SPECIALTY LABORATORIES INC
Form 10-K
March 15, 2005

QuickLinks -- Click here to rapidly navigate through this document

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15 OF THE SECURITIES EXCHANGE ACT OF 1934

(MARK ONE)

o **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2004

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission file number 001-16217

SPECIALTY LABORATORIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

California	**95-2961036**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

27027 Tourney Road
Valencia, California 91355
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: **(661) 799-6543**

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, no par value	New York Stock Exchange

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

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 ý o

Indicate by a 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 registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ý o

As of June 30, 2004, the last business day of the registrant's most recently completed second fiscal quarter, the approximate aggregate market value of voting and non-voting Common Stock held by non-affiliates of the registrant was $73,592,252 (based upon the last closing price for shares of the registrant's Common Stock as reported by the New York Stock Exchange as of that date). Shares of Common Stock held by each officer, director, and holder of 10% or more of the outstanding Common Stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 8, 2005, there were approximately 23,090,541 shares of Common Stock outstanding.

Documents Incorporated By Reference

Part III incorporates certain information by reference from the registrant's definitive proxy statement (the "Proxy Statement") for the Annual Meeting of Shareholders scheduled for May 12, 2005, to be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year ended December 31, 2004 covered by this report.

SPECIALTY LABORATORIES, INC.
FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

ABOUT THIS ANNUAL REPORT

In this Annual Report, "Specialty Laboratories," "Specialty," "we," "us" and "our" refer to Specialty Laboratories, Inc., a California corporation. We own or have rights to certain product names and trademarks that we use in conjunction with the sale of our products, including GenotypR , ANAlyzer®, TARO , HANA , DataPassportMD®, Outreach Express® and DataPassport®. This report also contains other product names, trade names and trademarks that may belong to other organizations.

This Annual Report on Form 10-K, includes information incorporated herein by reference, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as "projects," "believes," "anticipates," "will," "estimate," "plans," "expects," "intends," and similar words and expressions are intended to identify forward-looking statements. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. Important language regarding factors which could cause actual results to differ materially from such expectations are disclosed in this Annual Report, including without limitation under the caption "Risk Factors" beginning on page 22 of this Annual Report, and in filings with the Securities and Exchange Commission ("SEC") made from time to time by Specialty Laboratories, including our periodic filings on Form 10-Q and current reports on Form 8-K. All forward-looking statements attributable to Specialty Laboratories are expressly qualified in their entirety by such language.

PART I.

ITEM 1. BUSINESS

Overview

Specialty Laboratories is a leading hospital-focused clinical reference laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist's nationwide. We believe we offer one of the most comprehensive menus of esoteric assays in the industry, many of which have been developed or enhanced through our internal research and development efforts. Esoteric assays are complex, comprehensive or unique tests used to diagnose, evaluate and monitor patients. These assays are often performed by highly skilled personnel using sophisticated instruments and are therefore offered by a limited number of clinical laboratories.

Our primary customers are hospitals, independent clinical laboratories and physicians. We have aligned our interests with those of hospitals by generally not competing for routine testing that provides them with a valuable source of revenue. We educate physicians on the clinical value of our assays through our information-oriented marketing campaigns. Our technical, experienced sales force concentrates on the hospitals and independent laboratories that serve as distribution channels for physician assay orders. We use our advanced information technology solutions to accelerate and automate electronic assay ordering and results reporting with these customers.

We are a California corporation and were incorporated in 1975 under the name Clinical Immunology Laboratories, Inc. In 1985 we changed our name to Specialty Laboratories, Inc. Our principal offices are located at 27027 Tourney Road, Valencia, California 91355.

We maintain a World Wide Web site at www.specialtylabs.com. We make available free of charge through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished to the SEC as soon as reasonably practicable after filing with or furnishing to the SEC. We also make available on our website copies of our Audit Committee Charter, Compensation Committee Charter, Nominating Committee Charter, Code of Conduct/Ethics and Corporate Governance Guidelines, copies of which are also available in print to any shareholder upon request. The information on our web site should not be considered part of this Report.

Clinical Laboratory Industry

Clinical laboratory testing is critical to the delivery of quality healthcare to patients. Laboratory tests are used by physicians to assist in the detection, diagnosis, evaluation, monitoring and treatment of diseases and other medical conditions through the measurement and analysis of chemical and

cellular components in blood and other bodily fluids and tissues. Clinical laboratory tests are frequently ordered as part of physician office visits and hospital admissions. Most clinical laboratory tests ordered are considered routine and can be performed by most clinical laboratories. Esoteric assays generally require more sophisticated instruments and highly skilled personnel, and are typically outsourced to independent clinical laboratories that specialize in such assays.

Routine Segment of Clinical Laboratory Industry

Routine tests are ordered by physicians and may be performed by clinical laboratories through the use of standardized prepared kits manufactured by diagnostic companies. Routine tests include procedures in the areas of blood chemistry, hematology, urine chemistry, bacteriology, tissue pathology and cytology. Commonly ordered individual routine tests include red and white blood cell counts, Pap smears, blood cholesterol level tests, urinalyses and pregnancy tests. Because routine tests often employ mass-produced commercial kits, which can be performed with limited training, they are usually more competitively priced than esoteric assays. Although we can perform routine tests, we generally do not compete in the routine segment of the clinical laboratory industry.

Esoteric Segment of Clinical Laboratory Industry

Esoteric assays are typically ordered when a physician requires additional information to complete a diagnosis, establish a prognosis or to choose and monitor a therapeutic regimen. Esoteric assays include procedures in the areas of molecular diagnostics, protein chemistry, cellular immunology and advanced microbiology. Commonly ordered esoteric assays include viral and bacterial detection assays, drug therapy monitoring assays, autoimmune panels and complex cancer evaluations. In contrast to routine tests, esoteric assays generally require sophisticated instruments and materials and highly skilled personnel to perform and analyze results. Consequently, esoteric assays are generally priced substantially higher than routine tests. Because it is not cost-effective for most hospitals, independent laboratories or physician office laboratories to develop and perform a broad menu of esoteric assays, these assays are generally outsourced to independent clinical laboratories that specialize in performing these complex assays.

Our Competitive Advantages

Comprehensive Menu of Esoteric Assays

We currently offer a comprehensive menu of more than 2,500 esoteric assays. The breadth of our assay menu distinguishes us from large independent laboratories which typically offer only a select number of esoteric assays, and from smaller niche laboratories focused on specific clinical areas. Our comprehensive menu allows our customers to rely on us for substantially all of their esoteric testing needs.

Many of our assays were developed or modified through our R&D efforts and are unique to us. We have historically leveraged our expertise in molecular diagnostics and applied it to high growth segments of the esoteric testing industry including fields of medicine such as infectious disease, gastroenterology, oncology, endocrinology, and cardiology. We believe that we have developed one of the most extensive menus of assays in these attractive growth areas.

Beginning in 2000, we broadened our assay development effort and initiated technology partnerships with leading biotechnology companies. Rather than rely solely on internal R&D, we work closely with these companies to incorporate their intellectual property and technological advances into commercially viable clinical applications. We believe that our expertise in assay development and commercialization makes us an excellent partner to biotechnology companies with emerging technologies.

We market and sell many of our esoteric assays under trademarks such as GenotypR , our assays for predicting resistance to HIV, and ANAlyzer®, our assays used to help diagnose complex autoimmune disorders. For the year ended December 31, 2004, approximately 31% of our net revenue was derived from branded esoteric assays. We believe these branding efforts have contributed to increased market share and premium pricing as physician specialists often continue to rely on our products, even after the introduction of a similar assay by a competitor.

Interests Aligned With Our Hospital Customers

Our predominant focus on the esoteric segment of the clinical laboratory industry allows us to align our interests with those of our hospital customers. Many hospital-based laboratories attempt to increase revenue by marketing and performing routine tests for physicians, commonly known as laboratory "outreach." Hospitals compete with national independent clinical laboratories for these routine tests. We believe that hospitals are more inclined to refer their esoteric testing to independent clinical laboratories that do not compete with them for routine tests.

We enhance our hospital customers' outreach capabilities by marketing our comprehensive menu of esoteric assays as a complement to their routine testing. We also emphasize our laboratory outreach advisory services that help hospitals market their outreach laboratories to their physician community. These advisory services include information technology tools that will help connect hospital laboratories to physician offices. This connectivity improves communications and logistics between the hospital laboratories and their physician clients. We potentially benefit by receiving more esoteric assay referrals from these hospitals as they may receive more routine and esoteric laboratory referrals from their physicians. Ultimately, we believe this strategy enhances our access to esoteric assays that might otherwise be referred to our competitors.

Customer-Focused Information Technology Platforms

We offer our customers information technology that accelerates and automates assay ordering and results reporting. We believe that many of our competitors still manage a large portion of their order and results transactions manually. In 1998, approximately 40% of our transactions were transmitted electronically, principally through direct computer-to-computer links with a small number of our largest customers. At that time, we began a customer-focused information technology initiative to efficiently utilize the Internet. This project reduced the implementation time and cost of providing electronic links to large and small customers alike. This led to substantial cost savings, fewer data entry errors, improved ease of assay ordering and shorter turn-around time for results reporting. Today, more than 85% of our transactions with our customers are conducted electronically. Furthermore, we believe that our customer-focused information technology offerings include a number of features that cannot be easily duplicated.

Research and Development Expertise

We focus our R&D efforts on introducing novel assays, improving existing technologies and enhancing our reputation as an industry leader in new assay development. As an example, in 1988, we believe we were the first commercial laboratory to capitalize on the use of polymerase chain reaction technology, or PCR, by introducing and making PCR tests for HIV widely available. In emergency situations, we endeavor to develop new assays within a shorter period of time. For example, in 1999, within two weeks of learning about the outbreak of West Nile Fever in the New York metropolitan area, we developed a breakthrough detection assay and worked with the Centers for Disease Control and Prevention to notify physicians that this assay was available to monitor the spread of the virus causing the outbreak.

Our R&D expertise also places us in a position to collaborate with biotechnology companies to commercialize their proprietary assays, methods and technologies. For example, in 2001, we signed an agreement with VIRalliance, a subsidiary of BioAlliance Pharma of Paris, France, to perform testing for resistance to HIV therapy using their procedures for phenotyping. With this exclusive technology transfer agreement, we are currently the only full-service reference laboratory in the United States to perform drug resistance testing by phenotyping. In 2003, we developed in collaboration with Tm Bioscience Corporation an improved genetic screening test for Cystic Fibrosis (CF) and Cystic Fibrosis carrier status.

Operating Efficiency and Flexibility

We regularly evaluate our operations for process improvement opportunities and have made substantial investments in advanced process automation projects. In the second half of 2000, we began the implementation of our automated specimen management system known as TARO . This high speed sorting system reduces the potential for human error, increases the productivity of laboratory staff and shortens turn-around time within the laboratory. The TARO system became fully operational in the first quarter of 2001 and we believe the TARO system has boosted our laboratory productivity. As part of our continuing emphasis on process improvements, we have developed an ancillary system to TARO that is designed for high-throughput, precise division of specimens, a process commonly known as aliquoting. This robotic aliquoting system, designated as HANA , became operational in second half of 2002. Due to the precision of this automation, HANA had an immediate impact by identifying patient samples containing insufficient specimen volume for tests to be performed, and thus lowering the number of patient samples that had to be handled.

Our research orientation affords us the flexibility to choose between standardized prepared kits, other available testing technologies, and our own internally developed methodologies depending on cost, quality and market preference. This flexibility provides us the opportunity to gain additional operating efficiencies, as we are not solely dependent on platforms designed for specific commercial kits.

Products and Services

We perform all of our testing services at our laboratory facility in Valencia, California. We do not have patient service centers and therefore do not obtain specimens directly from patients. Typically, our customers collect a patient's specimen and forward it directly to our laboratory facility. Our laboratory facility accepts specimens 24 hours a day, seven days a week, 365 days a year. Most specimens are analyzed and the results are reported within 48 hours of receipt.

We currently offer a comprehensive menu of esoteric assays. Following a business evaluation of our testing menu in the second half of 2002 and the resultant elimination of certain low-volume or clinically redundant services, the menu currently consists of more than 2,500 esoteric assays. The breadth of our assay menu distinguishes us from large independent laboratories that typically offer only a select number of esoteric assays and from smaller niche laboratories focused on specific clinical areas. Our comprehensive menu allows our customers to rely on us for substantially all of their esoteric testing needs. Esoteric assays are typically ordered when a physician requires additional information to complete a diagnosis, establish a prognosis, or to choose and monitor a therapeutic regimen.

Many of our assays were designed by our R&D team and are unique to us. We have historically leveraged our expertise in molecular diagnostics and applied it to high growth segments of the esoteric testing industry including fields of medicine such as infectious disease, gastroenterology, oncology, endocrinology and cardiology. Molecular diagnostic assays comprised approximately 27% of our net revenue for the year ended December 31, 2004. Broadly speaking, molecular diagnostics includes all test procedures incorporating or identifying DNA- or RNA-based targets. This includes assays detecting

the presence of a gene for a given disorder such as cystic fibrosis and assays examining DNA to help predict a patient's response to different drugs, such as HIV resistance assays. These assays can also detect viruses by identifying their unique genetic profile. We believe that we have developed one of the most extensive menus of molecular diagnostics assays. As a result of this expertise, we intend to develop novel, first-to-market assays and capture additional revenues by capitalizing on recent advances in the accumulated knowledge of the human genome.

Our assays for Hepatitis B and C and cardiovascular disease illustrate our ongoing application of advanced diagnostic techniques to diseases affecting a large or growing segment of the population. Hepatitis B and C together affect more than five million Americans, of whom nearly four million are chronically infected. In this market, we offer more than 50 assays using molecular diagnostics and other techniques to help physician specialists diagnose and monitor therapy effectiveness. In the cardiovascular disease market, we offer more than 45 assays designed to help physicians identify high-risk individuals. These assays help identify genetic mutations and infectious, metabolic and autoimmune markers all associated with increased cardiovascular risk.

We market and sell many of our assays under trademarked names such as GenotypR and Phenoscript , our assays for predicting resistance to HIV, and ANAlyzer®, our assays used to diagnose complex autoimmune disorders. For the year ended December 31, 2004, approximately 31% of our net revenue was derived from branded esoteric assays. We believe these branding efforts have contributed to increased market share and premium pricing as physician specialists often continue to rely on our products, even after the introduction of a similar assay by a competitor.

While we offer more than 2,500 esoteric assays, 59 of our esoteric assays currently account for a substantial portion of our net revenue. These assays, on a net revenue basis, accounted for approximately 47% and 45%, respectively, of our net revenue for the years ended December 31, 2004 and 2003. For more information, see "Risk Factors We rely on a few assays for a significant portion of our net revenue. If demand for these assays were to weaken for any reason, our net revenue would decrease."

Marketing and Sales

Marketing and Sales Organization

Our marketing and sales organization consists of a staff of seven marketing professionals and approximately 36 technical representatives and sales managers. Sales representatives principally focus on large accounts including hospitals or independent laboratories throughout the United States, with a small percentage of their time spent selling directly to physician specialists. Currently three sales representatives focus primarily on national accounts and group purchase organizations. We continually educate our sales representatives on the technical and clinical merits of our products. We use traditional sales meetings, technical on-line sales training and in-the-field training to ensure our sales representatives are properly informed about all areas of our product lines and selling processes.

Marketing Strategy

Our core marketing strategy is centered around our hospital clients. We continue to provide our clients with tools, such as customized turn-around time reports, that make it easier to use us as their reference laboratory. In 2003, we launched the next generation Outreach Express®, a proprietary, Web-based laboratory test order and result reporting system, providing hospital organizations with a tool for strengthening the laboratory services they provide to physician offices, medical groups and affiliated healthcare organizations. With a renewed focus on service, we are also promoting the value that our service enhancements afford each facility.

We intend to continue educating physician specialists on the clinical value of our assays through research publications, print advertisement, direct mail, and the Internet. These targeted marketing tools are designed to be effective while minimizing the need for direct physician contact by our sales representatives. We actively pursue publication of our scientific research in peer-reviewed journals and have had more than 800 articles published. We periodically update ten widely used, proprietary reference manuals on the use and interpretation of our assays, focusing on medical specialties such as infectious disease, gastroenterology, oncology, rheumatology, genetics, and cardiology. We present our research at scientific meetings and we exhibit at more than 60 national and regional conferences throughout the year. Our web site is another vehicle for educating physicians about our assays and contains our entire directory of services, on-line technical materials and links to other medical sites that support the role of esoteric assays in effective diagnosis and treatment of diseases.

Sales Strategy

We concentrate our selling efforts on the management teams of hospitals and other independent laboratories that serve as distribution channels for physician assay orders. These management teams typically include laboratory managers, pathologists, finance, and information technology personnel. To a lesser extent, we also call directly on physician specialists who create the demand for our assays.

In connection with our hospital-focused strategy, we concentrate on increasing the volume of testing we perform for existing clients. Our goal is to grow the percentage of total testing these existing clients send to us, so that we become their primary provider of esoteric reference testing. Our marketing department provides our sales representatives with a comprehensive database containing pertinent information on hospital information technology systems, key contacts and existing competition. Sales representatives are trained to find new market opportunities and provide solutions to address unmet customer needs, which may include outreach support, information technology products, assay information and general servicing.

We also facilitate hospital sales through affiliations with group purchasing organizations. Although hospitals participating in group purchasing organizations are not obligated to use the group purchasing organization contracted laboratory for their reference testing, a group purchasing organization contract may provide us with access to additional hospital business. For further discussion of our group purchasing organization relationships, see "Customers Hospitals" below.

Customers

Our customers include hospitals, independent laboratories, physician specialists and other medical providers. The following table provides percentages of our net revenue by class of customer:

	Years Ended December 31,		
	2002	**2003**	**2004**
Hospitals	60.9%	64.2%	60.6%
Independent Laboratories	29.4%	26.0%	30.2%
Physician Specialists and Others	9.7%	9.8%	9.2%
Total	100.0%	100.0%	100.0%

Hospitals

Hospitals accounted for approximately 61% of our net revenue for the year ended December 31, 2004. Of the estimated 5,000 hospitals to which we target our services, approximately 2,000 are currently our customers. We are a primary provider of esoteric reference laboratory testing services for approximately 250 of these hospital customers.

Many of our hospital customers are part of one or more group purchasing organizations which typically pool independent hospitals together to negotiate for pricing and services, including prices for laboratory tests. Generally, hospitals participating in group purchasing organizations are not obligated to use the group purchasing organization contracted laboratory for their reference testing, and many hospitals are affiliated with multiple group purchasing organizations. In addition to several small group purchasing organizations, we are currently under contract with the following voluntary group purchasing organizations:

Group Purchasing Organization	Estimated Number of Member Hospitals	Contract Expiration Date
Novation	1,800	April 2006
Premier Partners	1,453	September 2007
MedAssets HSCA**	1,500	June 2005
AmeriNet	1,400	March 2008
MAGNET	900	December 2006
Managed Healthcare Associates	600	January 2009
Consorta	510	June 2008

** MedAssets HSCA agreement now includes Shared Services Healthcare members.

Each of our agreements with group purchasing organizations provide for discounted fee structures for our assays including capped price increases. Some of these contracts provide additional discounts for certain assays. Most of these contracts also provide that we pay a periodic administrative fee to the group purchasing organization.

Independent Laboratories

For the year ended December 31, 2004, independent laboratories represented approximately 30% of our net revenue. Regional and national independent laboratories together comprise more than 1,300 accounts in the independent laboratory segment that we can potentially serve. Regional independent laboratories typically receive test requests directly from physicians. Regional laboratories will perform the routine tests and outsource the esoteric assays to an esoteric national laboratory like us. Although other national independent laboratories perform some esoteric testing, they may outsource to us any esoteric assays they are unable to perform and also honor requests from physician specialists who specify that we perform particular assays.

Physician Specialists and Others

For the year ended December 31, 2004, physician specialists comprised approximately 4% of our net revenue and represented approximately 352 accounts. Currently, there are more than 200,000 physician specialists in the U.S., of which approximately 120,000 fall directly into our targeted medical specialties. Although they account for a small percentage of direct net revenue, physician specialists can influence the clinical acceptance of an assay, and can specifically influence laboratory choice by specifying that a particular specimen be sent to us or by ordering a particular assay that is unique to or branded by us.

Our remaining net revenue is derived primarily from clinical trials drug development testing, international and industrial accounts. Altogether, these testing services comprised approximately 5% of our net revenue for the year ended December 31, 2004.

Payors, Billing & Reimbursement

We typically bill our customers, such as hospitals or other independent laboratories, directly. In some instances, we bill the individual patient directly or third party payors such as Medicare, Medicaid or private insurance. The following table illustrates our payor mix as a percent of net revenue:

	Years Ended December 31,		
	2002	2003	2004
Customer	85.4%	86.4%	85.3%
Patient	8.0%	5.3%	5.4%
Medicare	2.9%	4.0%	4.6%
Medicaid	1.9%	2.5%	2.6%
Other Insurance	1.8%	1.8%	2.1%
Total	100.0%	100.0%	100.0%

All of our billing and payment functions are executed through a centralized computerized billing system. Our web-based DataPassportMD® and Outreach Express® products collect required billing information for Medicare, Medicaid and other insurance reimbursements at the time of assay ordering.

Information Technology

We have invested significant resources into proprietary information technology that accelerates and automates test ordering and results reporting with our customers. These information technology products, branded as DataPassport® and Outreach Express®, are designed to take advantage of Internet-based technologies. Although some customers only require a simple electronic transfer of orders and results, others are seeking solutions to help them connect disparate systems or connect physician practices associated with laboratory outreach programs. Compared to other currently available information technology applications designed to have similar functionality, we believe all of our information technology products have the advantages of faster system implementation, greater ease of use and lower customer costs. We have also invested resources designed to provide patient confidentiality and compliance with governmental regulations regarding data privacy and security.

In 1998, approximately 40% of our transactions were transmitted electronically, principally through direct computer-to-computer links with a small number of our largest customers. At that time, we began a customer-focused information technology initiative to effectively utilize the Internet and provide electronic connectivity to large and small customers alike. Today, more than 85% of the transaction volume with our customers is transmitted electronically.

Our current offering of information technology products include DataPassport® client interface module, DataPassportMD® and Outreach Express®. We believe that our evolving suite of information technology products will continue to lead to greater customer loyalty, a reduction of data entry errors, acceleration of test ordering and results reporting, and substantial cost savings. The security features on our information technology products are intended to protect the confidentiality of patient information in accordance with state and federal law.

DataPassport® Client Interface Module

Because of the volume of assays ordered, our larger accounts require a direct connection between us and their Laboratory Information System, also known as LIS, to streamline the assay ordering and results reporting process. Traditional methods of connecting directly with a customer's LIS system are generally cumbersome and require a significant amount of time to implement because such links are dependent on the involvement of a third party LIS vendor to assist in software programming. Our DataPassport® client interface module greatly decreases this implementation lag-time and bypasses the

need for the LIS vendor by emulating the hospital's LIS data format. Consequently, our client interface module may be operative within six to eight weeks, as compared with six months or more for traditional computer-to-computer links. The client interface module also provides additional features not available with traditional computer-to-computer links, such as assay and physician utilization reports, and a flexible architecture that can accommodate future expansion and require fewer internal customer resources.

DataPassportMD®

We believe this product is the most widely used web-based laboratory order entry and resulting system in hospitals today. Currently, approximately 1,200 of our customers are using DataPassportMD®. One of the key benefits of DataPassportMD® is that it permits electronic order entry and results reporting for our smaller volume customers, and can be used alone or as part of a flexible architecture. DataPassportMD® does not require any specialized hardware at the user site, making implementation almost immediate. We have added unique features to enhance the order entry and results reporting screens, including on-line access to our proprietary "use and interpretation of tests" books, graphical reporting features and extensive report generation tools for monitoring test or customer usage. We believe this product is user friendly, requiring only simple training for system users and on-site data maintenance.

Outreach Express®

We anticipate that our hospital and independent laboratory customers wishing to grow their testing business will use Outreach Express®. This product is intended to allow these customers to connect with physicians directly over the Internet. Outreach Express® uses the functionality of DataPassportMD® and is hosted through our servers. The advantages to these customers are that no specialized hardware must be purchased and the entire information technology product can be supported outside their laboratory. We designed Outreach Express® to enable physicians to access assay results from hospitals and independent laboratories electronically and, thus, more quickly than receiving such information manually. We believe that Outreach Express® provides these customers with a competitive advantage in their respective market. By aiding these customers in their outreach efforts, we believe that they will continue to utilize our services. An upgraded version of Outreach Express® became available to all customers in October 2003.

Process Automation

We have implemented an automation system known as the Total Accessioning Re-Organization system, or TARO , for our pre- and post-analytical specimen management. This high speed automated sorting system reduces the potential for human error, increases the productivity of laboratory staff and decreases overall turn-around time within the laboratory. Specifically, TARO automates specimen sorting to the appropriate assay batch, enhances specimen-tracking applications and reduces manual set up procedures at the analytical workbench.

As part of our continuing emphasis on productivity improvements, we have developed an ancillary system to TARO that is designed for high-throughput, precise aliquoting. This automated system, known as the Harmonized Assignment of Nanoliter Aliquots, or HANA , we believe is substantially reducing the traditional manual process of dividing specimens into smaller components when multiple tests are requested on a single patient. Like TARO , this system is expected to deliver higher quality service levels to our customers while at the same time improve our operating efficiencies. This system became operational in the second half of 2002. Due to the precision of this automation, HANA had an immediate impact by identifying patient samples as containing insufficient specimen volume for tests to be performed, and thus lowering the number of patient samples that had to be handled.

We utilize information technology applications extensively in conjunction with automated specimen management systems at the analytical site within the laboratory. We will continue to explore other projects to enhance our processes for improved accuracy and productivity.

Research and Development

The role of R&D at Specialty continues to be the driving force of new assay development, evaluating alternatives to costly diagnostics, improving existing assay performance and commercializing existing technologies developed by our strategic partners. Our new, more focused approach on assay development will result in a smaller number of tests developed than in the past, and a greater emphasis on revenue opportunities. Our process of creating a new assay begins with input from many sources, including our scientific team, our marketing department, scientific symposia, customers, and scientific journals. A team composed of representatives from R&D, marketing and operations evaluates the potential for a proposed assay, examining issues from disease prevalence to production costs. In addition to clinical utility of the tests, we review other decision-making variables such as physician acceptance, relationship to an available therapeutic, reimbursement, and other variables impacting the possible success of a test release. All of our R&D efforts have been company-sponsored. No R&D efforts have been sponsored by our customers. R&D spending has averaged $1.7 million per year for the past three years. Our R&D efforts enable us to grow revenues, increase market share and provide the opportunity for premium pricing.

To advance our internal development efforts of new technology applications, we seek strategic partners whose technology can be applied to a variety of disease conditions and produce advantages related to accuracy, performance, and speed of testing or cost reduction.

Strategic Partnerships and Licensing Arrangements

We actively pursue strategic partnerships with the developers of both new diagnostic assays and new platform and process technologies that accelerate assay development and commercialization. Such relationships allow us to expand our range of offered services, reduce our costs and increase the accuracy of performing assays. In addition, some of these agreements provide us with the potential to collect royalties from diagnostic product manufacturers for assays that we commercialize using such technologies.

New Assay Technologies

During recent years, we licensed intellectual property that has enabled us to commercialize several new assays. Among them are CF-70, an expanded panel cystic fibrosis assay that we license from Tm Bioscience; Phenoscript , an HIV phenotyping assay that we licensed from VIRalliance, a subsidiary of Paris-based BioAlliance Pharma; TPMT, a genetic marker for reduced metabolism of thiopurine-based drugs that we licensed from DNA Sciences; and *COL1-A1*, a genetic marker for predisposition to osteoporosis that we licensed from Axis-Shield. We anticipate that licensing new-assay intellectual property will be increasingly important in the future.

Platform and Process Technologies

We have a large and growing number of diagnostic platform and process technology partners, including:

Beckman Coulter's Progressive MicroArray platforms and Universal Linkers technology for multi-analyte detection and quantitation.

Luminex' *x*MAP Technology for multi-analyte detection and quantitation. Two assay panels (with 6 and 13 analytes, respectively) have been commercialized on this platform to date. In addition, the CF-70 assay is being performed on the Luminex platform.

Epoch Biosciences' technology which improves performance of assay systems for molecular analysis that is used to monitor therapeutic response in patients with cancer. Two such assays for leukemias have been developed and commercialized.

Third Wave Technologies' novel DNA detection system for rapid and accurate detection of SNP's. We have successfully commercialized six assays with the Invader technology.

Gen-Probe's patented TMA technology for assaying for viruses and bacteria with sensitivity greater than PCR or LCX. We have successfully launched two assays using the Gen-Probe technology.

Proprietary Rights

We protect the proprietary methodologies for assays developed by our R&D group as our trade secrets. All of our employees and consultants sign a proprietary information and inventions agreement upon hiring. To date, we have experienced no known material theft of trade secrets. We have copyrighted the proprietary software developed for products such as DataPassport®, DataPassportMD®, Outreach Express® and TARO . We also have obtained copyright registrations, as appropriate, for our published books and clinical information which we provide either electronically or in print to requesting clinicians. Many of our assays are branded products and we have applied for trademark registrations accordingly. We also have registered marks used in our clinical information and other advertising materials.

In the past, we have also received letters from the National Institutes of Health, the NIH, advising us that it believes that two of our assays, HIV-1 GenotypR and HIV GenotypR-PLUS , infringe its U.S. Patent 5,252,477. The patent is generally directed to the human HIV protease amino acid and DNA sequences and methods for synthesis and purification.

NIH has not filed suit against us, and based on our communications with NIH and our understanding of their patent rights, we do not expect such a suit to be brought; however, we cannot provide any assurances that they will not do so in the future. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us. Such a suit could be expensive to defend and could divert management's time and resources, regardless of the merit or validity of any such suit. Furthermore, we cannot provide any assurances that we would be successful in defending any such suit, and if we were found to have infringed the patents at issue, including those of NIH, we could be forced to pay substantial damages, including possible treble damages for allegations of willful infringement.

We received a letter from Chiron Corporation in or about February 1998 claiming that some of our Hepatitis C, or HCV, assays may be covered by its U.S. Patent 5,714,596. In 2000, we entered into an agreement to purchase the majority of our HCV assays from Bayer Corporation, which has represented that it has a license for U.S. Patent 5,714,596. On August 15, 2003 Specialty entered into a letter agreement with Chiron Corporation, and a separate Settlement and License Agreement with the Diagnostics Division of Bayer Healthcare LLC of Tarrytown, New York. Under the agreements, Specialty made payments to Bayer and Chiron for alleged past infringement of several Chiron patents by certain Hepatitis C Virus ("HCV") and Human Immunodeficiency Virus ("HIV") testing performed by us.

Under the agreement with Chiron, Chiron agreed not to assert its patent rights, or bring any claim against us for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to

October 15, 2003. In the agreement with Bayer, Bayer agreed to indemnify Specialty in the event Chiron brings such a suit or claim against Specialty for infringement of Chiron's patent rights with respect to HCV and HIV testing during this period. Bayer also provided Specialty with a royalty-bearing non-exclusive sublicense to perform laboratory-developed HCV and HIV nucleic acid assays. Separately, Specialty agreed to modify its supply agreement with Bayer to convert to using Bayer products, which are licensed under certain Chiron patent rights, for HCV and HIV genotyping. For more information, please see "Risk Factors Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and/or enter into appropriate licenses which may cause us to pay substantial damages or royalties, and could prohibit or restrict us from selling our assays."

Competition

The esoteric clinical laboratory business is highly competitive and is dominated by several national laboratories, as well as many smaller niche and regional organizations. Our primary competitors include large independent laboratories, such as Quest Diagnostics and Laboratory Corporation of America Holdings, or LabCorp, that offer a wide test and product menu on a national scale. These large national independent laboratories have significantly greater financial, sales and logistical resources than we do and may be able to achieve greater economies of scale, or establish contracts with payor groups on more favorable terms than we can. We also compete with smaller niche laboratories, like Prometheus Laboratories and Athena Diagnostics, that address a narrow segment of the esoteric market by offering very specific assay menus. Finally, institutions that are affiliated with large medical centers or universities, such as Mayo Medical Laboratories and Associated Regional University Pathologists, or ARUP, generally lack the advantages of larger commercial laboratories and compete with us in the esoteric market.

We believe that healthcare providers consider the following factors, among others, in selecting an esoteric clinical laboratory:

- accuracy, timeliness and consistency in reporting assay results;
- number and types of assays performed by the laboratory;
- ability to develop new and useful assays;
- service capability and quality;
- ability to transfer assay results electronically;
- reputation in the medical community;
- pricing of assay services; and
- reputation as a source of clinically useful, assay-related information.

We believe that we compete favorably with our principal competitors for esoteric testing services in these areas. However, we cannot assure you that we will maintain our competitive position in the future.

Quality Improvement

We maintain a comprehensive quality and process improvement program that monitors and evaluates performance to ensure accuracy and precision in pre-analytical, analytical, and post-analytical processes of clinical laboratory testing. The processes are documented with policies and procedures that are based upon nationally standardized guidelines on test performance and results interpretation. This also includes the routine monitoring of control results, and blind specimen submissions to assess accuracy and reproducibility. We believe that we have obtained all material approvals and licenses for

providing clinical laboratory testing services. We participate in numerous quality and proficiency testing programs, including the proficiency programs administered by the College of American Pathologists and other state, national and international programs. In addition, the laboratory participates in the College of American Pathologists Laboratory Accreditation Program, which requires inspection by outside experts and self-evaluation.

All laboratory testing and associated processes are described in written policies, procedures and validations under electronic document control. These documents include instructions for routine monitoring of quality control data, tolerance limits, and corrective actions taken if tolerance limits are exceeded.

Government Regulation

Antifraud Laws/Overpayments

Numerous federal and state laws provide for penalties in connection with improper billing practices involving healthcare services. Remedies under these laws include imprisonment, monetary penalties, multiples of damages, asset forfeitures, and exclusion from federal and state healthcare payment programs. These laws include, among others, the federal False Claims Act, which prohibits the submission of fraudulent claims in connection with Medicare, Medicaid and certain other governmental programs. Monetary penalties of up to $11,000 for each improper claim plus treble damages can be recovered under the False Claims Act. In addition to direct suits by the federal government, the False Claims Act authorizes private parties to bring suit on behalf of the government against providers and entitles such a person to a portion of any final recovery. In addition, the Social Security Act provides for civil monetary penalties of up to $10,000 for each service improperly billed for and recovery of treble damages for services which are fraudulently billed to the Medicare program or a Medicaid program. Providers convicted of any criminal offense relating to their provision of Medicare or Medicaid covered services or of certain felonies in connection with other private or governmental healthcare programs are subject to mandatory exclusion from the Medicare and Medicaid programs. In addition, the federal Centers for Medicare & Medicaid Services (CMS) may exclude from the Medicare and Medicaid programs any provider convicted under state or federal law of certain offenses relating to fraud or other misconduct in connection with the provision of health care services, or who has been subjected to a civil monetary penalty under the above-described provisions of the Social Security Act. CMS also may suspend Medicare payments to any provider it believes has engaged in fraudulent billing practices. Remedies generally similar to those described above are also available to state Medicaid programs, and California law also denies Medi-Cal enrollment to any provider that has entered into a settlement in lieu of conviction for fraud or abuse in any government program and further provides that a provider that is under investigation by certain government agencies for fraud or abuse shall be subject to temporary suspension from the Medi-Cal program.

The federal government has investigated and continues to investigate the billing practices of numerous clinical laboratories. Such investigations and related litigation have involved a broad range of issues, including the practices of laboratories of grouping tests into panels for billing and ordering purposes, the marketing of tests to physicians, billing for hematology tests and indices, billing for tests not performed, double billing, billing for tests which are not medically necessary, improper coding, and numerous other potentially improper practices. These investigations have resulted in all of the largest national independent laboratory companies, as well as many regional and local laboratories, having entered into settlement agreements in amounts that in several instances have exceeded $100 million. While most fraud enforcement activity has involved the Medicare and Medicaid programs, lawsuits by private insurance companies based upon fraud theories are also common. To our knowledge, we are not subject to any investigations or lawsuits alleging fraudulent billing practices. However, there can be no assurance that our activities will not be challenged under the fraud laws in the future.

Independent of fraud allegations, Medicare and Medicaid programs and private payors may retroactively determine that certain payments for services must be repaid due to a failure to satisfy applicable payor requirements. Significant delays in or recoupments of payments could have a material adverse effect on our revenues.

Laboratory/Physician/Hospital Relationships

"Self-Referral" Legislation. We are subject to "self-referral" prohibitions under federal Medicare law, commonly known as the Stark Law and to similar restrictions of California law, such as the Physician Ownership and Referral Act, which apply to referrals by California physicians. We are also subject to similar self-referral laws of several other states in which we conduct business. When taken together, these restrictions generally prohibit us from billing the patient or any governmental or private payor for any test when the physician ordering the test, or any relative of such physician, has an investment interest in, or compensation arrangement with us.

Both the Stark Law and the Physician Ownership and Referral Act contain an exception for referrals made by physicians who hold investment interests in a publicly traded company that has shareholders' equity of $75 million at the end of its most recent fiscal year, and satisfies certain other requirements. California's self-referral restrictions applicable to referrals of workers' compensation testing also contain a similar exception, except that this exemption requires that total gross assets at the end of the laboratory's most recent fiscal year has to be at least $100 million. At our fiscal years ended December 31, 2000 through 2005, our shareholders' equity and total assets exceeded $100 million, and we are therefore entitled to the benefit of the public company exemptions. However, the public company exemptions most likely were not available to us prior to January 1, 2000. Because many of our shareholders hold stock in the name of their stock brokerage firm, it may not have been possible for us to fully comply with the self-referral requirements prior to our qualifying for the public company exemptions. Despite the public company exemptions, we will need to monitor our compensation relationships with physicians under the self-referral laws on an on-going basis. For example, our provision of information technology support to physician customers must be carefully structured in order to comply with the self-referral laws. Laboratories which violate the Stark Law must refund any amounts collected in connection with prohibited referrals and are also subject to monetary penalties of $15,000 for each test improperly billed for and exclusion from the Medicare and Medicaid programs. In addition, billings for services where the referral was prohibited may be actionable under false claims statutes. Substantial penalties may also be imposed in the event of Physician Ownership and Referral Act violations. Although we believe that we are in compliance in all material respects with the Physician Ownership and Referral Act and the Stark Law, there can be no assurance that we will not be found to be in violation of these laws in the future. In addition, other states have self-referral restrictions with which we may have to comply that may differ from those imposed by federal and California law.

Extensive regulations implementing and interpreting certain provisions of the Stark Law have been released by CMS. Provisions contained in the regulations which define the types of indirect compensation relationships to which the Stark Law applies and which create new exceptions for certain types of financial relationships may have some relevance to us. In addition, the regulations interpret an exception under the Stark Law which allows laboratories to provide physicians with supplies used solely to collect, transport, process or store specimens. CMS believes this exception is limited to items of low value, such as single use needles, vials and specimen cups, and that biopsy needles, and similar items such as snares, reusable aspiration and injection needles and gloves, do not function solely as specimen collection devices, and therefore trigger the self-referral restrictions if they are provided without a fair market value charge. However, California's self-referral restrictions contain no exemption which would allow such items to be sold to physicians, even at fair market value, and a laboratory complying with CMS interpretations may be required to have its California physician customers obtain the restricted

types of supplies from third parties. The Stark Law regulations also acknowledge that a laboratory's provision of the services of a phlebotomist without charge is permitted so long as the phlebotomist performs solely laboratory functions for the laboratory providing the phlebotomist.

Anti-kickback Laws. The federal Medicare/Medicaid anti-kickback statute prohibits laboratories from paying remuneration as inducement for referrals of patients or specimens for testing paid for by the Medicare or Medicaid programs. Certain practices that might otherwise violate the anti-kickback statute are protected under certain "safe harbor" regulations which have been promulgated by Medicare's Office of Inspector General (OIG). Based upon a federal court decision specifically considering physician ownership of laboratories and an anti-kickback safe harbor regulation applicable to investments in certain publicly traded companies, we believe that a challenge to physician investments in our company is unlikely.

A number of business practices in the clinical laboratory industry have been criticized by the OIG, including the provision of phlebotomy or processing staff to clients who perform clerical or other functions for the client which are not directly and solely related to the collection or processing of laboratory specimens, the provision of computers or fax machines to clients which are not used exclusively in connection with performance of the laboratory's work, the lease of space in a physician's office for rent which exceeds the fair rental value of such space, certain acquisition agreements where the sellers may make referrals to the buyer after the sale and other compensation relationships between laboratories and entities from which they receive referrals, or to which they make referrals, if such relationships are intended to induce referrals. In addition, the OIG has indicated that discounts given by laboratories to clients with respect to their private pay patients and/or HMO patients must not be intended to induce referrals of Medicare or Medicaid patients by the client to the laboratory. Our business practices are governed by the anti-kickback laws, including our negotiated discounted pricing arrangements, our participation in group purchasing organizations and provision of information technology to our customers. We believe the Office of Inspector General's concerns regarding discounts should not apply to us, in part because statutory exceptions and safe harbor regulations are available to protect certain discounts offered to customers. We also believe that certain payments we make to group purchasing organizations are protected under a safe harbor regulation.

Many states, including California, also prohibit payments from being given to physicians, hospitals or others by clinical laboratories as compensation or inducement for referrals of patients or test specimens, regardless of the source of payment for such testing. In addition, laboratories offering pricing to their customers that is more favorable than that offered directly to patients may be deemed to pay prohibited kickbacks under state laws. However, we believe that a kickback will not result under California law if the laboratory's customer passes all of such discount to its patients in the form of lower testing charges. Because we expect our California customers to comply with the "pass through" requirements applicable to them, we do not believe that any favorable pricing we offer to California physicians or hospitals violates California's anti-kickback laws. However, it is possible that markups by our non-California customers who are not bound by anti-markup restrictions may implicate anti-kickback laws.

Any action taken against us under the Medicare/Medicaid anti-kickback statute could result in criminal penalties being imposed, civil monetary penalties of $50,000 per violation plus treble damages, and exclusion from Medicare and Medicaid participation. Laboratories that violate the California anti-kickback laws or similar anti-kickback, anti-markup, or direct billing laws of other states may be subject to loss of licensure and substantial fines.

While we believe that we are in compliance in all material respects with the anti-kickback statutes, there can be no assurance that our relationships with physicians, hospitals and other customers will not be subject to investigation or a successful challenge under such laws. If imposed for any reason, sanctions under the anti-kickback laws could have a material adverse effect on our business.

Certification and Licenses

We are required to maintain various federal and state licenses, certifications and permits. Our laboratory is certified pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), which subject clinical laboratories to national standards. Because of the location of our laboratory in Valencia, licensure is also required under the laws of the State of California. Since we perform testing for patients from all states, we hold licenses in additional states where such licensure is required by local state law, including Florida, Maryland, New Hampshire, New York, Pennsylvania, Ohio, West Virginia, and Rhode Island. We will apply for licenses in other states as needed, and if and when other states require licensure of out-of-state laboratories, we may need to obtain additional state licenses. Our laboratory is also accredited by the College of American Pathologists, a private accrediting agency that has deemed status under CLIA.

The federal and state agencies have established requirements and detailed specifications for the day-to-day operation of a clinical laboratory. These requirements address: training, education, and competency of testing and supervisory personnel; design and implementation of a scientific quality control program; documents that fully characterize method performance (validations) and execution (procedures); and a comprehensive quality improvement program. In addition, federal law mandates performance in a graded and CLIA-approved proficiency testing program. This involves testing of unknown specimens that have been specifically prepared for the laboratory to evaluate performance. If a laboratory is out of compliance with CLIA or other applicable requirements, CMS and/or the California Department of Health Services (CDHS) may assess substantial civil money penalties, restrict tests that the laboratory may perform, impose specific corrective action plans, suspend the laboratory's approval to receive Medicare and Medicaid payments, and/or suspend, revoke or limit the laboratory's CLIA certificate or state license. If a laboratory's CLIA certificate or state license is suspended or revoked, its ability to perform further testing is terminated. In addition, certain types of non-compliance may make a laboratory's services ineligible for reimbursement under Medicare and/or Medicaid programs, even in the absence of any formal enforcement action. Sanctions imposed by individual states may restrict testing for residents of that state.

We previously received sanctions based on alleged failures to comply with certain state and federal regulations, and we will be subject to additional future inspections. We can provide no assurances that our facilities will pass all future inspections conducted to ensure compliance with federal or any other applicable licensure or certification laws.

Compliance

We have reviewed the pertinent regulations of CLIA and related rulings and policy guidelines and believe that our business practices adhere to the stated requirements in all material respects. We will continue to monitor legislation and implement required guidelines or regulations. However, there can be no guarantee that we will pass all future inspections or otherwise be found to be in full compliance with these and other regulations.

In addition, the Department of Health and Human Services' (HHS) Office of the Inspector General has suggested that laboratories adopt a written compliance plan to promote standards of ethics and business practice that will help to prevent fraudulent conduct. We have adopted such a compliance plan, and have two Compliance Officers to assist us with our compliance with these ethics and business practices, as well as applicable state and federal regulations relating to billing, structuring of relationships between ourselves and our partners and clients, and with other non-CLIA requirements.

Regulation of Genetic Testing

The federal Food and Drug Administration (FDA) regulates the manufacture of medical devices, including laboratory testing equipment, diagnostic kits and certain reagents. While the FDA believes

that it has authority to regulate tests developed by laboratories for their own use, the FDA, to date, has allowed the development of such tests to proceed under the regulations under CLIA governing a laboratory's development of its own assays. The FDA has also subjected the commercialization of certain immunohistochemical stains, tumor markers and analyte specific reagents to limited regulation, and requires us to make certain disclosures in connection with their use. In addition, the FDA has announced that it is evaluating whether it should regulate analyte specific reagents as either Class II or Class III medical devices. Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. If the FDA seeks to regulate in-house genetic testing, depending the nature and scope of such regulation, it could have detrimental effect on our business. At the state level, the New York State Department of Health now requires detailed review of our scientific validations and technical procedures for each assay before approval for New York residents. This level of scrutiny delays test availability in New York.

Other Regulations

Pursuant to the Occupational Safety and Health Act (OSHA), laboratories must provide a safe workplace to their employees. In response to this requirement, OSHA has issued rules and regulations to protect workers from blood-borne pathogens and other hazards that are commonly found in laboratories. We are also subject to licensing and regulation under federal, state and local laws relating to the handling and disposal of medical specimens, hazardous waste and radioactive materials. We are also subject to regulations of the Department of Transportation, the Public Health Service's Centers for Disease Control & Prevention and the Postal Service which apply to the surface and air transportation of laboratory specimens. Although we believe that we are currently in compliance in all material respects with the above laws, failure to comply could subject us to denial of the right to conduct business, fines, criminal penalties and other enforcement actions.

Changes in Laboratory Reimbursement

Health Care Reform

A number of proposals aimed at reducing healthcare costs or increasing healthcare insurance coverage have been considered in recent years which, if enacted, would have affected major reforms of the healthcare system. Such proposals include: decreases in reimbursement amounts, increased enrollment of Medicare and Medicaid beneficiaries in managed care systems, increased availability of health insurance to individuals and to small businesses, requirements that all businesses offer health insurance coverage to their employees, the provision of tax credits for purchase of health insurance, the formation of regional "health alliances" to act as healthcare purchasing agents and the creation of a government health insurance plan that would cover all citizens. We cannot predict whether any of these or other proposals will be adopted at the state or federal levels, or what effect, if any, such proposals would have on our business.

Reductions to Medicare or Medicaid Fee Schedules

For testing performed other than for hospitals, nursing facilities and other laboratories, laboratories are required to bill Medicare and Medicaid directly, and generally must accept reimbursement from these programs as payment in full for services performed for Medicare and Medicaid patients. During 2002, 2003 and 2004 such direct billings by us to Medicare as a percentage of our net revenue accounted for approximately 2.9%, 4.0% and 4.6%, respectively. As a percentage of our net revenue, billings by us to Medicaid during 2002, 2003 and 2004 accounted for approximately 1.9%, 2.5% and 2.6%, respectively. However, a substantial portion of the testing for which we bill our hospital and independent laboratory customers is for Medicare and Medicaid patients, and we do not

know the percentages of our net revenue that are indirectly derived from these programs. Any pricing pressure exerted by these programs on our customers may cause them to reduce their payments to us.

Congress has established maximum fee schedules for clinical laboratory testing performed for Medicare beneficiaries, excluding hospital and nursing facility patients. Payment by Medicare for laboratory services performed for hospital inpatients and outpatients and for nursing facility inpatients is included in the prospective payment rates paid to the patient's facility. State Medicaid programs are prohibited from paying more for testing than the Medicare fee schedule amounts and, in most instances, they pay significantly less. When initially established, the Medicare fee schedules were set at 60% of prevailing local charges. Maximum reimbursement rates for clinical laboratory testing have subsequently been substantially reduced, and it could be expected that such fee schedules would be further reduced in the future. For example, a ceiling on Medicare and Medicaid payments to laboratories commonly referred to as the "national cap" amount has been reduced numerous times in recent years, and most recently was set by Congress at 74% of the national median of local fee schedules. However, while Congress eliminated consumer price index increases to the national cap and local fee schedules from 1998 through 2002 and 2004 through 2008, a 1.1% inflation increase to the fee schedules (and therefore also to the national cap) was made for 2003. Medicare reimbursement has also been reduced from time to time by an effective rate of between 1% and 2% pursuant to Gramm-Rudman-Hollings sequestration. In addition, from time to time, proposals have been made that beneficiary cost sharing again be applied to laboratory testing paid for by Medicare. If such a proposal were adopted, the costs of billing and collecting co-payment amounts and associated bad debt could reduce the revenue actually realized by laboratories.

In December 2002, the Centers for Medicare & Medicaid Services ("CMS") issued a new Interim Final Rule which sets forth the process for establishing a "realistic and equitable" payment amount for all Medicare Part B services (except physician services and services paid under a prospective payment system) when the existing payment amounts are determined to be inherently unreasonable because they are either "grossly excessive or deficient." We cannot predict what effect, if any, this rule and its implementation will have on our business.

Current economic conditions have caused many states to face substantial budget shortfalls. As a result, many states are considering reducing payments made to providers of health care services by their Medicaid programs. For example, the 2003-2004 California State Budget called for a 5% reduction in Medi-Cal reimbursement effective January 1, 2004. However, laboratories were exempted from those cuts, and the cuts were not made to other providers based on a court injunction issued in December 2003 citing potential beneficiary access problems. Nevertheless, some cuts to laboratory payments resulted from the enactment of an across the board cap on Medi-Cal reimbursement for laboratory services to a rate of 80% of the Medicare payment rates for the same tests. While reductions to Medi-Cal payments to laboratories and other providers were again proposed for the 2004-2005 budget, concerns over the injunction led to no cuts being made. A major redesign of the Medi-Cal program has been proposed as part of the 2005-2006 budget. Direct reductions to provider payments are not part of this proposed redesign. However, an increased emphasis on managed care programs would shift Medi-Cal enrollees into managed care programs, which typically pay less to laboratories than does the Medi-Cal fee-for-service program, and a proposal to impose premiums on certain Medi-Cal enrollees could cause them to elect not to have Medi-Cal coverage at all. As a result, substantial reductions may be made in the future to our Medi-Cal reimbursements, and it is possible that we will face substantial reductions in the reimbursement which we receive under other states' Medicaid programs as well.

Medicare Reimbursement for Technical Component of Hospital Pathology Services. In the past, independent laboratories have been permitted to bill for the technical component of certain pathology services which are performed for Medicare hospital patients. CMS promulgated regulations to end such separate billing as of January 1, 2001. The Medicare Prescription Drug, Improvement and

Modernization Act delayed implementation of the CMS rules until January 1, 2007 for hospitals who had qualifying outsourcing contracts for pathology services in place as of July 22, 1999. Any such services we perform for hospitals without qualifying arrangements or after the new requirements become effective will have to be billed to the patient's hospital. Hospitals will receive no additional reimbursement from Medicare for these pathology services provided to inpatients, and reimbursement for these services under the new outpatient prospective payment system may be lower than it was previously. Such changes therefore may result in a reduction in the payments we receive from hospitals for these services.

Elimination of Dual Charge Structure. Proposals have been made to restrict "dual charge" billing practices under which laboratories charge higher fees to Medicare and Medicaid than are charged to physicians, hospitals, laboratories and other purchasers who are in a position to negotiate favorable rates. Thus, it has been proposed that existing authority for HHS to exclude from Medicare and Medicaid program participation any providers that charge amounts to the Medicare program that are "substantially in excess" of their "usual charges" be used to respond to laboratory pricing practices. The Office of the Inspector General of the Department of Health and Human Services has proposed regulations which would implement this authority. As proposed, certain discounts we negotiate with our private clients would be taken into account by these regulations in setting the maximum amounts that we could bill to the Medicare program. The regulations could therefore require us to lower our charges to the Medicare program or to increase our charges to our clients, or a combination of both. We cannot predict what effect, if any, this rule and its implementation will have on our business. Similarly, CMS is permitted to adjust statutorily prescribed fees for some medical services, including clinical laboratory services, if the fees are grossly excessive and therefore not inherently reasonable. CMS has issued an interim final rule setting forth criteria to be used in determining whether the otherwise statutorily prescribed fees should be reduced which includes consideration of whether such fees are grossly higher or lower than the payment made for the services by other purchasers in the same locality. Fees payable by Medicare for clinical laboratory services may be reduced as a result of the application of the above rules or by similar restrictions which may be applied in the future.

In addition, the California Medi-Cal program is required by California regulations to pay no more for testing than the amount which a laboratory charges pursuant to any fee schedule it applies generally to its physician or hospital customers. While the extent to which this rule applies to our discounts which are negotiated on a case-by-case basis is unclear, it is possible that a recoupment action could be bought against us based upon discounts which we give to certain customers.

Contracts for Laboratory Services. The Secretary of the Department of Health and Human Services has been directed to conduct several pilot projects to examine payment alternatives to the traditional Medicare Part B fee schedule. Among the projects is a competitive demonstration project for independent laboratory services. The Secretary is to provide a progress report to Congress by December 31, 2005, although no date has been set for implementation. Similarly, California legislation enacted several years ago required the implementation of a program of negotiated laboratory service contracting for the Medi-Cal program. The Medi-Cal program has moved forward in implementing a contracting program. This first phase of Medi-Cal laboratory contracting does not contemplate a competitive bidding process. We have submitted an application to contract with the Medi-Cal program pursuant to its submission protocol. While it is expected that contracts will be awarded to many laboratories within California, there can be no assurance that we will be awarded a contract.

There is at least one competitive Medicaid bidding demonstration project underway that may result in only one laboratory being reimbursed for the provision of laboratory services to an entire state's Medicaid population. It is possible that in the future, other competitive bidding demonstration projects in other states or pursuant to other Medicaid programs may also award contracts to a sole-source vendor. In the event we are not allowed to participate in such awarded competitive bidding contracts or

are otherwise not awarded such contracts, we may not be reimbursed for testing we perform for Medicaid patients in these states.

In addition, a large portion of the Medi-Cal program has been converted into a managed care system, resulting in negotiated laboratory service contracts between laboratories and other providers of healthcare services. There has also been a push to enroll more Medicare beneficiaries in Medicare HMO plans. Increased enrollment of Medicare or Medicaid beneficiaries in HMOs or negotiated contracting arrangements may also result in a larger portion of our business being subject to negotiated contracts with payors.

So far, Medi-Cal laboratory contracting has not set negotiated payment rates. However, to obtain contracts to perform Medicare, Medi-Cal or Medicaid services in the future, it might be necessary for us to engage in competitive bidding and to agree to substantial reductions in our payments from these programs. Such contracts may be exclusive and laboratories which do not hold such contracts may be denied access to the Medicare/Medi-Cal/Medicaid testing market and could have difficulty obtaining private patient testing from physicians participating in the contracting or managed care program.

Nongovernmental Efforts. Managed care arrangements may become increasingly prevalent in the clinical laboratory services market. For example, HMOs, insurance companies and self-insured employers may provide laboratory services directly or contract with laboratories at favorable fee-for-service or capitated rates and require their enrollees to obtain service only from such contracted laboratories. To the extent that our customers or we are unable to obtain contracts to provide such testing services or must discount prices to obtain such contracts, our revenues and profit margins could be adversely affected.

Requirements of Diagnosis Codes

Certain tests are only reimbursable by Medicare when the laboratory submits an appropriate diagnosis code which it has obtained from the ordering physician. California's Medicaid program, known as Medi-Cal, has also adopted a policy requiring that a diagnosis code be submitted in connection with all bills for laboratory tests which are submitted to the Medi-Cal program where Medicare would require a diagnosis code if it were being billed for the tests. To the extent that the requirements for such diagnosis codes are expanded to additional tests or are adopted by additional Medicaid programs or by private insurance programs, or we are unable to obtain required codes from physicians, our reimbursement could be adversely affected.

Privacy of Medical Information

The confidentiality of patient medical information is subject to substantial regulation by state and the federal governments. Specific state and federal laws and regulations govern both the disclosure and use of confidential patient medical information, as well as access of patients to their own medical records. Similarly, many other federal laws also may protect such information, including the Electronic Communications Privacy Act of 1986 and federal laws relating to confidentiality of genetic testing results, mental health records and substance abuse treatment records.

Congress passed the Health Insurance Portability and Accountability Act, known as HIPAA, in 1996. Among other things, HIPAA calls for the establishment of national standards to facilitate the electronic exchange of health information and to maintain the security of both the health information and the system that enables the exchange of this information. HHS has promulgated numerous regulations pursuant to its authority under HIPAA, including regulations that pertain to the security of individually identifiable health information that is electronically maintained or transmitted and the privacy of individually identifiable health information that is transmitted, received and maintained in any form or medium. Pursuant to these regulations, all medical records and other patient identifiable health information must be maintained in confidence, must not be used for non-health purposes and

must be disclosed to the minimum extent required. In addition, patients must be given a clear notice of their rights and access to their records by laboratories (other than to the extent that access to their records is restricted by CLIA and by state law) and, unless permitted by applicable laws or regulations, a patient's authorization generally must be obtained before information is released. To ensure that these requirements are satisfied, covered entities must adopt appropriate policies and practices, designate a privacy officer, train employees and establish a grievance procedure. The privacy regulations recognize, however, that laboratories have little direct contact with patients, and therefore they allow healthcare providers with an indirect treatment relationship with the patient to use protected health information for purposes of treatment and health care operations without a separate consent. Nonetheless, laboratories still have to directly address HIPAA regulations in other circumstances.

In most circumstances, entities covered by HIPAA must have been or be in compliance with the HIPAA regulations by the following compliance dates: (1) privacy regulations by April 14, 2003; (2) electronic transactions regulations by October 16, 2003 (if, like us, the organization covered by HIPAA filed for an extension); and (3) security regulations by April 21, 2005. While we believe that we are in compliance in all material respects with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information, including HIPAA, our failure to comply could subject us to fines and penalties, and have a detrimental effect on our business. We may be subject to inspections or investigations by state or federal regulatory entities that enforce privacy laws and regulations, and we can provide no assurances that we will be found fully compliant with HIPAA or other related laws and regulation. If we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties. Because laboratory orders and reports fall within the scope of HIPAA, the costs of HIPAA compliance will impact us and others in the clinical laboratory industry. Compliance with the HIPAA rules could require us to spend substantial sums, which could negatively impact our profitability. At this time, we cannot assess the total financial or other impact of the HIPAA regulations upon us.

Employees

As of December 31, 2004, we employed 689 individuals, including 136 in administration and clerical functions, 55 in sales and marketing, 32 in information technology and 454 in our clinical laboratory and related operations. None of our employees are represented by labor unions, and we believe our employee relations are good.

RISK FACTORS

This Annual Report contains forward-looking statements based on our current expectations, assumptions, estimates and projections about Specialty Laboratories, Inc. and the esoteric clinical laboratory industry. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those discussed in these forward-looking statements as a result of certain factors, as more fully described in this section and elsewhere in this Annual Report. If any of these risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially adversely affected. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business. Any adverse effect on our business, financial condition or results of operations could result in a decline in the trading price of our common stock and the loss of all or part of your investment.

Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed.

As a provider of healthcare-related services, we are subject to extensive and frequently changing federal, state and local laws and regulations governing licensure, billing, financial relationships, referrals, conduct of operations, purchases of existing businesses, cost-containment, direct employment of licensed professionals by business corporations and other aspects of our business relationships.

If we do not comply with existing or additional laws or regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing laws or regulations, or new laws or regulations, may delay or prevent us from marketing our products or cause us to reduce our pricing.

Fraud and Abuse

Of particular importance to our operations are federal and state laws prohibiting fraudulent billing and providing for the recoupment of non-fraudulent overpayments, as a large number of laboratories have been forced by the federal and state governments, as well as by private payors, to enter into substantial settlements under these laws. Government investigations of clinical laboratories have been ongoing for a number of years and are expected to continue in the future. Written "corporate compliance" programs to actively monitor compliance with fraud laws and other regulatory requirements are recommended by the Department of Health and Human Services' Office of the Inspector General and we have a program following the guidelines in place.

Federal and State Clinical Laboratory Licensing

The operations of our clinical laboratory are highly regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). For certification under CLIA, laboratories such as ours must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. Since we perform patient testing from all states, our laboratory is also regulated by California, New York and various other states. We are accredited by the College of American Pathologists, a private accrediting agency, and are also subject to their accreditation requirements and evaluation. Our failure or inability to comply with CLIA, state or other applicable requirements could result in various penalties, including restrictions on tests the laboratory may perform, substantial civil monetary penalties, imposition of specific corrective action plans, suspension of Medicare payments and/or loss of licensure, certification or accreditation. Such penalties could result in our being unable to continue performing laboratory testing. Compliance with such standards is verified by periodic inspections and requires participation in proficiency testing programs.

In June and October 2001, we underwent unannounced inspections by CDHS representing both the State of California and acting as agent of CMS under CLIA. Based upon these inspections, and

findings that we were permitting unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law, in 2002 CDHS and CMS separately imposed sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed, and civil money penalties.

After filing supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, CDHS conducted additional unannounced inspections, and we provided additional documentation supporting our compliance with CDHS requirements. CDHS subsequently indicated that we were in substantial compliance with California clinical laboratory law, and CMS also notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA. CDHS and CMS assessed civil money penalties in excess of $700,000, and we did not challenge the penalties.

We will be subject to additional future inspections. No assurances can be given that our facilities will pass all future inspections conducted to ensure compliance with federal or any other applicable licensure or certification laws. Any inability to comply with federal, state or other applicable regulations could result in substantial monetary penalties, suspension of Medicare and/or Medicaid payments and/or loss of licensure, certification or accreditation, and could divert a substantial amount of management's time and resources. In addition, substantial expenditures are required on an ongoing basis to ensure that we comply with existing regulations and to bring us into compliance with newly instituted regulations.

Food & Drug Administration

Neither the FDA nor any other governmental agency currently fully regulates the new assays we internally develop. Although the FDA previously asserted that its jurisdiction extends to tests generated in a clinical laboratory, it has allowed these tests to be run and the results commercialized without FDA premarket approval. Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. If the FDA seeks to regulate in-house genetic testing, depending the nature and scope of such regulation, it could have a detrimental effect on our business. We cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require premarketing clearance. Hence, we might be subject in the future to greater regulation, or different regulations, that could have a material effect on our finances and operations.

The FDA has also asserted that its jurisdiction includes the ability to inspect our facilities in connection with certain testing we do for blood donation and collection centers. An inspector from the FDA conducted an unannounced site inspection of our laboratory facilities in 2003 and 2004 in connection with this testing for blood centers. The FDA inspector's report of these inspections did not indicate any material issues or deficiencies of our facilities. However, we will likely be subject to future FDA inspections, and no assurances can be given that our facilities will satisfactorily pass all such inspections. Any inability to comply with applicable FDA regulations could result in substantial monetary penalties, revocation of our FDA registration, suspension or cancellation of our ability to conduct testing for blood donation and collection centers, and could divert a substantial amount of management's time and resources, and any such action could materially harm our business.

Anti-Kickback Regulations

Existing federal laws governing Medicare and Medicaid and other similar state laws impose a variety of broadly described restrictions on financial relationships among healthcare providers, including clinical laboratories. These laws include federal anti-kickback laws which prohibit clinical laboratories

from, among other things, making payments or furnishing other benefits intended to induce the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. In addition, they also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal healthcare programs, and criminal and civil fines and penalties.

Fee-Splitting

The laws of many states prohibit physicians from sharing professional fees with non-physicians and prohibit non-physician entities, such as us, from practicing medicine and from employing physicians to practice medicine. If we do not comply with existing or additional regulations, or if we incur penalties, it could increase our expenses, prevent us from increasing net revenue, or hinder our ability to conduct our business. In addition, changes in existing regulations or new regulations may delay or prevent us from marketing our products or cause us to reduce our pricing.

Our accessions have declined in the past, and may decline again in future periods.

Because of uncertainty surrounding the sanctions imposed on us by CMS in 2002, questions about our clients' ability to bill for services we performed for them, and a reduction in the number of assays we offer, some of our clients suspended or stopped sending us specimens for testing. As a result, our total accessions declined in 2002 and 2003. While our accession volumes rose in 2004, we cannot provide any assurances that our clients will continue sending us specimens for testing due to a variety of factors, including competition from other reference laboratories and our clients internalizing testing we now perform for them. We also cannot provide assurances that our accessions will continue increasing, and they may decline again. If our accessions decline again, or if they fail to continue increasing, it could materially adversely affect our business, financial condition, results of operations and prospects.

Some of our customers are also our primary competitors. If they reduce or discontinue purchasing our assays for competitive reasons, it will reduce our net revenue.

Some of our customers, such as Quest, LabCorp and ARUP, also compete with us by providing specialized testing services. They often refer assays to us that they either cannot or elect not to perform themselves. During 2002, we saw a significant decline in test volumes referred to us from our competitors. Sales to our competitors were approximately 4% of our net revenue for each of the years ended December 31, 2002, 2003 and 2004. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours, and we may experience a further decline in our net revenues from these competitors. For example, in April 2002, Quest announced that they had entered into a definitive agreement to acquire Unilab Corporation. As a result, we experienced a significant decline in testing volumes sent to us from Unilab. We previously experienced a significant reduction in volume from Quest, LabCorp, Mayo and ARUP, and if these or other laboratories decide to reduce or discontinue purchases of our assays for competitive or other reasons, it will reduce the number of our accessions and reduce our net revenue.

The clinical laboratory industry is intensely competitive, and we may be unable to successfully compete.

The esoteric clinical laboratory industry is highly competitive. This industry is dominated by several national independent laboratories, but includes many smaller niche and regional independent laboratories as well. Our primary competitors include:

- large commercial enterprises, such as Quest Diagnostics, or Quest, and Laboratory Corporation of America, or LabCorp, that offer a wide test and product menu on a national scale;
- smaller niche laboratories like Prometheus Laboratories or Athena Diagnostics that focus on a narrow segment of the market for specialized testing; and
- institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or ARUP, that are affiliated with large medical centers or universities.

Large commercial enterprises, including Quest and LabCorp, have substantially greater financial resources and may have larger research and development programs and more sales and marketing channels than we do, enabling them to potentially develop and market competing assays. These enterprises may also be able to achieve greater economies of scale or establish contracts with payor groups on more favorable terms. Smaller niche laboratories compete with us based on their reputation for offering a narrow test menu. Academic and regional institutions generally lack the advantages of the larger commercial laboratories but still compete with us on a limited basis.

Any of our competitors may successfully develop and market assays that are either superior to, or are introduced prior to, our assays. If we do not compete effectively with other independent clinical laboratories, we may be unable to maintain or grow our revenues.

Intense competition and consolidation in our industry could materially adversely affect our business, financial condition, results of operations and prospects.

The clinical laboratory industry is intensely competitive and fragmented. Our current competitors include large national laboratories that offer a wide test and product menu on a national scale as well as smaller niche and regional organizations. Some of our large competitors have expanded, and may continue to expand, their competitive product offerings through acquisitions. For example, Quest, the nation's leading provider of diagnostic testing and related services for the healthcare industry, acquired American Medical Laboratories Incorporated, a national provider of esoteric testing to hospitals and specialty physicians, Clinical Diagnostic Services, Inc., a provider of routine and esoteric testing, and Unilab Corporation, a leading clinical testing laboratory. LabCorp acquired Dianon Systems Inc., a leading U.S. provider of anatomic pathology and oncology testing services. More recently, LabCorp announced the acquisition of U.S. Labs, a cancer testing provider. Acquisitions among existing and future competitors may allow them to rapidly gain greater market share. In addition, some of our customers refer assays to us that they cannot perform themselves. These customers may no longer need to refer assays to us if they develop assays similar to us through the acquisition of other esoteric laboratories. A loss of business and customers from such acquisitions could materially adversely affect our business, financial condition, results of operations and prospects.

Our quarterly operating results may fluctuate and this could cause our stock price to fluctuate or decline.

Our quarterly operating results have varied significantly in the past and may vary significantly in the future. If our quarterly net revenue and operating results fall below the expectations of securities analysts and investors, the market price of our common stock could fall substantially. Operating results

vary depending on a number of factors, many of which are outside our control, including, but not limited to:

- demand for our testing and ancillary services;
- loss of a significant customer or group purchasing organization contract;
- new assay introductions by competitors;
- changes in our pricing policies or those of our competitors;
- the hiring and retention of key personnel;
- our ability, and that of our clients, to bill and to collect from Medicare and Medicaid programs for our services;
- changes in healthcare laws and regulations;
- costs of reagents and supplies, as well as other operating costs;
- costs related to acquisitions of technologies or businesses
- the impacts of possible service disruptions; and
- the effect of litigation.

Due to these and other factors, results of operations and quarterly revenues are difficult to forecast, and we believe that period-to-period comparisons of our operating results are neither meaningful nor predictive of future performance. In one or more future quarters our results of operations may fall below the expectations of securities analysis and investors. In that event, the trading price of our common stock would likely decline.

In addition, the trading price of our common stock may materially decline regardless of our operating results and performance. The market price of our common stock has been subject to significant fluctuations since our initial public offering in December 2000. The stock market has experienced significant price and volume fluctuations that have affected the market prices of securities, including securities of clinical laboratory, biotechnology and other health care service companies. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. As previously announced, such securities claims were filed against us in 2002 and have since been settled. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurance that we will not face any similar future actions.

We plan to expand our sales and marketing efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, financial condition, results of operations, or cash flows could be materially harmed and operating results in a given quarter could be worse than expected.

For a more detailed description of our operating results, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations" above.

Our net revenue will be diminished if payors do not authorize reimbursement for our services.

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the reimbursement status of new assays. Third party payors, including state payors and Medicare, are challenging the prices charged for medical products and services. Government and other third party payors increasingly are limiting both

coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. In 2002, 2003 and 2004, third party payors accounted for approximately 6.6%, 8.3% and 9.3%, respectively, of our net revenue. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payors and we do not know the percentage of our net revenue that is indirectly derived from these payors. Any pricing pressure exerted by these third party payors on our customers may, in turn, be exerted by our customers on us. If government and other third party payors do not provide adequate coverage and reimbursement for our assays, our net revenue may decline.

Requirements for competitive bidding procurement of Medicare/Medicaid laboratory testing services could exclude us from providing testing to certain patients.

Proposals have been made to require competitive bidding procurement of Medicare laboratory testing services. The Centers for Medicare and Medicaid Services (CMS) has recently selected a vendor to begin a demonstration project of a competitive bidding for clinical laboratory services, although the project has not yet begun. A competitive Medicaid bidding proposal was made in Florida (and later withdrawn) that would permit only one laboratory to provide services as the sole vendor under the contract. It is possible that other future competitive bidding demonstration projects may also award the contract to a sole-source vendor. We can provide no assurances that future competitive bidding processes will allow us to compete successfully for the Medicare/Medicaid contracts. In the event that we are not successful in the competitive bidding process, or are otherwise not allowed to participate in such awarded competitive bidding contracts, we may not be reimbursed for testing we perform for Medicaid patients in these states. Any restriction on our ability do testing for Medicare/Medicaid patients, or be reimbursed for testing we perform for such patients, could materially affect our revenue and business. Any restriction on our ability to do testing for Florida Medicaid patients could also significantly negatively affect the amount of business we receive from our Florida clients, as such clients might be less inclined to divide the work they send to outside reference laboratories. Loss of business from our Florida clients could materially affect our revenue and business.

Increasing restrictions in government-funded payment programs, and reductions in government-funded spending on laboratory testing reimbursement, could restrict or exclude us from providing testing to certain patients, and could materially affect our revenue and business.

Recent state and federal budget constraints have forced cuts in many government-funded payment and reimbursement programs. For example, in 2004, California implemented a reduction of approximately 10% in the reimbursement schedule for laboratory testing performed for Medi-Cal patients. Florida has recently proposed an alternative to a competitive bidding sole-source process that would reduce its fee schedule by 10%. Other states may make similar or larger reductions in reimbursement schedules. Such reductions could cumulatively have a material negative effect on our business and net revenue. Furthermore, some states are implementing increased restrictions on healthcare providers' access to such payment programs, including sole-source contracts and restrictions based on past regulatory issues. While we currently believe that such restrictions should not exclude us from participation in such programs, we can provide no guarantees that we will not be excluded from, or have reduced access to, such programs. For example, because of our past regulatory issues with the California Department of Health Services and the Centers for Medicare and Medicaid Services, we could be prohibited from bidding on certain bidding projects or proposals. In the event we are excluded from, or have reduced access to, any government-sponsored payment program, it could have material negative effect on our revenue and on our business.

Our effective tax rate may fluctuate and we may not be able to fully realize all or a portion of our deferred tax assets.

We reported $5,864,000 of deferred income taxes (current and long-term) in the December 31, 2004 balance sheet, with approximately $15,187,000 of this amount related to federal and state net operating loss carryforwards (NOL's). Statement of Financial Accounting Standards No. 109, "*Accounting for Income Taxes*", requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. Our valuation allowance totaled approximately $7.2 million at December 31, 2004. Realization of the NOL's generated through December 31, 2004 is dependent on our ability to generate approximately $33.5 million of federal and $42.8 million of state ordinary income in future years. We cannot provide any assurances that the NOL's will be realized. Inability to generate the necessary ordinary income, and our inability to realize the NOL's, could have a material adverse effect on our results of operations in future quarters. The federal NOL's begin expiring in 2024 and the state NOL's begin expiring in 2014.

If we lose key personnel or cannot recruit additional personnel, our business may suffer.

We depend substantially on the continued services and performance of our senior management and certain other key personnel. While we have employment agreements with our executive officers and other members of our current senior management group, the loss of the services of any of these executive officers or other key employees could hurt our business.

On February 14, 2005 we announced the departure of Douglas S. Harrington, M.D., our chief executive officer and laboratory director, effective March 29, 2005. While we have engaged a search firm to assist us in locating a new chief executive officer, we may not be able to promptly identify and recruit a suitable candidate.

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate other highly skilled technical, managerial, marketing and customer personnel, including California licensed laboratory scientists. Competition for such personnel is intense. We may not be able to attract, assimilate or retain sufficient qualified personnel. In particular, we may encounter difficulties in attracting a sufficient number of qualified California licensed laboratory scientists. Additionally, we may not be able to retain and attract necessary highly skilled technical, managerial, marketing and customer personnel at our new laboratory and operational headquarters facility in Valencia, California, which is approximately 30 miles from our former laboratory location in Santa Monica, California.

Any failure to retain and attract necessary personnel, including a new chief executive officer, could hurt our business and impair our growth strategy.

If group purchasing organizations do not renew and maintain our contracts, we may lose an important mechanism by which to further penetrate the hospital customer base.

Many of our existing and potential hospital customers are part of group purchasing organizations, which typically pool independent hospitals together to negotiate for pricing and services, including prices for laboratory tests. These group purchasing organizations provide incentives to their participating hospitals to utilize clinical laboratories which have contracts with the group purchasing organizations.

Our participation in group purchasing organizations constitutes one aspect of our overall strategy to attract new hospital customers. We have contracts with several group purchasing organizations: AmeriNet, Consorta, MedAssets HSCA (formerly Health Services Corporation of America), Managed Healthcare Associates (MHA), Novation, Premier Purchasing Partners, and Shared Services Healthcare (now affiliated with MedAssets HSCA). We are typically granted non-exclusive provider status under

these contracts. Our contracts with our group purchasing organizations will expire at various times from 2005 to 2009.

If our agreement with any group purchasing organization is terminated or not renewed, we may not be able to retain any of the accounts of their participating hospitals. If any hospital customer affiliated with a group purchasing organization no longer uses our services, it will reduce our net revenue. In addition, if we are unable to attract new hospital customers because any group purchasing organization contract is terminated, it may adversely affect our ability to grow our business.

If advances in technology allow others to perform assays similar to ours, the demand for our assays may decrease.

The field of specialized clinical laboratory testing is characterized by advancing technology which may enable other clinical laboratories, hospitals, physicians or other medical providers to perform assays with properties similar to ours in a more efficient or cost-effective manner than is currently possible. Such technological advances may be introduced by our competitors, or other third parties. For instance, a diagnostic manufacturing company could release an instrument or technology that would make it cost-effective for our customers to perform complex assays internally, rather than through us. If these or other advances in technology allow other entities to perform testing we currently perform, it could result in a decreased demand for our assays, and our assay volume and net revenue would decline. We may also be forced to lower prices on our assays to reduce the likelihood that other entities, including our clients, will perform such testing. Any assay volume, test price or revenue reductions would significantly harm our business.

If we do not comply with laws and regulations governing the confidentiality of medical information, it will adversely affect our ability to do business.

The confidentiality of patient medical information is subject to substantial regulation by the state and federal governments. State and federal laws and regulations govern both the disclosure and the use of confidential patient medical information. Most states have laws that govern the use and disclosure of patient medical information and the right to privacy. Similarly, many federal laws also may apply to protect such information, including the Electronic Communications Privacy Act of 1986 and federal laws relating to confidentiality of mental health records and substance abuse treatment.

Legislation governing the dissemination and use of medical information is continually being proposed and enacted at both the state and federal levels. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, and regulations promulgated under HIPAA require certain healthcare providers and holders or users of electronically transmitted patient health information to implement measures to maintain the security and privacy of such information. Ultimately, this and other legislation may even affect the dissemination of medical information that is not individually identifiable. Physicians and other persons providing patient information to us are also required to comply with these laws and regulations. If a patient's privacy is violated, or if we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties. The HIPAA regulations required that covered entities (including us) be in compliance with the privacy regulations on or before April 14, 2003.

The commercialization of our Internet products including Outreach Express®, DataPassportMD®, and DataPassport Clinical Trials is strictly governed by state and federal laws and regulations, including the regulations under HIPAA. We have implemented encryption technology to protect patient medical information, but use of encryption technology does not guarantee the privacy and security of confidential information.

We believe that we are in material compliance with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information. However, differing interpretations of existing laws and regulations, or the adoption of new laws and regulations, could reduce or eliminate our ability to obtain or use patient information which, in turn, could limit our ability to use our information technology products for electronically transmitting patient data. While we believe we are in compliance in all material respects with the applicable HIPAA regulations, our failure to comply could subject us to fines and penalties, and have a detrimental effect on our business. We may be subject to inspections or investigations by state or federal regulatory entities that enforce privacy laws and regulations, and we can provide no assurances that we will be found fully compliant with HIPAA or other privacy laws and regulations. Any findings of non-compliance with HIPAA or other privacy laws and regulations could significantly harm our client's confidence in our processes relating to the confidentiality, dissemination and use of medical record information, and could significantly harm our business.

The premium prices that we initially charge for new assays may drop if our competitors are able to develop and market competing assays more quickly than they currently do.

Typically, we market new specialized assays at premium prices until similar assays are developed as either standardized prepared kits for broad application or as internally developed assays by competing laboratories. The opportunity to sell our products at premium prices may be reduced or eliminated if our competitors are able to develop and market competing assays more quickly than they currently do. We may also be forced to lower prices on our assays to reduce the likelihood that other entities, including our clients, will perform testing we currently perform for them.

Our average selling price has fluctuated, and may go down depending on the ordering patterns of our clients.

As our clients internalize some tests we perform for them, or as they find alternative sources of testing, they may change the mix of testing sent to us. If our clients send us fewer higher-priced tests, the average selling prices for our assays could drop, and our revenue could be negatively affected. Our average selling price has gone down previously, and we can provide no guarantees that it will grow in the future, and it may go down again. Our business and potential profitability could be significantly affected if we are not able to grow our average selling price.

If we are unable to develop and successfully market new assays or improve existing assays in a timely manner, our profit margins may decline.

In order to maintain our margins and benefit from the premium prices that we typically charge for our newly introduced specialized assays, we must continually develop new assays and improve our existing assays through licensing arrangements with third parties and through the efforts of our R&D department. We can provide no assurance, however, that we will be able to maintain our current pace of developing and improving assays in the future. Even if we develop such assays in a timely manner, our customers may not utilize these new assays. If we fail to develop new technologies, release new or improved assays on a timely basis, or if such assays do not obtain market acceptance, our profit margins may decline.

If we fail to acquire licenses for new or improved assay technology platforms, we may not be able to accelerate assay improvement and development, which could harm our ability to increase our net revenue.

Our ability to accelerate new assay development and improve existing performance will depend, in part, on our ability to license new or improved assay technology platforms on favorable terms. We may not be able to negotiate acceptable licensing arrangements and we cannot be certain that such

arrangements will yield commercially successful assays. Further, even if we enter into such arrangements with these third parties, their devotion of resources to these efforts may not be within our control or influence. If we are unable to license these technologies at competitive rates, our research and development costs may increase. In addition, if we are unable to develop new or improved assays through such research and development efforts, our assays may be outdated when compared with our competition's assays, and our net revenue may decrease.

Failure in our information technology systems could significantly increase turn-around time, reduce our production capacity, and otherwise disrupt our operations, which may reduce our customer base and result in lost revenue.

Our success depends, in part, on the continued and uninterrupted performance of our information technology systems, including our DataPassport®, Data PassportMD® and Outreach Express® suite of products, and our laboratory information system. Sustained or repeated system failures that interrupt our ability to process assay orders, deliver assay results or perform assays in a timely manner would reduce significantly the attractiveness of our products to our customers. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any damage or failure that interrupts or delays our operations, or that reduces the attractiveness of our products to our customers.

Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite reasonable security measures we have implemented, some of our information technology systems are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because we conduct business on the Internet and because some of these systems are located at third party web hosting provider, Qwest Communications in Burbank, California, and we cannot control the maintenance and operation of the Qwest data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems, leading to lost revenue, deterioration of customer confidence, or significant business disruption. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any problem that interrupts or delays our operations.

While we have insurance policies that may cover losses arising from such interruptions, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our systems as a result of moving to a new provider, or any losses that may occur due to any failures in our information technology systems.

If we lose our competitive position in providing valuable information technology solutions as an ancillary service to our customers, we may not be able to maintain or grow our business.

Over the past five years, we have made a substantial investment in our information technology solutions, such as DataPassport®, DataPassportMD®, and Outreach Express®, to facilitate electronic assay ordering and results reporting as a value added service for our customers. We believe that these solutions are one factor considered by our customers when selecting a reference laboratory. In the future, our competitors may offer similar or better information technology solutions to our existing and potential customer base. If this occurs, we may lose this competitive advantage, and as a result, may be unable to maintain or increase our business growth.

We rely on a few assays for a significant portion of our net revenue. If demand for these assays were to weaken for any reason, our net revenue would decrease.

A significant portion of our net revenue is derived from 59 assays. Net revenue from these 59 assays comprised approximately 47% of our total net revenue for the year ended December 31, 2004. If

competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

Clinicians or patients using our products or services may sue us and our insurance may not sufficiently cover all claims brought against us, which will increase our expenses.

The development, marketing, sale and performance of healthcare services expose us to the risk of litigation, including professional negligence. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain insurance with coverage up to $15 million, either singly or in the aggregate, which we believe to be adequate to cover our exposure in our current professional liability claims and employee-related matters which were incurred in the ordinary course of business. Although we believe that these claims may not have a material effect on us, because we expect them to be covered by this insurance, we may be faced with litigation claims which exceed our insurance coverage or are not covered under our insurance policy. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

If protection of the intellectual property underlying our technology and trade secrets is inadequate, then third parties may be able to use our technology or similar technologies, thus reducing our ability to compete.

We currently rely on certain technologies for which we believe patents are not economically feasible and therefore may be developed independently or copied by our competitors. Furthermore, we rely on certain proprietary trade secrets and know-how, which we have not patented. Although we have taken steps to protect our unpatented trade secrets and know-how, principally through the use of confidentiality agreements with our employees and consultants, there can be no assurance that these agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently developed or discovered by competitors. If our trade secrets become known or are independently developed or discovered by competitors, it could have a material adverse effect on our ability to compete.

Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and/or enter into appropriate licenses which may cause us to pay substantial damages or royalties, and could prohibit or restrict us from selling our assays.

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. For example, in response to a patent infringement allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease.

We also received letters from Chiron Corporation ("Chiron") in February 1998, and the National Institute of Health (NIH) in 2000-2003 claiming that some of our assays may violate their patents. In August 2003 we reported that we had entered into a letter agreement with Chiron that called for us to make payments to Chiron for alleged past infringement of Chiron patents by certain Hepatitis C Virus ("HCV") and Human Immunodeficiency Virus ("HIV") testing performed by us, and Chiron agreed not to assert its patent rights, or bring any claim against Specialty for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. We cannot provide any assurances that the NIH or other patent holders will not bring suit against us in the future for alleged patent infringement. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us.

In June 2004 we became aware of a lawsuit filed against us in the U.S. District Court for the Southern District of California by Prometheus Laboratories, Inc. ("Prometheus"). The complaint alleged infringement of Prometheus' patent rights by a new assay we announced for the monitoring of drug levels in connection with the treatment of Inflammatory Bowel Disease. Based partly on the threat of the litigation, and the service disruption the lawsuit could have on our clients, we chose not to make this new assay available to our clients, and the matter with Prometheus was resolved without admission of liability or the payment of any settlement amounts. Prometheus has since dismissed their lawsuit against us.

Patent infringement suits can be very expensive to defend and could divert management's time and resources, regardless of the merit or validity of any such suit. Furthermore, we cannot provide any assurances that we would be successful in defending any such suit, and there can be no assurance that there will be no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and such litigation, or the threat of such litigation, could force us to do one or more of the following:

cease developing, performing or selling products or services that incorporate the challenged intellectual property;

obtain and pay for licenses from the holder of the allegedly infringed intellectual property right; or

redesign or reengineer our assays.

We can provide no assurances that we will be able to secure licenses for such patents on commercially reasonable terms, if at all. Licenses for such patents may require the payment of material sums of money as license fees and royalties, including fees and royalties for past infringement. Any efforts to reengineer our assays or any inability to sell our assays, or an obligation to pay license fees and royalties could substantially increase our costs, force us to interrupt product sales, delay new assay releases, decrease our competitiveness in the marketplace, reduce our revenues, and materially impair our business. In addition, if a suit were brought against us alleging patent infringement, and we were found to have infringed the patents at issue, we could be forced to pay substantial damages, including possible treble damages. While we intend to defend any such suit vigorously, and assert all available defenses, we cannot provide any assurances that we would be successful in defending any such suit. If we were to lose such a suit, it could create a material financial liability, negatively affect our operating results, and negatively impact our stock price.

We may acquire other businesses, products or technologies in order to remain competitive in our market and our business could be adversely affected as a result of any of these future acquisitions.

We have made in the past and we may continue to make acquisitions of complementary businesses, products or technologies. If we identify any additional appropriate acquisition candidates, we may not be successful in negotiating acceptable terms of the acquisition, financing the acquisition, or integrating the acquired business, products or technologies into our existing business and operations. Further, completing an acquisition and integrating an acquired business will significantly divert management time and resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business. If we consummate any significant acquisitions using stock or other securities as consideration, our shareholders' equity could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash or incur significant indebtedness. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results.

We may need or elect to raise additional funds to fund our operations and activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies.

While we expect existing cash and cash equivalents, short-term investments, and lines of credit will be sufficient to fund our operations, meet our capital requirements to upgrade our IT infrastructure, support our growth, and allow strategic technology licensing and acquisitions for the next year, and we believe we have sufficient capital to fund our activities for at least the next twelve months, our future capital requirements may vary materially from those now planned. It is possible that we may need or elect to raise additional funds to fund our activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies. We could raise such funds by selling additional equity securities to the public or to selected investors, or by borrowing money. In addition, even though we may not need additional funds, we may still elect to sell additional equity securities or obtain credit facilities for other reasons. We cannot assure you that we will be able to obtain additional funds on commercially favorable terms, or at all. If we raise additional funds by issuing additional equity or convertible debt securities, the ownership percentages of existing shareholders would be reduced. In addition, the equity or debt securities that we issue may have rights, preferences or privileges senior to those of the holders of our common stock.

We may encounter problems or delays in operating or implementing our automated processing systems, which could disrupt our operations, require us to develop alternatives and increase our costs.

In order to meet growth in demand for our specialized assays, we will have to process many more patient samples than we are currently processing. We have implemented a high-speed specimen sorting system known as the Total Accessioning Re-Organization System, or TARO , and a specimen splitting system, known as the Harmonized Assignment of Nanoliter Aliquots, or HANA . In addition, we plan to develop and implement other automated systems to enhance our testing procedures. We will need to develop sophisticated software to support these other automated procedures, analyze the data generated by these tests and report the results. Further, as we attempt to increase the number of patient samples we process, throughput or quality-control problems may arise.

If we are unable to consistently process patient samples on a timely basis because of delays or failures in our implementation of these automated systems, or if we encounter problems with our established automated processes, we will be required to develop alternate means to process our business which may increase our costs.

If a catastrophe were to strike our clinical laboratory facility, we would be unable to process our customers' samples for a substantial amount of time and we would be unable to operate our business competitively.

Our specimen processing facilities, our clinical laboratory, and our corporate offices may be affected by catastrophes such as fires, earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because our current clinical laboratory facilities are located in Valencia, California, an earthquake-prone area. In the event our existing facilities or equipment are affected by man-made or natural disasters, we may be unable to process our customers' samples in a timely manner and unable to operate our business in a commercially competitive manner. To address these risks, we have in place formal recovery plans for such interruptions of service. This includes identification of alternate laboratory testing facilities and disaster recovery protocols. We also carry earthquake insurance with a coverage amount of up to $20 million and we have outsourced part of our data storage and processing equipment to a facility designed to withstand most earthquakes. Despite these precautions, the self-insured retention amount for earthquake insurance is very high, and there is no assurance that we could recover quickly from a serious earthquake or other disaster.

We rely on a continuous power supply to conduct our operations, and California's energy crisis could disrupt our operations and increase our expenses.

Our specimen processing facilities, our clinical laboratory, and our corporate offices are located Valencia, California. California is still in an energy crisis that could disrupt our operations and increase our expenses. In the event power reserves for the state of California fall to critically low levels, California may implement rolling power blackouts throughout the state. The state of California has already experienced such occasional power blackouts. We currently have power generators for partial backup of our laboratory operations in the event of a blackout. Our current insurance, however, does not provide coverage for any damages we may suffer as a result of any interruption in our power supply. If blackouts interrupt our third party power supply, we may be temporarily unable to continue operations. Any such interruption in our ability to continue operations would delay our processing of laboratory samples, disrupt communications with our customers and suppliers and delay product shipment. Power interruptions could also damage our reputation and could result in lost revenue. Any loss of power could have a material adverse effect on our business, operating results and financial condition. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If wholesale prices continue to increase, our operating expenses will likely increase which will have a negative effect on our operating results.

Disruption similar to the September 2001 terrorist attacks in the future on the U.S. may adversely impact our results of operations, future growth and stock price.

The operation of our laboratories may be harmed by terrorist attacks on the U.S. For example, after the September 2001 terrorist attacks transportation systems and couriers that we rely upon to receive and process specimens were disrupted. In addition, we may experience a rise in operating costs, such as costs for transportation, courier service, insurance and security. We may also experience delays in receiving payments from payors that have been affected by the attack, which, in turn, would harm our cash flow. The U.S. economy in general may be adversely affected by terrorist attacks or by any related outbreak of hostilities. Any such economic downturn could adversely impact our results of operations, revenues and costs, impede our ability to continue to grow our business and may result in the volatility of the market price of our common stock and on the future price of our common stock.

We are controlled by a single existing shareholder, whose interests may differ from other shareholders' interests.

Our principal shareholder is the Specialty Family Limited Partnership, whose sole managing general partner, James B. Peter, M.D., Ph.D., is a member of our board of directors. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 61% of the outstanding shares of our common stock. Accordingly, the Specialty Family Limited Partnership along with Dr. Peter will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including election of directors, mergers, consolidations and the sale of all or substantially all of our assets. Our principal shareholder will also have the power to prevent or cause a change in control. The interests of this shareholder may differ from other shareholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a change in control and could deprive other shareholders of an opportunity to receive a premium for their common stock as part of a sale of our business.

Anti-takeover provisions in our charter documents could prevent or delay a change in control and, as a result, negatively impact our shareholders.

We have taken a number of actions that could have the effect of discouraging a takeover attempt. For example, provisions of our amended and restated articles of incorporation and amended and restated bylaws could make it more difficult for a third party to acquire us, even if doing so would be

beneficial to our shareholders. These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock.

These provisions include:

limitations on who may call special meetings of shareholders;

advance notice requirements for proposing matters that can be acted upon by shareholders at shareholder meetings; and

the ability of our board of directors to issue preferred stock without shareholder approval.

ITEM 2. PROPERTIES

During 2001, we made the decision to consolidate our laboratory and administrative functions in a single building. In December 2001, we purchased a 13.8 acre site in Valencia, California. We began constructing a 198,000 square foot facility in the second quarter of 2002. The construction project was originally scheduled to be completed in the second half of 2003; however, in October 2002, we announced that we would postpone the move to our new facility in Valencia until the second half of 2004 and halt the construction project once the Core and Shell of the building was completed. The Core and Shell was substantially completed in January 2003, with the remaining work of punch lists and sign-off of systems concluded in April 2003.

On February 11, 2004, we signed an agreement for the sale and leaseback of the Valencia facility with Lexington Corporate Properties Trust (Lexington), a real estate investment trust. Under the terms of the agreement, Lexington purchased the existing facility for $47.0 million. We planned to complete the construction project and entered into a 20-year lease for use and occupancy of the facility. The sale and leaseback transaction was completed on March 18, 2004.

Lease payments began in September 2004. Based on interest rates in effect on December 31, 2004, rent expense for the new facility is expected to be approximately $4.6 million per year, approximately $2.0 million higher than comparable costs at our former facilities in Santa Monica, and includes the effect of scheduled rent increases in future years under our 20-year lease. We expect certain other operating expenses at the Valencia facility, such as utilities and property taxes, may also exceed cost levels incurred at the former Santa Monica facilities by as much as $2.0 million annually, based primarily on the considerably larger size of the Valencia facility.

During the third quarter 2004, we substantially completed construction activities and relocated our administrative functions from Santa Monica to our facility in Valencia. The move of our laboratory functions from the facilities in Santa Monica to Valencia was substantially completed during the fourth quarter 2004. During 2004, we incurred approximately $4.7 million in costs to relocate our operations to our new facility in Valencia. These costs relate to planning and executing the physical move, the disposal of equipment not used in the new facility, the remaining rental obligation on the closed Santa Monica laboratory, the required validation of laboratory equipment upon arrival, charges associated with leaving our former Santa Monica facilities and bonuses paid to personnel who contributed to the successful relocation process. During the first quarter 2005, we anticipate to incur additional expenses associated with the closure of the Santa Monica facilities of approximately $500,000.

We also operate one stand-alone triage collection and processing center in Shrewsbury, Massachusetts to serve Boston area customers. This facility contains 2,890 square feet and is leased at approximately $52,000 per year. In early 2004, we extended our lease agreement to expire in March 2005, and we have since negotiated an extension on a month-to-month basis.

In addition, we lease a 60,000 square foot building in Memphis, Tennessee, and in June 2002, we subleased the facility for the period July 1, 2002 through September 14, 2007, the end of our lease

commitment. We recorded charges in 2000 and 2002 for future unrecoverable lease costs. Assuming no change in the sublease, no future costs should be incurred.

ITEM 3. LEGAL PROCEEDINGS

In addition to the California state and federal investigations described in "Business Government Regulation Certification and Licenses" and "Risk Factors Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed", we are involved in various legal proceedings arising in the ordinary course of business.

Securities Litigation: In May and June 2002, we were named as a defendant, together with certain of our current or former board members and officers, in four substantially identical class-action lawsuits filed in the United States District Court for the Central District of California, and subsequently consolidated as "In re Specialty Laboratories Securities Litigation". The lawsuit purported to state claims on behalf of an alleged class of investors who bought our stock in the open market between December 8, 2000 and April 15, 2002 ("Class Period"). The lawsuit alleged that the market price of our stock was artificially inflated during the Class Period as a result of alleged misrepresentations made in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with our initial public offering of common stock and subsequent public disclosures. The lawsuit alleged, among other things, false and misleading statements about our compliance with certain regulatory requirements imposed by the California Department of Health Services and the federal Centers for Medicare & Medicaid Services. Plaintiffs sought compensatory damages, including interest, costs and expenses, attorneys' fees, and other relief. Plaintiffs have filed several amended complaints, and we in turn have filed motions to dismiss these complaints. The court ruled on these motions, dismissing some claims and not dismissing others, and allowed plaintiffs to proceed with their claims against the Company and several current and former officers and directors for alleged violations of both the Securities Act of 1933 and the Securities Exchange Act of 1934. We provided notice to our directors and officer's insurers, and believe that the claims against us and our current and former officers and directors are without merit, and intend to defend these lawsuits vigorously. On June 14, 2004, we announced an agreement in principle to settle the consolidated lawsuits for $12 million, which is to be paid fully by our insurance carriers. On December 22, 2004, the court entered a final order approving the settlement and providing for notice to shareholders. As the settlement and defense costs are being paid by our insurance carriers, we do not anticipate any costs associated with the defense or settlement of the claims to have a material impact on our finances.

Specialty Laboratories Asia: Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, ("SLA"), is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation ("SLIL"). SLA was headquartered in Singapore but, in early 1999, SLA ceased all operations and is currently insolvent. A former employee of SLA has obtained a judgment for $350,000 against SLA and a default judgment of approximately $1.95 million in a wrongful termination action against SLA filed by him in Singapore. The former employee has filed an action against SLA in San Diego Superior Court to attempt to collect on the Singapore judgment and has obtained a default judgment of approximately $2.5 million against SLA in California. The former employee served discovery upon us and certain of our directors and officers. Our management believes that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit, and we would vigorously defend any such action.

Singapore Litigation: In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company ("Dragon"), one of the shareholders in SLA. Dragon has also brought the lawsuit in the name of SLA as a derivative action. The lawsuit alleges, among other things, that SLA and

Dragon suffered damages as a result of the winding up of the affairs of SLA and disposition of its assets. The lawsuit also alleges that certain of the defendants breached certain written agreements to allow Dragon to acquire more shares of SLA, that certain of our former officers conspired to run down and dissipate the assets of SLA, and that they fraudulently concealed their actions from Dragon and the other minority shareholder of SLA. We have provided notice to the applicable insurance carriers. While we believe that we have insurance applicable to the defense of the lawsuits, and continue to work with the relavent insurance carriers on the coverge issue, such carriers have not yet acknowledged coverage of the matter.

From time to time, we receive letters alleging infringement of patent or other intellectual property rights. Our management believes that these letters generally are without merit and intend to contest them vigorously. For more information, please see "Risk Factors Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and/or enter into appropriate licenses which may cause us to pay substantial damages or royalties, and could prohibit or restrict us from selling our assays."

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

None.

PART II.

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON STOCK AND RELATED SHAREHOLDER MATTERS

Market Information

Our common stock has traded on the New York Stock Exchange under the symbol "SP" since December 8, 2000. Prior to that time, there was no public market for our common stock. The following table sets forth the high and low sales prices reported on the New York Stock Exchange for our common stock for the periods indicated.

	Price Range of Common Stock	
	High	Low
Year 2003:		
First Quarter	$ 10.40	$ 6.17
Second Quarter	$ 11.15	$ 8.05
Third Quarter	$ 14.50	$ 9.80
Fourth Quarter	$ 17.40	$ 12.14
Year 2004:		
First Quarter	$ 17.50	$ 10.10
Second Quarter	$ 10.94	$ 8.96
Third Quarter	$ 11.71	$ 9.00
Fourth Quarter	$ 11.72	$ 9.49
Year 2005:		
First Quarter (through March 1, 2005)	$ 10.74	$ 9.52

On March 1, 2005, the last reported sales price of our common stock was $9.92.

Holders

As of March 1, 2005, there were 26 holders of record of our common stock.

Recent Sales of Unregistered Securities

None.

Dividend Policy

We have not declared or paid any cash dividends on our capital stock since 1992. We currently intend to retain future earnings, if any, to provide funds to finance the expansion of our business. We do not anticipate paying any cash dividends in the foreseeable future.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following selected financial data is derived from audited consolidated financial statements. The consolidated statement of operations data for the years ended December 31, 2000 and 2001 and the consolidated balance sheet data at December 31, 2000, 2001 and 2002 were derived from our audited consolidated financial statements that are not included in this Annual Report. You should read the selected financial information set forth below in conjunction with "Management's Discussion and

Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this Annual Report.

	Years Ended December 31,				
	2000	2001	2002	2003	2004
	(amounts in thousands, except per share data)				
Statements of operations data:					
Net revenue	$ 153,245	$ 175,169	$ 140,150	$ 119,653	$ 134,803
Costs and expenses:					
Costs of services	86,856	99,955	104,379	86,095	93,716
Selling, general and administrative (exclusive of provision for doubtful accounts charges and stock-based compensation charges (credits))	44,237	48,780	45,361	39,628	46,756
Provision for doubtful accounts charges	5,040	6,833	5,887	3,836	5,414
Stock-based compensation charges (credits)(1)	1,073	1,103	(28)	65	147
Facility exit costs(2)					2,309
Restructuring charge(3)			5,050		
Charge related to regulatory matters(4)			2,253		
Write-down of unused facilities(5)	369				
Total costs and expenses	137,575	156,671	162,902	129,624	148,342
Operating income (loss)	15,670	18,498	(22,752)	(9,971)	(13,539)
Interest expense (income), net	941	(3,451)	(1,455)	(721)	(408)
Income (loss) from continuing operations before income taxes	14,729	21,949	(21,297)	(9,250)	(13,131)
Provision for income taxes (benefits)	6,056	8,870	(7,912)	(2,889)	(181)
Net income (loss)	$ 8,673	$ 13,079	$ (13,385)	$ (6,361)	$ (12,950)
Income (loss) per share(6):					
Basic	$ 0.54	$ 0.62	$ (0.61)	$ (0.29)	$ (0.57)
Diluted	$ 0.49	$ 0.59	$ (0.61)	$ (0.29)	$ (0.57)
Statements of cash flow data:					
Cash flow provided by (used in) operating activities	$ 15,464	$ 19,507	$ (1,427)	$ 2,272	$ (8,404)
Cash flow (used in) provided by investing activities	(5,965)	(82,531)	6,845	(3,249)	3,758
Cash flow provided by (used in) financing activities	65,388	2,603	1,804	6,135	(4,634)

	As of December 31,				
	2000	2001	2002	2003	2004
	(amounts in thousands)				
Balance sheet data:					
Working capital	$ 88,789	$ 58,736	$ 51,548	$ 50,843	$ 40,898
Total assets	142,005	153,988	143,307	142,553	126,142
Long-term debt, including current portion				5,019	
Total shareholders' equity	111,797	132,656	123,734	120,500	109,534

(1)

Stock-based compensation charges resulted from amortization of deferred stock-based compensation and totaled $1.1 million for both the years ended December 31, 2000 and 2001. For the years ended December 31, 2002, 2003 and 2004, we recorded stock-based compensation charges of $(28,000), $65,000 and $147,000, respectively. The net credit of $28,000 in 2002 resulted from the amortization of deferred stock-based compensation charges coupled with the forfeited stock options resulting from the June and November 2002 reductions in workforce that had the effect of reducing previously recorded and future amortization.

(2)

During 2004 we substantially completed construction of our new facility in Valencia, California and relocated our administrative and laboratory functions from our former facilities in Santa Monica to Valencia. In connection with our relocation, we recorded facility exit costs of $2.3 million related to exiting our Santa Monica facilities, the disposal of equipment not used in the new facility and the remaining rental obligation on the closed Santa Monica laboratory. Our cost of services include $1.2 million for relocation of our laboratory facilities and our S,G&A include $1.2 million for relocation of our administrative offices from Santa Monica to Valencia.

(3)

As part of an overall restructuring and reorganization plan, three reductions in workforce were conducted during 2002 that resulted in charges totaling $5.1 million during the year ended December 31, 2002. These charges comprised $4.3 million of severance payments and related obligations for employees whose positions were eliminated, a $0.3 million write-off of certain assets related to our clini