balance on this note as of October 31, 2008 was approximately $3,333,000.

In January 2007, the Company issued a ten year term note of $4,100,000 for the financing of equipment. The note is payable in equal monthly installments of $47,000 including principal and interest, with payment commencing on March 1, 2007 at an effective interest rate of 6.63% per annum. The balance on this note as of October 31, 2008 was approximately $3,564,000.

Dependence on our Chief Executive Officer

Our success is substantially dependent on the efforts and abilities of Marc D. Grodman, M.D., our founder, president and chief executive officer. The unavailability of Dr. Grodman, whether as a result of his death, disability or otherwise, could have a material adverse effect upon our business.

Possible Volatility of Stock Price

There is a history of volatility in the market price for shares of companies in the healthcare marketplace. Factors such as fluctuations in our quarterly revenues and operating results, announcements of new innovations or services by us or our competitors, changes in third party payment policies and government regulations may have a material effect on the market price of our Common Stock. In addition, any announcement of a material pending legal action could have a negative impact on the market price of our Common Stock regardless of the outcome of any such matter.

Factors In Place To Discourage Takeover Attempts

The substantial percentage ownership of our outstanding Common Stock by our executive officers and directors; our charter provision providing for a staggered board of directors so that only one-third of the board is elected each year to serve a three year term; and the requirement that the holders of not less than 80% of our outstanding Common Stock must approve any merger, consolidation, asset sale or acquisition of the Company not approved by the board of directors may discourage attempts by third parties to tender for or otherwise obtain control of the Company, even if such an attempt might be deemed beneficial to the Company and its shareholders. See Item 11 Employment Agreements with Executive Officers as to employment agreements signed by the Company which provide for substantial Severance Payments upon termination of employment in the event of a Change in Control of the Company. These Severance Payment provisions may also discourage attempts by third parties to tender for or otherwise obtain control of the Company.

Item 1B. Unresolved Staff Comments

The Company has received a comment letter from the staff (the Staff) of the Securities and Exchange Commissions regarding its periodic and current reports under the Exchange Act. Two of the comments have not yet been resolved.

The first comment related to the provision in the GeneDx acquisition agreement which required the stock portion of the upside contingent purchase price to be valued at the value per share of the closing date stock value (i.e. $21.65 per share). The Staff contends that the value of the stock portion of the upside contingent purchase price payments should be determined based on its fair value when the contingency is resolved. It is the Company s position that any revaluation of the stock portion of the upside contingent purchase price payment would be quantitatively insignificant and would have no material effect on the Company s financial statements.