SPECIALTY LABORATORIES
Form 10-K
March 21, 2003

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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)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2002

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.)

2211 Michigan Avenue
Santa Monica, California 90404
(Address of principal executive offices, including zip code)
Registrant's Telephone Number, Including Area Code: **(310) 828-6543**

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 No 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 o No ý

As of June 28, 2002, 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 $61,740,596 (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 February 28, 2003, there were approximately 22,094,832 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 8, 2003.

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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 23 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 Form 8-K. All forward-looking statements attributable to Specialty Laboratories are expressly qualified in their entirety by such language. We do not undertake any obligation to update any forward-looking statements.

PART I.

ITEM 1. BUSINESS

Overview

Specialty Laboratories is a leading hospital-focused clinical laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist communities nationwide. We believe we offer the most comprehensive menu of esoteric assays in the industry, many of which have been developed 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, our fastest growing client segment, by not competing in the routine test market 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 2211 Michigan Avenue, Santa Monica, California 90404.

We maintain a World Wide Web site at www.specialtylabs.com. 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 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, which we believe is greater than the esoteric offering of any other clinical laboratory in the United States. 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 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, 2002, approximately 34% 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 80% 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 2002, we worked on an exclusive basis with research laboratories at UCLA to introduce a commercial assay for genetic resistance to Gleevec®, the breakthrough new therapeutic for chronic myelogenous leukemia.

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.

Acquisitions

On February 20, 2001, we acquired certain assets and liabilities of BBI Clinical Laboratories, Inc. (BBICL), a Massachusetts corporation, for $9.5 million in cash. The purchase price was allocated to the assets acquired and liabilities assumed based on the estimated fair values as of the purchase closing date. The acquisition agreement provided for a reduction of the purchase price if certain performance measurements (i.e., asset delivery, client retention and accounts receivable collections) were not achieved. A subsequent evaluation of these performance measurements resulted in the return of $358,000 by BBICL to us in December 2001. Of the $9.1 million net purchase price, approximately $5.9 million was allocated to goodwill and $1.9 million was allocated to the customer list. The acquisition has been accounted for under the purchase method of accounting. The operating results of BBICL are included in the financial statements from the acquisition date.

Products and Services

We perform all of our testing services at our laboratory facility in Santa Monica, 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 what we believe is the most comprehensive menu of esoteric assays in the industry. 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 32% of our net revenue for the year ended December 31, 2002. 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 approximately five million Americans, including three million with active infections. In this market, we offer approximately 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, 2002, approximately 34% 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, 30 of our esoteric assays currently account for a substantial portion of our net revenue. These assays, on a net revenue basis, accounted for approximately 45% of our net revenue for the years ended December 31, 2002 and 2001. 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 9 marketing professionals and approximately 50 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 two 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 Specialty as their reference laboratory. In the IT area, we intend to continue our development of our next generation web-based order entry system, Outreach Express®, providing hospitals with a tool for growing their physician-based business. 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 have printed and regularly 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 and cardiology. We present our research at scientific meetings and we exhibit at nearly 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,		
	2000	**2001**	**2002**
Hospitals	51.3%	56.0%	60.9%
Independent Laboratories	35.7%	34.0%	29.4%
Physician Specialists and Others	13.0%	10.0%	9.7%
Total	100.0%	100.0%	100.0%

Hospitals

Hospitals accounted for approximately 61% of our net revenue for the year ended December 31, 2002. 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. We are currently under contract with the following voluntary group purchasing organizations:

Group Purchasing Organization	Estimated Number of Member Hospitals	Contract Expiration Date
AmeriNet	2,000	December 2004
MedAssets HSCA	800	December 2004
Shared Services Healthcare	550	June 2003
Managed Healthcare Associates	350	January 2006

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 quarterly administrative fee to the group purchasing organization.

Independent Laboratories

For the year ended December 31, 2002, independent laboratories represented approximately 29% 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.

In October 1999, we entered into a multi-year agreement with Unilab Corporation pursuant to which it agreed to refer to us, until the agreement expired in October 2002, at least 90% of the esoteric laboratory services it outsources each year or, in the event of a change of control of Unilab or the purchase by Unilab of a licensed clinical laboratory with a test menu materially broader than that of Unilab, at least $800,000 of esoteric laboratory services per month. As announced in April 2002, and completed in February of 2003, Unilab was acquired by Quest Diagnostics, Inc. Following the expiration of our multi-year agreement with Unilab, in October 2002, we experienced a significant decline in the test volumes sent to us from Unilab. We entered into a new agreement with Unilab in October 2002 that allows for an orderly transfer and wind-down of work in light of the acquisition of Unilab by Quest. As part of this wind-down, in March 2003 Unilab provided us notice that it would stop sending us certain tests covered under the new agreement. For the year ended December 31, 2002, Unilab represented approximately 10% of our net revenues.

Physician Specialists and Others

For the year ended December 31, 2002, physician specialists comprised approximately 8% of our net revenue and represented approximately 800 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. Our clinical trials business focuses primarily on pharmaceutical and biotechnology companies trying to develop new drugs. We offer these companies customized assays to aid in the study and development of new therapeutic agents and applications. Testing services for the drug development market comprised approximately 2% of our net revenue for the year ended December 31, 2002. We believe that companies may choose us for their drug development testing because of our experience in developing new assays.

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,		
	2000	2001	2002
Customer	82.6%	82.9%	85.4%
Patient	10.1%	10.2%	8.0%
Medicare	4.0%	3.4%	2.9%
Medicaid	1.5%	1.4%	1.9%
Other Insurance	1.8%	2.1%	1.8%
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® product collects 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 80% 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. We currently have Outreach Express® in production at eleven sites.

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. We began implementation of TARO in the second half of 2000 and it became fully operational in the first quarter of 2001. 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 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 $2.2 million per year for the past three years. Our R&D efforts enable us to grow revenues, increase market share and command premium pricing for many of our assays.

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 the past two years, we licensed intellectual property that has enabled us to commercialize several new assays. Among them are 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.

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 April 2000 and June 2001, we 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.

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. As of June 23, 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.

Neither NIH nor Chiron has filed suit against us, though 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

suits 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 and of Chiron, we could be forced to pay substantial damages, including possible treble damages for allegations of willful infringement.

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 Impath 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, generally lack the advantages of larger commercial laboratories, competing with us on the limited basis of a perceived higher quality of service.

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 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 appropriate 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) (formerly known as the Health Care Financing Administration or HCFA) 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, 2002, 2001 and 2000, our shareholders' equity and total assets exceeded $100 million, and we are therefore now 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.

Regulations implementing and interpreting certain provisions of the Stark Law were released by CMS with an effective date of January 4, 2002. 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 sterile 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. Because the prior regulations largely implemented the Stark Law as it applies to clinical laboratory services, we do not believe that the 2002 regulations will have any material impact on us.

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 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 of 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 pursuant to the U.S. Sentencing Guidelines, 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 Santa Monica, licensure is also required under the laws of the State of California. Since we perform patient testing from all states, we hold licenses in additional states where such licensure is required by local state law, including Florida, Maryland, New York, Pennsylvania, Ohio, West Virginia, and Rhode Island. Our laboratory is also accredited with distinction 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. A final rule revising the CLIA regulations was published on Januarys 24, 2003. This new regulation deals primarily with quality control procedures, and we do not expect that the new regulations will have a significant impact upon us. 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.

In June 1999, CMS informed us that we were not in compliance with CLIA regulations pertaining to specific quality assurance functions, and imposed certain fines in connection therewith. After a CMS resurvey in June 2000, we were able to satisfy CMS that we were in compliance with the applicable requirements. We appealed the fine imposed by CMS, and subsequently settled the matter by paying CMS the sum of $87,400.

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. As a result, we were cited by CDHS with 20 deficiencies under California law and CLIA. A separate statement indicating 12 overlapping deficiencies under CLIA was issued by CMS in February 2002 based upon the same inspections. We submitted a response and corrective action plan to CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance.

By letter dated March 28, 2002, CDHS notified us of its intent to impose sanctions of a directed plan of correction, random onsite monitoring, and a civil money penalty based upon deficiencies cited on November 28, 2001 following laboratory inspections conducted during June and October 2001. The sanctions were based on findings that we were permitting unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law.

By letter dated April 12, 2002, CMS notified us of its conclusions regarding the laboratory inspections in June and October 2001. CMS concluded that our February 2002 response to deficiencies detected in the inspections did not constitute a credible allegation of compliance. As a result, CMS imposed certain sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare

and Medicaid payments for services performed, imposing a civil money

penalty of $3,000 per day for each day during the sanction period, and imposing a directed plan of correction by which CMS could notify our customers of our non-compliance and the nature and effective date of any sanctions imposed. We filed an appeal to the CMS action on April 17, 2002, and the appeal stayed the revocation of our CLIA certificate during our administrative appeal. The cancellation of Medicare and Medicaid payments was effective for services performed by us on and after February 22, 2002.

We filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS on April 26, 2002. In addition, on April 26, 2002, we requested that CDHS rescind its proposed sanctions outlined in the March 28, 2002 letter based on our supplemental submission. In May and June 2002, CDHS conducted additional unannounced inspections, and we provided additional documentation supporting our compliance with CDHS requirements. By letter dated June 28, 2002, and amended on July 18, 2002, CDHS indicated that we were in substantial compliance with California clinical laboratory law. CDHS also imposed sanctions of a civil money penalty of $1,000 per day for 344 days (i.e., $344,000), plus $20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections. We did not appeal these imposed sanctions.

On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's right to bill Medicare and Medicaid for its testing services was reinstated as of June 19, 2002, and that all actions against our CLIA certificate were rescinded. In order to facilitate an immediate resolution with CMS, we elected to withdraw the appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. However, because CMS had imposed its sanctions retroactively to February 22, 2002, we had billed Medicare and Medicaid programs for some services before we were notified of the actual imposition of the sanctions by CMS on April 12, 2002. We have sought guidance from CMS as to how the period of retroactive sanctions should be treated, and we have set aside and reserved those Medicare or Medicaid payments from the period of February 22, 2002 through April 12, 2002 until we receive additional guidance from CMS. We also did not challenge CMS' imposition of a monetary fine of $351,000, representing $3,000 per day during the sanction period. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services performed from February 22, 2002 through June 19, 2002 did not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly.

In October 2002, the College of American Pathologists (CAP) completed a regularly scheduled inspection of our laboratory facilities. The CAP inspection found that we had met the CAP requirements and standards for accreditation, and CAP issued us its Accreditation with Distinction as a result of the October 2002 inspection.

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 a Compliance Officer 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.

"Corporate Practice" of Medicine

California law, as well as the laws of many other states, prohibit physicians from sharing professional fees with non-physicians such as laboratories, and prohibit non-physicians from practicing medicine, including pathology, and from employing pathologists or other physicians.

California law provides that the practice of medicine without a license is a misdemeanor, and a violation of the laws governing the practice of medicine could be a basis for assessment of fines and penalties, imposition of a cease and desist order, and the suspension or revocation of a California laboratory license. State and federal law also prohibit us from being compensated for referrals we make to our pathologists. We have previously employed pathologists, and are restructuring our relationships with pathologists in a manner that we believe does not violate the prohibitions against the "corporate practice" of medicine in any material respect. We do not believe that any violations which we may have committed in the past are likely to result in sanctions that would have a material adverse effect on our business, financial condition, results of operations, or cash flows.

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 is testing methods for laboratories to register their in-house 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. The federal Centers for Disease Control and Prevention (CDC) is revising the regulations under CLIA to specifically recognize and regulate a genetic testing specialty. In addition, the Department of Health and Human Services' (HHS) Secretary's Advisory Committee on Genetic Testing (SACGT) until recently advised HHS as to various issues raised by the development and use of genetic testing. SACGT published recommendations that included FDA review of individual tests, and augmentation of revised CLIA standards to be written by the CDC. In January 2003, HHS indicated it is still assessing the feasibility of regulating in-house genetic testing, and HHS recently created a new committee, the Secretary's Advisory Committee on Genetics, Health and Society, to take over and expand on the role of SACGT. 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 NY residents; the level of scrutiny delays test availability.

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 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. Such direct billings by us to Medicare accounted for approximately 3.4% of our net revenue in 2001 and approximately 2.9% of our net revenue for 2002. Medicaid net revenue was approximately 1.4% of our net revenue in 2001 and 1.9% of our net revenue in 2002. 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 should be expected that such fee schedules will 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 had eliminated consumer price index increases to the national cap and local fee schedules through the year 2002, 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. As an example, California's governor has announced his intention to propose a budget that would generally reduce Medi-Cal reimbursements by 15%. CDHS has announced that laboratories will not be exempted from any cuts that may be made. Based upon the limited information available, it appears that such cuts may become effective as early as July 1, 2003. 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. Congress has enacted legislation delaying implementation of the CMS rules until January 1, 2003 for hospitals who had qualifying outsourcing contracts for pathology services in place as of July 22, 1999. While legislation was introduced in Congress in 2002 to further delay implementation of the new requirements, no such legislation was enacted. It is expected that Congress will take this issue up again in 2003. On January 17, 2003, CMS issued a program memorandum instructing carriers to continue payment for these services indefinitely. It is not clear if or when the new requirement will come into effect, or what time period it will cover. 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. 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. Proposals have been made to require competitive bidding procurement of Medicare laboratory testing services. CMS is required to complete five Medicare bidding demonstrations involving various types of medical services and CMS is expected to include a clinical laboratory demonstration project in a metropolitan statistical area. 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 announced its intent to move forward with implementing its contracting program, but has not yet announced details as to how the contracting program will work. While it is expected that contracts will be entered into with many laboratories, there can be no assurance that we will be allowed to participate under the new program or that we will be able to enter into contracts on favorable terms. 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. 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.

To obtain competitively bid contracts to perform services, it might be necessary for us to agree to substantial reductions in our payments from the Medicare and Medi-Cal programs. Such contracts may be exclusive and laboratories which do not hold such contracts may be denied access to the Medicare/Medi-Cal 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 we or our customers 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