

SPECIALTY LABORATORIES  
Form 10-K  
March 30, 2001

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-K**

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

(MARK ONE)

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

For the fiscal year ended December 31, 2000

OR

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

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**SPECIALTY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

**California**  
(State or Other Jurisdiction  
of Incorporation or Organization)

**95-2961036**  
(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**

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

Title of Each Class	Name of Each Exchange on Which Registered
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Common Stock, no par value	New York Stock Exchange
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Securities registered pursuant to Section 12(g) of the Act: None

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

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. //

As of March 20, 2001 the approximate aggregate market value of voting stock held by non-affiliates of the registrant was \$126,479,370 (based upon the closing price for shares of the registrant's Common Stock as reported by the New York Stock Exchange on that date). Shares of Common Stock held by each officer, director, and holder of 5% 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 20, 2001, there were approximately 20,937,507 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 to be held on May 11, 2001.

## SPECIALTY LABORATORIES, INC. FORM 10-K ANNUAL REPORT

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*This Annual Report on Form 10-K, including 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 Report, including without limitation under the caption "Risk Factors" beginning on page 20 of this Report, and in our Registration Statement on Form S-1 (No. 333-45588) declared effective by the Securities and Exchange Commission ("SEC") on December 7, 2000. 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 research-based clinical laboratory predominantly focused on developing and performing esoteric clinical laboratory tests, which we refer to as assays. We believe we offer one of the industry's most comprehensive menus, comprised of more than 3,500 esoteric assays, 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 on sophisticated instruments by highly skilled personnel 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.

Our principal executive offices are located at 2211 Michigan Avenue, Santa Monica, California 90404.

#### Recent Developments

On February 20, 2001 we completed the acquisition of substantially all of the assets of BBI Clinical Laboratories, Inc., a wholly-owned subsidiary of Boston Biomedica, Inc., a public company. We paid \$9,500,000 in cash which will be accounted for as a purchase in the first quarter of 2001. BBI Clinical Laboratories, a private company founded in 1989, is a leading esoteric clinical reference laboratory specializing in infectious disease testing, such as Lyme Disease and viral hepatitis. BBI Clinical Laboratories' primary customers include hospitals, physician specialists, pharmaceutical and diagnostic companies and other clinical and research laboratories.

#### Clinical Laboratory Industry

Clinical laboratory testing is critical to the delivery of quality healthcare to patients. Laboratory tests are used generally 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, 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 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. 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 3,500 esoteric assays, which we believe is greater than 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 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 and proprietary 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 and cardiology. We believe that we have developed one of the most extensive menus of assays in these attractive growth areas.

We market and sell many of our esoteric assays under trademarks such as GenotypR<sup>®</sup>, our assays for predicting resistance to HIV, and ANalyzer<sup>®</sup>, our assays used to help diagnose complex autoimmune disorders. For the year ended December 31, 2000, approximately 43% 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.

#### ***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. We have developed and introduced over 600 new or improved esoteric assays over the past five years and we have the ability to bring a new esoteric assay to market within approximately three months. 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

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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.

### *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, which 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 all of 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, over 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.

### *Operating Efficiency and Flexibility*

We continually evaluate our operations for process improvement opportunities and have made substantial investments in advanced process automation projects. In the third quarter of 2000, we began implementing an 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

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turn-around time within the laboratory. In the first quarter of 2001, we installed a second TARO system. We believe both TARO systems will be operational and part of production in the second half of 2001. As part of our continuing emphasis on productivity improvements, we are currently developing an ancillary system to TARO that is designed for high-throughput, precise division of specimens, a process commonly known as aliquotting. This system is scheduled to be introduced by the fourth quarter of 2001.

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 dependant on platforms designed for specific commercial kits.

### **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 forwards 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 more than 3,500 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 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.

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Many of our assays were designed by our R & D team and are unique and proprietary 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 and cardiology. Molecular diagnostic assays comprised nearly 40% of our net revenue for the year ended December 31, 2000. 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 over 45 assays using molecular diagnostics and other techniques to help physician specialists diagnose and monitor therapy effectiveness. In the cardiovascular disease market, we offer over 40 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 , our assays for predicting resistance to HIV, and ANALyzer®, our assays used to diagnose complex autoimmune disorders. For the year ended December 31, 2000, approximately 43% of our net revenue was derived from branded assays. We believe these branding efforts have contributed to increased market share and

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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 over 3,500 esoteric assays, 20 of our esoteric assays currently account for a substantial portion of our net revenue. These assays, on a net revenue basis, accounted for 54.5% of our net revenue for the year ended December 31, 2000, and 53.4% for the year ended December 31, 1999. In addition, a single assay accounted for more than 10% of our net revenue for the years ended December 31, 1998, 1999 and 2000. 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 14 marketing professionals and over 60 technical representatives and sales managers. Our sales representatives average over ten years of selling experience, including seven years in clinical laboratory or diagnostic testing sales. 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. 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*

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 nearly 800 such articles published. We have printed and continually 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 exhibit at over 50 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.

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Increasing revenue from smaller existing accounts is an important strategy due to the large number of hospitals with whom we are already doing business. 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

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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,		
	1998	1999	2000
Hospitals	38.5%	46.7%	51.3%
Independent Laboratories	45.7%	36.5%	35.7%
Physician Specialists and Others	15.8%	16.8%	13.0%
Total	100.0%	100.0%	100.0%

### *Hospitals*

Hospitals, our fastest growing customer segment, accounted for over 51% of our net revenue for the year ended December 31, 2000. Of the estimated over 5,000 hospitals to which we target our services, approximately 2,200 are currently our customers. We are a primary provider of esoteric reference laboratory testing services for over 330 of these hospital customers.

Many of our 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. 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	August 2001
Joint Purchasing Corporation	400	December 2001
Managed Healthcare Associates	300	May 2003
Novation (formerly known as VHA)	800	April 2004
Shared Services Healthcare	550	June 2003

The other material terms of these agreements are as follows: the agreements with group purchasing organizations each 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 an administrative fee to the group purchasing organization.

### *Independent Laboratories*

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For the year ended December 31, 2000, regional independent laboratories represented approximately 19% of our net revenue and national independent laboratories represented approximately 16% of our net revenue. Together, we service over 1,300 accounts in the independent laboratory segment. 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.

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In October 1999, we entered into an agreement with Unilab pursuant to which it has agreed to refer to us, until the agreement expires 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. For the year ended December 31, 2000, Unilab represented less than 10% of net revenues. This agreement can only be terminated for cause and will automatically renew for successive renewal terms of one year each unless terminated by either party.

### *Physician Specialists and Others*

For the year ended December 31, 2000, physician specialists comprised approximately 13% of our net revenue and represented over 3,200 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.

The majority of our remaining net revenue is derived from clinical trials. Our clinical trials business focuses primarily on pharmaceutical and biotechnology companies trying to develop new drugs. Testing services for the clinical trials market comprise approximately 2% of our net revenue for the year ended December 31, 2000. We believe that many companies choose us for their clinical trials because of our experience in developing new assays and offering the necessary tools to manage the resulting data.

### **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 since 1998:

	Years Ended December 31,		
	1998	1999	2000
Customer	87.6%	84.3%	82.6%
Patient	5.6%	8.3%	10.1%
Medicare	3.2%	3.5%	4.0%
Medicaid	1.6%	2.0%	1.5%
Other Insurance	2.0%	1.9%	1.8%
Total	100%	100.0%	100.0%

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

### **Information Technology**

We have invested significant resources into information technology that accelerates and automates test ordering and results reporting with our customers. Our proprietary information technology products, collectively branded as DataPassport®, are designed to take advantage of new 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

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lower customer costs. We have also invested resources designed to provide patient confidentiality and compliance with all governmental regulations regarding data 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, over 85% of the transaction volume with our customers is transmitted electronically.

Our current offering of information technology products include DataPassport® client interface module and DataPassportMD . We are in the process of developing Outreach Express described in detail below. 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, more than 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 will be hosted through our servers. The advantages to these customers are that no specialized hardware needs to be purchased and the entire information technology product may be supported outside their laboratory. We are designing 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 will provide 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 testing at eight pilot sites.

#### **Process Automation**

We are implementing 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. In the first quarter of 2001, we installed a second TARO system of which we believe that both TARO systems will be operational and part of production in the second half of 2001. Specifically,

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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 are currently developing an ancillary system to TARO that is designed for high-throughput, precise aliquotting. This automated system is expected to substantially reduce 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 reducing our operating costs. This system is scheduled to be introduced by fourth quarter of 2001.

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**

We focus our R & D efforts on accelerating new assay development, evaluating alternatives to costly diagnostics, improving existing assay performance and commercializing existing technologies developed by our strategic partners. All of our R & D efforts have been company-sponsored. No R & D efforts have been sponsored by our customers. We have spent over \$2.1 million in research and development during each of the years ended 1998, 1999 and 2000. Through our efforts, we have introduced over 600 new or improved esoteric assays in the past five years. Our R & D efforts enable us to grow revenues, increase market share and command premium pricing for many of our assays.

Our process of creating a new assay begins with input from many sources, including, our scientific team, our marketing department, scientific symposiums, 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. Once an assay is approved by this team, our R & D staff initiates development and validation of that assay. Currently, our average time to internally develop and market a new esoteric assay is three months.

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, speed of testing or cost reduction. Our adoption of the Sequenom MALDI-TOF system is an example of such an enabling platform. We expect turn-around time to be dramatically reduced by eliminating procedures typical with conventional DNA testing and we also expect lower costs by decreasing reagent use. This system has applications in many medical areas, including infectious diseases, bacterial identification and genomics.

### **Strategic Partnerships and Licensing Arrangements**

We actively pursue strategic partnerships that provide us with technologies or intellectual property that help facilitate accelerated assay development and commercialization. In addition, such agreements may provide us with the opportunity to collect royalties from third parties for sublicensing these

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technologies to others. Five important technologies that we have licensed through strategic relationships include:

Roche's PCR technology which is the technology platform for many of our gene-based assays;

Sequenom's MALDI-TOF technology which allows us to significantly accelerate the analytical time for our DNA assays;

Epoch Biosciences' technology which improves performance of assay systems for molecular analysis that is used to locate and identify genes associated with cancer;

Third Wave Technologies' novel DNA detection and quantitation system; and

Gen Probe's patented RNA gene to be used as a screen for identifying bacterial infections.

#### ***Roche Agreement***

In 1992, we entered into an agreement with Roche Molecular Systems under which we license polymerase chain reaction, or PCR, technology which is the foundation for many of our gene-based diagnostic assays. In 1999, this PCR technology was augmented by an additional license

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arrangement with Roche. Our licenses to use Roche's technology are not exclusive and Roche may grant similar rights to other parties. In exchange for these licenses, we have agreed to pay Roche royalties on our sale of assays incorporating the Roche technology. Both license agreements will terminate at the expiration of the last of the PCR technology patents, which expire in 2004.

### *Sequenom Agreement*

In June 2000, we purchased from Sequenom a high speed machine capable of detecting and characterizing pieces of DNA. In connection with this purchase, we pay Sequenom development fees to develop assays for us which we will utilize with the machine to facilitate genotyping of certain infections. In addition to the development fees, Specialty will pay royalties to Sequenom based on revenues generated from our sale of any new assays developed utilizing Sequenom's technology. For any newly developed assay for which we desire exclusive rights, a licensing agreement can be negotiated with Sequenom.

### *Epoch Biosciences Agreement*

In May 2000, we entered into a strategic partnership with Epoch Biosciences to collaborate our research and development effort to identify and commercialize new assays to detect human leukemias. In addition to fixed fees we pay to Epoch upon the identification of successful assay probes, Specialty will pay royalties to Epoch based on revenues generated from our sale of new assays developed utilizing Epoch's technology. If the collaboration is successful in developing new assays, we will have the exclusive right to commercialize these assays for a period of one year. This agreement will continue until the expiration of any patent rights licensed from Epoch, unless earlier terminated by mutual agreement or otherwise.

### *Third Wave Agreement*

In April 2000, we entered into a strategic relationship with Third Wave Technologies in order to utilize and incorporate Third Wave's DNA detection and quantification system in our assay menu. Our collaborative relationship will continue until terminated by either party with prior notice. There are no fees or royalties associated with this agreement.

### *Gen-Probe Agreement*

In March 2000, we entered into an agreement with Gen-Probe under which we license technology to facilitate our development of new assays and improve existing assays which identify bacterial infections. Our license to use Gen-Probe's technology is not exclusive and Gen-Probe may grant similar

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rights to other parties. In exchange for the Gen-Probe technology, we have agreed to pay Gen-Probe royalties on our sale of assays which incorporate the technology. We have granted Gen-Probe a non-exclusive license to any improvements we make upon the Gen-Probe technology. The agreement will expire in March 2002 and can be renewed for one year, on the same terms, with the mutual consent of the parties.

### **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 registered these trademarks accordingly. We also have registered our slogans used in our clinical information and other advertising materials.

On April 5, 2000, we received a letter 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.

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Neither NIH nor Chiron has filed suit against us. 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. We do not believe the outcome of either of these matters is likely to have a material adverse effect on our business, financial condition or results of operations.

### 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 and 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 or Athena Diagnostics, that occupy a narrow segment of the esoteric market by offering a very specific assay menu. Finally, institutions such as Mayo Medical Laboratories and Associated Regional University Pathologists that are affiliated with large medical centers or universities generally lack the advantages of the larger commercial laboratories but instead compete with us on the limited basis of offering a perceived higher quality.

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;

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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 Assurance

We maintain a comprehensive quality assurance system that monitors performance throughout the laboratory to ensure accuracy and precision in specimen handling and daily laboratory clinical testing. We also have written protocols based upon nationally standardized guidelines to guide our test performance and results interpretation, and to monitor and evaluate our problem solving procedures. 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 the Centers for Disease Control and Prevention, along with other independent state, national and international programs. Participation in the Laboratory Accreditation Program requires periodic self-evaluation, which is monitored by the College of American Pathologists. Routine monitoring of control results and blind specimen submissions provides information necessary to identify and resolve potential problems.

All laboratory testing and associated processes are described in written standard operating procedures and procedures which follow the format of the National Committee on Clinical Laboratory Standard's clinical laboratory procedure manual. Included therein are instructions for routine monitoring of quality control data, the frequency with which tests are to be run, the tolerance limits and the corrective action which is to be taken when 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, damages and asset forfeitures. Monetary penalties may reach \$10,000 for each test improperly billed. 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. 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 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 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 Health Care Financing Administration may exclude from the Medicare and Medicaid programs any provider convicted under any state or federal law of certain offenses relating to fraud, or who has been subjected to a civil monetary penalty under the above described provisions of the Social Security Act. The Health Care Financing Administration 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

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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 large and small 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, the Physician Ownership and Referral Act, which apply to referrals by California physicians. 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 Physician Ownership and Referral Act and the Stark Law 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 year end on December 31, 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, 2001. 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

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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 HCFA on January 4, 2001, with an effective date of January 4, 2002. The most substantial provisions of the new regulations address the provision of services by physicians in their offices and define the services, other than laboratory services, to which the Stark Law applies. Provisions contained in the new 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 the Company. In addition, the new 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. HCFA 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 HCFA's new interpretations may be required to have its California physician customers obtain the restricted types of supplies from third parties. The new interpretations also acknowledge that the provision of a phlebotomist without charge is permitted so long as the phlebotomist performs solely laboratory functions for the laboratory providing the phlebotomist complying with these new HCFA interpretations may result in cost-savings for laboratories. Nevertheless, because the prior regulations largely implemented the Stark Law as it applies to clinical laboratory services, the Company does not believe that the new regulations will have any material impact on it.

**Antikickback Laws.** The federal Medicare/Medicaid antikickback statute prohibits laboratories from paying remuneration as inducement for referrals of patients or specimens for testing paid for by the Medicare or Medicaid programs. Based upon a federal court decision specifically considering physician ownership of laboratories and an antikickback 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 Medicare's Office of Inspector General, 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, Medicare's Office of Inspector General 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 antikickback laws, including our negotiated discounted pricing arrangements, our participation in group purchasing organizations and provision of information technology to our customers. Because, in most instances, we bill our customers for both their Medicare and non-Medicare testing at a uniform price, we believe the Office of Inspector General's concerns regarding discounts will not apply to us. Moreover, statutory exceptions and "safe harbor" regulations are available to protect certain discounts offered to customers and certain payments we make to group purchasing organizations.

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

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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 antikickback laws. However, it is possible that markups by our non-California customers who are not bound by anti-markup restrictions may implicate California's antikickback laws.

Any action taken against us under the Medicare/Medicaid antikickback 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 antikickback laws or similar antikickback, anti-markup, or direct billing laws of other states may be subject to loss of licensure and substantial fines.

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While we believe that we are in compliance with the antikickback 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 antikickback 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 necessary to conduct our business. Our laboratory is certified pursuant to the Clinical Laboratory Improvement Amendments, which subject virtually all clinical laboratories to national standards for assuring quality of laboratory performance. Licensure is also required and maintained for our laboratory under the laws of the State of California. We are licensed in states which require us to be licensed in order for us to perform services for their residents, including Florida, Maryland, New York, Pennsylvania and Rhode Island. Our laboratory facilities are also certified by the College of American Pathologists.

The above programs establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, federal and state laws mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory. If a laboratory is out of compliance with the Clinical Laboratory Improvements Amendments or other applicable requirements, the Health Care Financing Administration or the California Department of Health Services may assess substantial civil money penalties, restrict the tests which the laboratory may perform, impose specific corrective action plans, suspend the laboratory's approval to receive Medicare payments, and/or suspend, revoke or limit the laboratory's Clinical Laboratory Improvements Amendments certificate or state license. If a laboratory's Clinical Laboratory Improvements Amendments certificate or state license is suspended or revoked, its ability to perform further testing terminates.

In June 1999, the Health Care Financing Administration asserted that we were out of compliance with Clinical Laboratory Improvements Amendments regulations pertaining to specific quality assurance functions, and imposed certain fines in connection therewith. After the Health Care Financing Administration's resurvey in June 2000, we were able to satisfy the Health Care Financing Administration that we were in compliance with the applicable requirements. We appealed the fine imposed by the Health Care Financing Administration, and subsequently settled the matter by paying HCFA the sum of \$87,400. We believe we are presently in compliance with all certification and licensure requirements.

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### *Compliance*

We have reviewed the pertinent regulations of the Clinical Laboratory Improvements Amendments and related rulings and policy guidelines and we believe that our business practices adhere to the stated requirements. We will continue to monitor legislation and implement the practices therein, but there can be no guarantee that we will pass all future inspections or otherwise be found to be in compliance with these and other regulations in the future.

The Department of Health and Human Services' Office of the Inspector General has in recent years suggested adoption of 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 appointed a compliance director to assist us with our regulatory compliance.

### *"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 in the process of restructuring our relationships with pathologists in a manner which we believe does not violate any prohibition against the "corporate practice" of medicine or otherwise violate state or federal law. 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 or results of operations.

### *Increased Regulation of Genetic Testing*

The federal Food and Drug Administration, or the 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 the Clinical Laboratory Improvements

Amendments 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. The federal Centers for Disease Control and Prevention, or CDC, has published notice of its intent to revise the regulations under the Clinical Laboratory Improvements Amendments to specifically recognize and regulate a genetic testing specialty. In addition, the Department of Health and Human Services' Secretary's Advisory Committee on Genetic Testing advises the Department of Health and Human Services as to various issues raised by the development and use of genetic testing. The Secretary's Advisory Committee on Genetic Testing has published and requested comments on its preliminary recommendations for increased participation on the part of the FDA and increased regulation of genetic testing under Clinical Laboratory Improvements Amendments. As a result of the activities of the FDA, the CDC and the Secretary's Advisory Committee on Genetic Testing, it is possible that our existing and future assays may be subject to a regulatory approval similar to the pre-marketing approval process which 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.

### ***Other Regulations***

Pursuant to the Occupational Safety and Health Act, known as OSHA, laboratories must provide a safe workplace to their employees, and OSHA has issued rules 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 increasing healthcare insurance coverage or reducing healthcare costs have been considered in recent years which, if enacted, would have affected major reforms of the healthcare system. Such proposals include: 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 3.5% of our net revenue in 1999 and 4.0% of our net revenue in 2000. Medicaid net revenue was 2.0% of our total net revenue in 1999 and represents 1.5% of our net revenue for the year ended December 31, 2000. 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 inpatients. Payment for in-patient laboratory services 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. Most recently, Congress reduced the national cap to 74% of the national median of local fee schedules and eliminated consumer price index increases to the national cap and local fee schedules through the year 2002. Medicare reimbursement has also been reduced from time to time by an effective rate of between 1% and 2% pursuant to Gramm-Rudman-Hollings



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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. For example, such a recommendation is contained in the HHS Office of Inspector General's 2001 "Red Book" of suggested Medicare program improvements. The costs of billing and collecting co-payment amounts and associated bad debt could reduce the revenue actually realized by laboratories.

**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. The Health Care Financing Administration has promulgated regulations to end such separate billing as of January 1, 2001. Congress has enacted legislation delaying implementation of HCFA's rules until January 1, 2003 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 January 1, 2003 date 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 generally 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 the Department of Health and Human Services 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, the Health Care Financing Administration 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. The Health Care Financing Administration 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. The Health Care Financing Administration is required to complete five Medicare bidding demonstrations involving various types of medical services by 2002, and the Health Care Financing Administration is expected to include a clinical laboratory demonstration project in a metropolitan statistical area. Similarly, California legislation requires the implementation of a program of negotiated laboratory service contracting for the Medi-Cal program. 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.

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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.

**"Bundling" of Medicare Services.** Proposals have been made to reimburse clinical laboratory testing services as part of a larger "bundle" of healthcare services. Under one proposal, physicians would be reimbursed an additional amount for each office visit they had with a Medicare beneficiary and would be responsible for paying for any required laboratory services out of this sum. This or other "bundling" proposals, if enacted, could have an adverse effect on our operations.

**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*

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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 adopted, and is in the process of implementing, 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.

### Employees

As of December 31, 2000, we employed 799 individuals. Thirty-three are engaged in research and development, 173 in administration and clerical functions, 84 in sales and marketing, 58 in information technology and 451 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

*Any investment in shares of our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with all of the other information contained in this Annual Report before you decide to buy our common stock. If any of the following 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.*

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

The esoteric clinical laboratory industry is characterized by advancing technology which may enable other clinical laboratories, hospitals, physicians or other medical providers to perform assays with

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properties similar to ours in a more efficient or cost-effective manner than is currently possible. Such technological advances may be introduced by, not just our competitors, but by any third party. For instance, a diagnostic manufacturing company may release an instrument or technology that would make it cost-effective for our customers to perform esoteric assays internally, rather than through us. If these or other advances in technology result in a decreased demand for our assays, our assay volume and net revenue would decline.

#### **The esoteric clinical laboratory industry is intensely competitive. If we are unable to successfully compete, we may lose market share.**

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 Impath or Athena Diagnostics that focus on a narrow segment of the esoteric market; and

institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or Associated, 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 market share.

**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 esoteric assays at premium prices for several years before 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.

For example, our net revenue from one assay for HIV Quantitation was:

in 1998, \$19.7 million, or 17.3% of total 1998 net revenue;

in 1999, \$17.3 million, or 13.3% of total 1999 net revenue; and

in 2000, \$16.3 million, or 10.7% of total 2000 net revenue.

This decreasing trend has been primarily due to competition from subsequently introduced assays. If we are unable to develop newer assays which meet market demand, our net revenue and profit margins may decrease.

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**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, Mayo and Associated, also compete with us by providing esoteric testing services. They often refer to us assays that they either cannot or elect not to perform themselves. For the year ended December 31, 2000, sales to our competitors were \$10.4 million or 6.8% of our net revenue. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours. For example, in July 1997, SmithKline Beecham Clinical Laboratories, or SmithKline Labs, began to significantly limit the number of assays it referred to us. We believe that SmithKline Labs terminated its relationship with us because it decided to offer assays similar to ours. In 1996, SmithKline Labs comprised 21.7% of our net revenue, whereas in 2000, after being acquired by Quest, SmithKline Labs (excluding Quest accounts prior to the acquisition) only comprised 1.5% of our net revenue. If other independent laboratories decide to reduce or discontinue purchases of our assays for competitive reasons, it will reduce our net revenue.

**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 esoteric 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. There is 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.

**A significant portion of our net revenue depends on a single customer, Unilab Corporation. If our relationship with Unilab is terminated or not renewed, our business may suffer.**

For the year ended December 31, 2000 and the year ended December 31, 1999, services to Unilab Corporation accounts comprised 9.6% and 7.4% of our net revenue, respectively. Although we have entered into an agreement with Unilab in which it has agreed to refer to us, until the agreement expires 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, there is no assurance that it will uphold this obligation. In addition, if Unilab does not renew this agreement in October 2002, it will then no longer be under any obligation to provide us with minimum assay referrals. If, for any reason, Unilab's purchase of our services were to be materially reduced or if Unilab failed to renew its contract with us in October 2002, it may decrease our net revenue.

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**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 20 assays. Net revenue from these 20 assays comprised approximately 54.5% of our total net revenue for the year ended December 31, 2000 and approximately 53.4% for the year ended December 31, 1999. In addition, for each of past three years, over 10% of our net revenue has been derived from one assay for HIV Quantitation. As a result, a significant portion of our net revenue is concentrated among these assays, and in particular, our HIV Quantitation assay. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue would decrease.

**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 five group purchasing organizations: AmeriNet, Joint Purchasing Organization, Managed Healthcare Associates, Novation (formerly known as VHA) and Shared Services Healthcare. We are typically granted non-exclusive provider status under these contracts. Our contract with our group purchasing organizations will expire at times from 2001 to 2004.

For the year ended December 31, 2000, sales of our services to hospitals which utilized the pricing structures under the Novation and AmeriNet group purchasing organization contracts comprised approximately \$34.3 million or 22.4%, and approximately \$7.6 million or 5.0% of our net revenues, respectively. Sales to hospitals within the other three group purchasing organizations comprised less than 1% of our net revenues for the same period. These group purchasing organizations offer a substantial growth opportunity to gain additional revenue from existing hospital customers. While we believe that over 1,800 of our 2,200 hospital customers are affiliated with these five group purchasing organizations, only approximately 400 of these customers qualify for discounts under these contracts.

We cannot be certain that if our agreement with Novation, AmeriNet or any other group purchasing organization is terminated or not renewed, that we will be able to retain any of the accounts of the 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.

**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 net revenue.**

Our success depends, in part, on the continued and uninterrupted performance of our information technology systems, including our DataPassport® suite of products. 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, results of operations and financial condition could be materially and adversely affected by any damage or failure that interrupts or delays our operations.

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Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite network security measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because they are located at a third party web hosting company, Exodus

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Communications, in El Segundo, California, and we cannot control the maintenance and operation of the Exodus data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems.

We have insurance policies designed to cover losses arising from such interruptions. Our policies include coverage for commercial general liability with a limit of \$10 million. However, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our 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 market share.**

Over the past four years, we have made a substantial investment in our information technology solutions, such as DataPassport® and DataPassportMD , to facilitate electronic assay ordering and results reporting as a value added service for our customers. Based on management's experience in the industry and discussions with our customers, we believe that our competitors have not yet implemented similar information technology tools. We further 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 will lose this competitive advantage, and as a result, may be unable to maintain or increase our market share.

**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 exposes us to the risk of litigation, including medical malpractice. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain insurance with coverage up to \$20 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, 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 which may cause us to pay substantial damages and prohibit 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. As a result, we may be found to be, or accused of, infringing on the proprietary rights of others. 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 have received letters from Chiron Corporation and the National Institute of Health in February 1998 and April 2000, respectively, claiming that some of our assays may violate their patents. The assays which may be affected by these claims comprised approximately \$22.9 million of our net revenue for the year ended December 31, 2000. While management believes that none of these claims will have a material adverse effect on our business, 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 intellectual property 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 infringed intellectual property right; or

redesign or reengineer our assays.

Any efforts to reengineer our assays or any inability to sell our assays could substantially increase our costs, force us to interrupt product sales, delay new assay releases and ultimately, reduce our revenues.

**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. In this regard, we recently acquired BBI Clinical Laboratories, Inc. Please see "Business Recent Developments." 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. If we consummate any significant acquisitions using stock or other securities as consideration, your equity in us 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. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of goodwill and other intangible assets in connection with future acquisitions, which would harm our operating results.

**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 esoteric 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 . In addition, we plan to

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develop and implement other automated systems to enhance our testing procedures, including the implementation of a specimen splitting system. 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.

**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. While written "corporate compliance" programs to actively monitor compliance with fraud

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laws and other regulatory requirements are recommended by the Department of Health and Human Services' Office of the Inspector General and are common in the clinical laboratory industry, we are only in the process of implementing such a program.

### *Federal and State Clinical Laboratory Licensing*

The operations of our clinical laboratory are subject to a stringent level of regulation under the Clinical Laboratory Improvement Amendments. For certification under the Clinical Laboratory Improvement Amendments, laboratories such as us must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. Our laboratory is also subject to strict regulation by California, New York and various other states. We are accredited by the College of American Pathologists, and therefore are subject to their requirements and evaluation. Our failure to comply with Clinical Laboratory Improvement Amendments, state or other applicable requirements could result in various penalties, including 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. 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. 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.

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### *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. However, 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.

### *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.

**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 at both the state and federal levels. For example, the Health Insurance Portability and Accountability Act of 1996 requires the U.S. Secretary of Health and Human Services to develop regulations to protect the security and privacy of individually identifiable health information that is electronically transmitted or received. In November 1999, the U.S. Secretary of Health and Human Services published proposed regulations under the Health Insurance Portability and Accountability Act of 1996 that would protect the privacy of individually identifiable health information that is transmitted or received

electronically. Prior to that, the Secretary of HHS published proposed regulations relating to security of individually identifiable health information. When and if the security regulation becomes final, and if the privacy regulation is not modified by HHS or invalidated by Congress under the Congressional Review Act, then they will require that holders or users of electronically transmitted

patient health information 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 commercialization of our Internet products including Outreach Express<sup>®</sup>, DataPassportMD<sup>®</sup>, and DataPassport Clinical Trials<sup>®</sup> is strictly governed by state and federal laws and regulations, including the new and proposed regulations under the Health Insurance Portability and Accountability Act of 1996. We have implemented encryption technology to protect patient medical information, however, 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.

**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 United States 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. Third party payors accounted for approximately 7.4% of our net revenue in 1999 and 7.3% of our net revenue for the year ended December 31, 2000. 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.

**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 clinical and processing facility may be affected by catastrophes such as earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because all of our clinical laboratory facilities are located in Santa Monica, California, an earthquake-prone area. In the event our existing clinical laboratory facility or equipment is affected by man-made or natural disasters, we would 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 all interruptions of service. This includes identification of alternate laboratory testing facilities and complete disaster recovery protocols. We also carry earthquake insurance with coverage amount of up to \$10 million and have outsourced part of our data storage and processing

equipment to a facility designed to withstand most earthquakes. Despite these precautions, 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 current energy crisis could disrupt our operations and increase our expenses.**

All of our laboratory operations are located in Santa Monica, California. California is in the midst of 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



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currently have backup power generators for our laboratories 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.

### **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:

demand for our assays 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;

changes in healthcare laws and regulations; and

costs related to acquisitions of technologies or businesses.

We plan to expand our sales and marketing, research and development and general and administrative efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, operating results and financial condition 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."

### **Our stock price is likely to be volatile and could drop unexpectedly.**

The price at which our common stock will trade is likely to be volatile. The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices of securities, particularly securities of clinical laboratory, biotechnology and other healthcare service companies. As a result, the market price of our common stock may materially decline, regardless of our

operating performance. 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. We may become involved in this type of litigation in the future. Litigation of this type is often expensive and diverts management's attention and resources.

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

Our principal shareholder is Specialty Family Limited Partnership, whose sole general managing partner is our Chairman and Chief Executive Officer, Dr. James B. Peter. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 70% of the

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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 nominations for election to the board of directors or 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**

Our primary facility is located in Santa Monica, California and is comprised of four separate buildings totaling 85,357 square feet. Three of our building leases expire in 2003 and one building lease expires in 2004. Additionally, three of our leases have options for five additional years upon expiration of the current leases. Our production, research and administrative functions occupy these buildings. Annual rent for these four buildings is approximately \$1.6 million plus applicable property taxes, maintenance costs and utilities.

We also operate one stand-alone triage collection and processing center in Worcester, Massachusetts to serve Boston area customers. This facility contains 1,578 square feet and is leased at approximately \$34,700 per year on a month-to-month basis. We also occupy a smaller 210 square foot administrative facility at the same address.

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## **ITEM 3. LEGAL PROCEEDINGS**

Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, or SLA, is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation. 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 California to attempt to collect on the Singapore judgment and has obtained a default judgment of \$2.5 million against SLA in California. The former employee has served discovery upon Specialty and certain directors and officers, has sought to compel these officers and directors to provide this discovery, and has requested sanctions in connection with these requests. 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.

## **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 New York Stock Exchange under the symbol "SP" since December 7, 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 Ended December 31, 2000:		
Fourth Quarter (December 7, 2000 through December 31, 2000)	\$ 35.50	\$ 21.38
First Quarter 2001 (through March 20, 2001)	\$ 33.375	\$ 16.75

On March 20, 2001, the last reported sales price of our common stock was \$21.40.

**Holdings**

As of March 20, 2001, there were 30 holders of record of our common stock.

**Recent Sales of Unregistered Securities**

During the fiscal year ended December 31, 2000, we granted options to purchase a total of 840,260 shares of our common stock to our employees and non-employee directors at a weighted-average exercise price of \$10.03 per share.

During the fiscal year ended December 31, 2000, 314,334 options to purchase our common stock were exercised.

The issuance and exercise of these options were exempt from registration under the Securities Act of 1933, as amended, in reliance on Rule 701 of the Securities Act as securities issued under a written compensatory benefit plan established by us for the participation of our employees, directors, officers or consultants and advisors.

**Use of Proceeds from Sales of Registered Securities**

On December 13, 2000, we completed our initial public offering of our common stock, no par value. The managing underwriters in the offering were Merrill Lynch & Co., UBS Warburg LLC and U.S. Bancorp Piper Jaffray (the "Underwriters"). The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement Form S-1 (the "Registration Statement") (Reg. No. 333-45588) that was declared effective by the SEC on December 7, 2000. The offering commenced on December 8, 2000 where all 5,000,000 shares of common stock registered under the Registration Statement were sold at a price of \$16.00 per share. The Underwriters also exercised an overallotment option of 750,000 shares on December 11, 2000. All 750,000 shares were sold at a price of \$16.00 per share. The aggregate price of the offering amount registered, including the overallotment was \$92,000,000. In connection with the offering, we paid an aggregate of \$6,440,000 in underwriting discounts and commissions to the Underwriters. In addition,

the following table sets forth the expenses incurred in connection with the offering, other than Underwriting discounts and commissions.

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SEC registration fee	\$	24,300
NASD filing fee		9,700
NYSE listing fee		152,000
Legal fees and expenses		825,800
Accountants' fees and expenses		455,000
Printing expenses		480,200
Blue sky fees and expenses		10,000
Transfer Agent and Registrar fees and expenses		4,000
Miscellaneous		266,200
Total		\$ 2,227,200

After deducting the underwriting discounts and commissions and the estimated offering expenses described above, we received net proceeds from the offering of approximately \$83,333,000. We have used the net proceeds from our initial public offering of common stock to purchase certain assets of BBI Clinical Laboratories, Inc. for \$9,500,000 in cash, repay outstanding term debt, revolving debt, and all accrued and unpaid interest thereon in the amount of approximately \$9,200,000, and invest in interest bearing investment grade instruments. We have used our existing cash balances to fund our general operations. The remaining proceeds will be used for general corporate purposes, including working capital, expansion of our sales and marketing capabilities, research and development, and acquisitions of, or investments in, businesses, products and technologies that are complementary to our business. None of our net proceeds were paid directly or indirectly to any director, officer, general partner of the Company or their associates, persons owning 10% or more of any class of equity securities of the Company, or an affiliate of the Company.

### 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. In addition, in connection with a loan and security agreement, we are restricted from paying dividends in cash. As a result, we do not anticipate paying any cash dividends in the foreseeable future.

### ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The statement of operations data set forth below for the years ended December 31, 1997, 1998, 1999 and 2000 and the balance sheet data at December 31, 1998, 1999 and 2000 are derived from our financial statements that have been audited by Ernst & Young LLP and are qualified by reference to those financial statements. The statement of operations data set forth below for the year ended April 30, 1996 and the balance sheet data as of April 30, 1996 and as of December 31, 1997 are derived from our financial statements that have been audited and to which reclassifications have been made to conform to the presentation of costs and expenses, continuing operations, discontinued operations and net assets of discontinued foreign operations for the other periods presented. The statement of operations data for the eight months ended December 31, 1996 and the balance sheet data at December 31, 1996 are derived from financial statements that are unaudited. We have prepared the unaudited information on the same basis as the audited financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of our financial position at such date and our operating results for these periods. You should read the selected financial information set forth below in conjunction with "Management's

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

Year Ended April 30 1996	Eight Months Ended December 31, 1996	Years Ended December 31,			
		1997	1998	1999	2000
	(unaudited)				

(amounts in thousands, except per share data)

#### Statement of operations data:

Net revenue	\$	55,710	\$	54,010	\$	106,357	\$	113,843	\$	130,142	\$	153,245
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	Eight Months Ended					
	December 31,					
	2016	2015	2014	2013	2012	2011
<b>Costs and expenses:</b>						
Costs of services	26,698	19,006	60,157	65,098	74,784	86,856
Selling, general and administrative (exclusive of stock-based compensation charges)	22,580	17,826	39,813	42,084	46,903	49,277
Stock-based compensation charges(1)					2,818	1,073
Write-down of unused facilities(2)	429				2,209	369
<b>Total costs and expenses</b>	<b>49,707</b>	<b>43,832</b>	<b>99,970</b>	<b>107,182</b>	<b>126,714</b>	<b>137,575</b>
<b>Operating income</b>	<b>6,003</b>	<b>10,178</b>	<b>6,387</b>	<b>6,661</b>	<b>3,428</b>	<b>15,669</b>
Interest expense, net	318	160	883	1,159	1,639	941
<b>Income from continuing operations before income taxes</b>	<b>5,685</b>	<b>10,018</b>	<b>5,504</b>	<b>5,502</b>	<b>1,789</b>	<b>14,729</b>
Provision for income taxes	2,058	3,910	2,506	2,273	930	6,056
<b>Income from continuing operations</b>	<b>3,627</b>	<b>6,108</b>	<b>2,998</b>	<b>3,229</b>	<b>859</b>	<b>8,673</b>
Loss from discontinued operations(3)	(895)	(1,080)	(936)	(3,060)	(2,001)	
<b>Net income (loss)</b>	<b>\$ 2,732</b>	<b>\$ 5,028</b>	<b>\$ 2,062</b>	<b>\$ 169</b>	<b>\$ (1,142)</b>	<b>\$ 8,673</b>
<b>Income (loss) per share(4):</b>						
<b>Basic:</b>						
Continuing operations	\$ 0.23	\$ 0.39	\$ 0.19	\$ 0.21	\$ 0.05	\$ 0.54
Discontinued operations	(0.06)	(0.07)	(0.06)	(0.20)	(0.12)	
	\$ 0.17	\$ 0.32	\$ 0.13	\$ 0.01	\$ (0.07)	\$ 0.54
<b>Diluted:</b>						
Continuing operations	\$ 0.23	\$ 0.39	\$ 0.19	\$ 0.21	\$ 0.05	\$ 0.49
Discontinued operations	(0.06)	(0.07)	(0.06)	(0.20)	(0.12)	
	\$ 0.17	\$ 0.32	\$ 0.13	\$ 0.01	\$ (0.07)	\$ 0.49
<b>Weighted average shares outstanding(4):</b>						
Basic	15,476	15,493	15,457	15,459	16,045	16,101
Diluted	15,489	15,514	15,477	15,505	17,004	17,639
<b>Other data:</b>						
Adjusted EBITDA(5)	\$ 7,803	\$ 11,384	\$ 9,942	\$ 10,844	\$ 13,864	\$ 23,063
Adjusted EBITDA as a % of net revenue	14.0%	21.1%	9.3%	9.5%	10.7%	15.0%
Cash flow provided by continuing operating activities	\$ 2,284	\$ 4,552	\$ 5,994	\$ 7,353	\$ 3,315	\$ 15,463
Cash flow used in investing activities	(2,867)	(4,659)	(15,128)	(5,131)	(3,696)	(5,965)
Cash flow provided by (used in) financing activities	589	336	11,047	2,942	(56)	65,388

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	As of December 31,					
	As of April 30, 1996	1996	1997	1998	1999	2000
		(unaudited)				
		(in thousands)				
<b>Balance sheet data:</b>						
Working capital	\$ 3,852	\$ 5,272	\$ 2,899	\$ 2,035	\$ 3,616	\$ 88,789
Total assets	22,066	30,839	48,229	55,998	59,859	142,005
Long-term debt, including current portion	3,378	3,714	14,761	17,703	18,382	
Total shareholders' equity	11,360	15,250	17,135	16,953	18,281	111,797

- (1) We recorded stock-based compensation charges of \$2.8 million for the year ended December 31, 1999 in connection with the sale of our common stock to management and the grant of stock options to management and directors in 1999. We recorded stock-based compensation charges of \$1.1 million for the year ended December 31, 2000 resulting from the amortization of deferred stock-based compensation and variable stock-based compensation charges on certain stock options.
- (2) During the year ended April 30, 1996, a proposed expansion to a new facility was abandoned, resulting in a write-down of the unused facility totaling \$0.4 million. During the year ended December 31, 1999, management decided to abandon our Memphis facility, resulting in a write-down of the unused facility totaling \$2.2 million, which included a reserve of \$0.8 million for future net lease costs. During the year ended December 31, 2000, a month-to-month lease with a related party was terminated on a facility resulting in a write-off of \$0.4 million for the unamortized leasehold improvements related to the facility.
- (3) We discontinued all foreign operations in 1999. For details of the components of discontinued operations, see note 3 of the consolidated financial statements contained elsewhere in this Annual Report. Because these operations were substantially shut down in 1999, we incurred no related ongoing losses during the year ended December 31, 2000.
- (4) All periods have been adjusted for a 2.2-for-1 stock split on October 30, 2000.
- (5) Adjusted EBITDA is defined as EBITDA adjusted to exclude stock-based compensation charges and write-down of unused facilities. EBITDA consists of income (loss) from continuing operations before interest, income taxes, depreciation and amortization. EBITDA and adjusted EBITDA should not be considered as measures of financial performance under GAAP. Items excluded from EBITDA and adjusted EBITDA are significant components in understanding and assessing financial performance. We present EBITDA and adjusted EBITDA which are non-GAAP measures, to enhance the understanding of our operating results. EBITDA and adjusted EBITDA should not be considered in isolation or as alternatives to net income, cash flows generated by operations, investing or financing activities, or other financial statement data presented in the consolidated financial statements as indicators of financial performance or liquidity. Because EBITDA and adjusted EBITDA are not measurements determined in accordance with GAAP and are thus susceptible to varying calculations, EBITDA and adjusted EBITDA as presented may not be comparable to other similarly titled measures of other companies.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

*The following discussion of our financial condition and results of operations should be read in conjunction with our selected consolidated financial data and the consolidated financial statements and related notes included elsewhere in this Annual Report. This section includes forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated by forward-looking information due to factors discussed under "Risk Factors," "Business" and elsewhere in this Annual Report.*

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*For purposes of the following discussion, adjusted EBITDA is defined as EBITDA adjusted to exclude stock-based compensation charges and the write-down of unused facilities. For a complete definition of EBITDA, please see footnote 5 under "Selected Consolidated Financial Data."*

### Overview

We are a leading research-based clinical laboratory predominantly focused on developing and performing esoteric clinical laboratory tests, which we refer to as assays. We offer one of the industry's most comprehensive menus comprised of more than 3,500 clinical esoteric assays, 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 on sophisticated instruments by highly skilled personnel and are therefore offered by a limited number of clinical laboratories.

We have grown rapidly in recent years. For the three years ended December 31, 2000, our net revenue grew at a compounded annual growth rate of 16.0%. This growth has resulted from expansion of our sales and marketing forces, our investments in information technology, our aggressive efforts to improve operating efficiency and economies of scale. We do not believe, however, that this past performance is necessarily indicative of future financial results. See "Risk Factors" for a discussion of some of the risks and uncertainties which may cause our actual results and performance to be materially different from our past performance.

We believe that our typical esoteric assay is priced at approximately twice that of a routine test. Our assays also have higher costs than routine tests due to the necessity of specialized laboratory instruments and highly skilled laboratory personnel. If we are successful in obtaining or renewing large customer or group purchasing organization contracts, our average price per assay may slightly decrease, as these contracts typically incorporate volume discounts.

Since 1997, we have made significant investments in our business to expand sales and marketing capabilities and develop information technology and process automation. As part of our strategy to increase our penetration of the hospital market, we have grown our sales force to over 60 persons at December 31, 2000 from 33 at December 31, 1997. We have spent approximately \$6.0 million since 1998 to develop our customer-focused information technology suite of products. Since 1998, we have invested approximately \$1.0 million in process automation, which we expect will increase our assay capacity and throughput, and reduce our cost of services.

R & D spending has averaged \$2.3 million per year since 1997. In 1999, we refocused our R & D efforts on the efficient introduction of new assays with significant potential for growth and higher average selling prices, many of these in molecular diagnostics. Gene-based diagnostic assays represented nearly 40% of our net revenue for the year ended December 31, 2000. We have also increased our efforts to license technologies developed by third parties that complement our internal R & D objectives. To continue growing our business, we intend to use a portion of the proceeds from our initial public offering to increase our overall level of R & D spending, including an accelerated pursuit of licensing arrangements.

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Prior to 1997, our revenues were heavily dependent on national clinical laboratories. In 1997, we refocused our sales and marketing efforts to increase our penetration of the hospital market. One of our primary strategies has been to align ourselves with hospitals by not competing with them for the routine tests that represent a valuable source of revenue. As a result, the proportion of our net revenue from hospitals has increased. Net revenue from hospital customers as a percentage of total net revenue increased to over 51% for the year ended December 31, 2000 from 32.5% for the year ended December 31, 1997.

Since 1997, we have achieved consistent net revenue growth despite the substantial reduction of business from a significant independent laboratory customer, SmithKline Beecham Clinical Laboratories, or SmithKline Labs. SmithKline Labs withdrew approximately \$10.0 million of annualized net revenue in July 1997, and an additional \$13.0 million of annualized net revenue in July 1998.

### *Revenue Recognition*

The vast majority of our net revenue is derived from the performance of esoteric assays for hospitals, independent laboratories, physicians and other medical providers. Although we typically bill our customers directly for these services, in some cases we bill various third party payors, such as private insurance, Medicare, Medicaid or individual patients. We recognize revenue at the time the assay result is reported to our customer.

### *Expense Recognition*

Expenses are recognized as incurred and are generally classified between cost of services and selling, general and administrative expenses. Components of cost of services include salaries and employee benefits, research and development costs, supplies and reagents, courier costs,

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depreciation of laboratory equipment and leasehold improvements. Selling, general and administrative expenses include salaries and employee benefits, sales and marketing, insurance and bad debt expense.

### *Stock-Based Compensation Charges*

Stock-based compensation charges represent the difference between the exercise price of options granted, or the price of stock sold to employees and directors, and the deemed fair value of our common stock on the date of grant or sale in accordance with Accounting Principles Board Opinion No. 25 and its related interpretations. In the case of options, we recognize this compensation charge over the vesting periods of the options using an accelerated amortization methodology in accordance with Financial Accounting Standards Board Interpretation No. 28. For purposes of the period-to-period comparisons included in "Results of Operations," selling, general and administration expenses exclude these stock-based compensation charges, which are reflected as a separate line item.

We have recorded deferred stock-based compensation related to unvested stock options granted to employees and directors. Based on the number of outstanding options granted as of December 31, 2000, we expect to amortize approximately \$2.1 million of deferred stock-based compensation in future periods. We expect to amortize this deferred stock-based compensation approximately as follows: \$1.4 million during 2001, \$0.5 million during 2002, \$0.2 million during 2003 and \$34,000 during 2004. We anticipate that the exercise price of stock options granted after the offering will be at the reported market price of our common stock, and therefore no deferred stock-based compensation will result from these grants.

### *Discontinued Operations*

In fiscal year 1995, we began operating internationally by providing routine laboratory services and kit manufacturing to create revenue growth. In August 1999, we implemented a plan to discontinue all of our foreign operations, due to continued losses incurred with these foreign operations. We have no further obligations nor any plans to fund any additional losses of these foreign operations. For details

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of the components of discontinued operations, see Note 3 of the consolidated financial statements contained elsewhere in this Annual Report. Since these operations were substantially shut down in 1999, we incurred no related ongoing losses during the year ended December 31, 2000.

## **Results of Operations**

The following table sets forth the percentage of net revenue represented by certain items in our consolidated statements of operations.

	Years Ended December 31,		
	1998	1999	2000
Net revenue	100.0%	100.0%	100.0%
Cost of services	57.2	57.5	56.7
Selling, general and administrative (exclusive of stock-based compensation charges)	37.0	36.0	32.2
Operating income	5.9	2.6	10.2
Income from continuing operations before taxes	4.8	1.4	9.6
Income from continuing operations	2.8	0.7	5.7
Loss from discontinued operations	(2.7)	(1.5)	
Net income (loss)	0.1	(0.9)	5.7

### **Year Ended December 31, 2000 Compared with Year Ended December 31, 1999**

#### *Net Revenue*

Net revenue increased \$23.1 million, or 17.8%, to \$153.2 million for the year ended December 31, 2000 from \$130.1 million for the comparable prior year period. This growth came from increased testing volume, as overall assays increased by approximately 18% in 2000, exceeding 2.6 million assays in 2000. Our continued strategy of concentrating our sales force toward hospital customers has resulted in an increase in net revenues from that customer segment of approximately \$18.0 million in 2000. The balance of the net revenue growth of approximately \$5 million has come from independent laboratories, including Unilab. There was a modest decline in revenue from direct physician customers, primarily due to a concentrated effort to eliminate unprofitable accounts.



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### *Cost of Services*

Cost of services increased \$12.1 million, or 16.1%, to \$86.9 million for the year ended December 31, 2000 from \$74.8 million for the comparable prior year period. This increase is directly attributed to the increase in assay volume during the same period. As a percentage of net revenue, cost of services decreased to 56.7% for the year ended December 31, 2000 from 57.5% for the comparable prior year period. The decrease reflects the economies of scale realized by processing significantly higher assay volume and efficiencies provided by the ongoing automation of our laboratory operations.

### *Selling, General and Administrative Expenses (Exclusive of Stock-Based Compensation Charges)*

Selling, general and administrative expenses increased \$2.4 million, or 5.1%, to \$49.3 million for the year ended December 31, 2000 from \$46.9 million for the prior year-end. This growth came primarily from increased provisions for bad debts and sales and marketing expenses, which resulted from increased revenues and a growth in third party payors. This resulted in a decline in selling, general and administrative expenses as a percentage of net revenue, decreasing from 36.0% in 1999 to 32.2% for the year ended December 31, 2000.

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### *Stock-Based Compensation Charges*

Stock-based compensation charges decreased by \$1.7 million to \$1.1 million for the year ended December 31, 2000 from \$2.8 million for the comparable prior year period. The charge in the year ended December 31, 1999 included \$0.3 million related to a sale of stock to management and \$2.4 million related to stock options granted in February 1999. For the year ended December 31, 2000, variable stock-based compensation charges included \$0.1 million related to certain stock options for the period from July 1, 2000 through their dates of exercise in September 2000 and \$0.9 million related to amortization of deferred stock compensation.

### *Write-Down of Unused Facilities*

Prior to SmithKline Labs substantially reducing its level of business with us, we had committed to lease and improve a building in Memphis, Tennessee, primarily to process assays for certain large independent laboratory customers. Subsequently, management decided in the second quarter of 1999 not to use the Memphis facility, resulting in a write-down of the facility totaling \$2.2 million, which included a reserve of \$0.8 million for future net lease costs. For more information concerning this write-down, see Note 4 of the consolidated financial statements appearing elsewhere in this Annual Report.

We terminated a facility lease in Santa Monica, California with Santa Monica Properties, a company owned by our Chairman and Chief Executive Officer, Dr. James Peter, effective September 1, 2000. A write-down of approximately \$0.4 million for the unamortized leasehold improvements to this facility was recorded in the third quarter of 2000.

### *Interest Expense, Net*

Net interest expense decreased \$0.7 million, or 42.6%, to \$0.9 million for the year ended December 31, 2000 from \$1.6 million for the comparable prior year period. The decrease is due primarily to the reduction of our bank borrowings as a result of favorable cash flows from improved earnings. In December 2000, the outstanding revolving and term loans totaling \$9.2 million were paid by proceeds from our initial public offering.

### *Provision for Income Taxes*

Provision for income taxes was \$6.1 million for the year ended December 31, 2000 as compared to \$0.9 million for the comparable prior year period. We had an effective income tax rate for continuing operations of 41.1% for the year ended December 31, 2000. For the year ended December 31, 1999, the effective income tax rate for continuing operations was 52.0%, which was affected by expenses incurred in connection with our sale of stock to members of management in that period which were not deductible for income tax purposes.

### *Loss from Discontinued Operations*

Loss from discontinued operations was \$2.0 million for the year ended December 31, 1999. We discontinued all of our foreign operations in 1999 and have no further obligations nor plans to fund any additional losses of these foreign operations. No further losses from discontinued operations were incurred during the year ended December 31, 2000.

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### *Net Income (Loss)*

Net income increased by \$9.8 million to \$8.7 million for the year ended December 31, 2000 from a net loss of \$1.1 million for the comparable prior year period. The increase is due primarily to increased operating income resulting from higher assay volume and efficiencies provided by ongoing automation of assays. The comparable 1999 period also contained charges in excess of current year charges of

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\$1.7 million for stock-based compensation, \$1.8 million for a write-down of unused facilities and \$2.0 million, net of income tax benefit, for discontinued operations.

### *Adjusted EBITDA*

Adjusted EBITDA increased by \$9.2 million, or 66.4%, to \$23.1 million for the year ended December 31, 2000 from \$13.9 million for the comparable prior year period. As a percentage of net revenue, adjusted EBITDA increased to 15.0% for the year ended December 31, 2000 from 10.7% for the comparable prior year period. These results reflect economies of scale associated with processing significantly higher assay volume and efficiencies provided by ongoing automation of assays.

### **Year Ended December 31, 1999 Compared with Year Ended December 31, 1998**

#### *Net Revenue*

Net revenue increased \$16.3 million, or 14.3%, to \$130.1 million for the year ended December 31, 1999 from \$113.8 million for the prior year. During 1999, net revenue from hospitals increased by \$16.9 million due to focusing our sales force on hospital customers. Net revenue from physicians and other medical providers also increased by \$3.8 million for the same period as we benefited in 1999 from a trial sales program utilizing a significant number of part-time sales persons focused on the physician market to supplement our full-time sales force in the prior year. These increases were partially offset by a \$4.4 million decline in net revenue from other independent laboratories due mainly to SmithKline Labs substantially reducing its business with us in the third quarter of 1998. This business represented 6.3% of our net revenue in 1998 as compared to 1.6% in 1999.

#### *Cost of Services*

Cost of services increased \$9.7 million, or 14.9%, to \$74.8 million for the year ended December 31, 1999 from \$65.1 million for the prior year. This increase is attributable to the increase in assay volume. As a percentage of net revenue, cost of services increased slightly to 57.5% for the year ended December 31, 1999 from 57.2% for the prior year.

#### *Selling, General and Administrative Expenses (Exclusive of Stock-Based Compensation Charges)*

Selling, general and administrative expenses increased \$4.8 million, or 11.5%, to \$46.9 million for the year ended December 31, 1999 from \$42.1 million for the prior year. The increase is attributable to the growth of our operations. As a percentage of net revenue, selling, general and administrative expenses decreased to 36.0% for the year ended December 31, 1999 from 37.0% for the prior year. The decrease reflects the economies of scale associated with processing significantly higher assay volume. As a percentage of net revenue, bad debt expense remained constant at 3.3% for both years ended December 31, 1999 and 1998.

#### *Stock-Based Compensation Charges*

In connection with the sale of our common stock to management and the grant of stock options to management and directors in 1999, we recorded stock-based compensation charges of approximately \$2.8 million for the year ended December 31, 1999. No stock-based compensation charges were recorded in 1998.

#### *Write-Down of Unused Facilities*

In connection with the decision in the second quarter of 1999 not to use the Memphis facility, we recorded a write-down totaling \$2.2 million for the year ended December 31, 1999. For more information concerning this write-down, see Note 4 of the consolidated financial statements appearing elsewhere in this Annual Report.

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*Interest Expense, Net*

Net interest expense increased to \$1.6 million for the year ended December 31, 1999 from \$1.2 million for the prior year, representing an increase of \$0.4 million, or 41.5%. This increase is due primarily to increased borrowings under our bank loan agreements for capital expenditures and working capital needs to support our growth.

*Provision for Income Taxes*

We provided for income taxes in the amount of \$0.9 million for the period ended December 31, 1999 as compared to \$2.3 million for the prior year. We had an effective income tax rate for continuing operations of 52.0% for the year ended December 31, 1999 compared to a rate of 41.3% for the prior year. The higher tax rate in 1999 is due primarily to expenses incurred in connection with our sale of stock to members of management in 1999 which were not deductible for income tax purposes.

*Loss from Discontinued Operations*

Loss from discontinued operations decreased \$1.1 million to \$2.0 million for the year ended December 31, 1999 from \$3.1 million for the prior year. We discontinued all of our foreign operations in 1999. For details of the components of the loss from discontinued operations in 1999 and 1998, see Note 3 of the consolidated financial statements contained elsewhere in this Annual Report.

*Net Income (Loss)*

Net income decreased by \$1.3 million to a net loss of \$1.1 million for the year ended December 31, 1999 from net income of \$0.2 million for the prior year. The decrease during 1999 was due primarily to the write-down of the Memphis facility of \$2.2 million and the recording of stock-based compensation charges of approximately \$2.8 million, offset in part by improved operating income (before charges for stock-based compensation and write-down of unused facilities) of \$1.8 million and a reduced loss of \$1.1 million, net of income tax benefit, from discontinued operations.

*Adjusted EBITDA*

Adjusted EBITDA increased by \$3.0 million, or 27.8%, to \$13.9 million for the year ended December 31, 1999 from \$10.8 million for the prior year. As a percentage of net revenue, adjusted EBITDA increased to 10.7% for the year ended December 31, 1999 from 9.5% for the prior year. These results reflect economies of scale associated with processing significantly higher assay volume and efficiencies provided by ongoing automation of assays.

**Liquidity and Capital Resources**

Our liquidity requirements have historically consisted of sales and marketing expenses, research and development expenses, capital expenditures, working capital, debt service and corporate expenses. We have typically funded these requirements and the growth of our business through net cash provided by continuing operating activities and borrowings under our bank credit facilities. We currently maintain a \$30.0 million line of credit. During 2000, we paid down \$18.4 million of bank debt of which \$9.2 million was paid from proceeds from the initial public offering.

We generated net cash provided by continuing operating activities of \$15.5 million and \$65.4 million from financing activities for the year ended December 31, 2000. We used \$6.0 million of net cash in investing activities during the same period. As of December 31, 2000, we had cash totaling \$75.6 million and working capital of \$88.8 million.

Net cash provided by continuing operating activities was \$15.5 million and \$3.3 million for the year ended December 31, 2000 and 1999, respectively. The \$12.2 million improvement in 2000 was primarily due to our improved operating performance. Net cash used in investing activities was \$6.0 million and

\$3.7 million for the years ended December 31, 2000 and 1999, respectively. The primary use of funds in 1999 and 2000 was for capital expenditures to expand our information technology platform and laboratory automation and equipment. Net cash provided in financing activities was \$65.4 million for the year ended December 31, 2000 compared to a net cash use of \$0.1 million for the year ended December 31, 1999. The

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primary source of funds in 2000 was proceeds from the initial public offering. The primary use of funds during 1999 were payments made on our bank line of credit.

We expect that existing cash, cash equivalents, and our current credit facility along with funds generated from operations will be sufficient to fund our operations, meet our capital requirements and allow strategic technology licensing and acquisitions to support our growth for the next 12 months.

### **Inflation**

Inflation was not a material factor in either revenue or operating expenses during the past three fiscal years ended December 31, 1998, 1999, and 2000.

### **Subsequent Events**

On February 20, 2001, we completed the acquisition of substantially all of the assets of BBI Clinical Laboratories, Inc., a wholly-owned subsidiary of Boston Biomedica, Inc., a public company. We paid \$9,500,000 in cash which will be accounted for as a purchase in the first quarter of 2001.

### **Recent Accounting Pronouncements**

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments and hedging activities. SFAS 133 requires that an entity recognize all derivatives as either assets or liabilities in the statement of financial position and measure those instruments at fair value. This statement was amended by SFAS 137 which defers the effective date to all fiscal quarters of fiscal years beginning after June 15, 2000. SFAS 133 is effective for our first quarter in the fiscal year ending December 31, 2001 and will not have a material effect on our consolidated financial position or consolidated results of operations.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Our exposure to market rate risk for changes in interest rates relates primarily to our investment portfolio. In addition, our holdings are also exposed to the risks of changes in the credit quality of the issuer. Our investments in cash equivalents consist primarily of commercial paper, U.S. corporate debt and U.S. government debt. At December 31, 2000, our holdings, which had an original maturity date of less than 90 days, were classified as cash and cash equivalents on our consolidated balance sheet. At December 31, 2000, we had cash and cash equivalents of \$75.6 million, which had a weighted average yield of 7.2% per annum and an average of 7.3 days until maturity.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

Specialty Laboratories, Inc. financial statements, schedules and supplementary data, as listed under Item 14, appear in a separate section of this Report beginning on page F-1.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

## **PART III.**

### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

(a) **Identification of Directors.** The information under the caption "Election of Directors," appearing in our Proxy Statement, is incorporated herein by reference.

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(b) **Identification of Executive Officers.** The information under the caption "Executive Officers, Directors and Other Key Employees," appearing in our Proxy Statement, is incorporated herein by reference.

(c) **Compliance with Section 16(a) of the Securities Exchange Act of 1934.** The information under the caption "Section 16(a) Beneficial Ownership Reporting Compliance," appearing in our Proxy Statement, is incorporated herein by reference.

### ITEM 11. EXECUTIVE COMPENSATION

The information under the caption "Executive Compensation and Related Information," appearing in our Proxy Statement, is incorporated herein by reference.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information under the caption "Beneficial Ownership of Securities," appearing in our Proxy Statement, is incorporated herein by reference.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information under the heading "Certain Transactions," appearing in our Proxy Statement, is incorporated herein by reference.

## PART IV.

### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)

Documents filed as part of this Report:

1. **Financial Statements.** The following financial statements, and related notes thereto, of Specialty Laboratories, Inc. and the Report of Independent Auditors are filed as part of this Form 10-K.

	<b>Page</b>
Report of Ernst & Young LLP, Independent Auditors	F-1
Consolidated Balance Sheets at December 31, 1999 and 2000	F-2
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2000	F-3
Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 2000	F-4
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2000	F-5
Notes to Consolidated Financial Statements	F-6

2. Schedule II Valuation and Qualifying Accounts is included at Item 14(d) of this Annual Report.

All other Schedules for which provision is made in the applicable accounting regulations of the SEC are not required under the release instructions or are inapplicable and therefore, have been omitted.

3. **Exhibits.** The Exhibits filed as part of this Annual Report are listed in Item 14(c) of this Annual Report on Form 10-K.

(b)

Reports on Form 8-K:

None.

(c)  
Exhibits.

The following exhibits are filed as part of, or are incorporated by reference in, this Report.

Number	Description
3.1**	Articles of Incorporation.
3.2**	Form of By-laws.
4.1**	Specimen Common Stock Certificate.
4.2	See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
10.1**	2000 Stock Incentive Plan.
10.2**	2000 Employee Stock Purchase Plan.
10.3**	Loan Agreement dated April 15, 1996 between Union Bank of California and Registrant, as amended and restated on April 7, 1997 and as amended on January 23, 1998, February 17, 1999 and August 30, 1999.
10.4**	Revolving Note dated August 30, 1999 in favor of Union Bank of California.
10.5**	Term Note dated February 17, 1999 in favor of Union Bank of California.
10.6**	Term Note dated January 23, 1998 in favor of Union Bank of California.
10.7**	Term Note dated April 7, 1997 in favor of Union Bank of California.
10.8**	Security Agreement dated April 3, 1996 between Union Bank of California and Registrant.
10.9**	Lease dated June 1996 between Howard Real Property Trust (lessor) and Registrant (lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California.
10.10**	License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property.
10.11**	Lease dated January 26, 2000 between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California.
10.12**	Lease dated July 17, 1993 between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California.
10.13A**	Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant.
10.14**	Agreement dated June 6, 1992, as amended on August 25, 1997 and as amended on January 1, 1997 between Roche Molecular Systems, Inc. and Registrant.
10.15**	Homogeneous PCR Clinical Agreement dated October 5, 1999 between Roche Molecular Systems, Inc. and Registrant.
10.16A**	Services Agreement dated February 1, 1998 between VHA, Inc. (now known as Novation) and Registrant.
10.17**	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant.

10.18A**	Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant.
10.19A**	Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant.
10.20**	Shared Services Health Care letter of confirmation dated June 5, 2000.
10.21A**	Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (sublandlord) and Registrant (subtenant) for the property located at 1620 20th Street, Santa Monica, California.
10.22**	Employment Agreement dated September 1, 2000 between James B. Peter and Registrant.
10.23**	Employment Agreement dated September 1, 2000 between Paul F. Beyer and Registrant.
10.24**	Employment Agreement dated September 1, 2000 between John W. Littleton and Registrant.
10.25**	Employment Agreement dated September 1, 2000 between Bart E. Thielen and Registrant.
10.26**	Employment Agreement dated September 1, 2000 between Thomas E. England and Registrant.
10.27A**	Employment Agreement dated October 12, 2000 between Frank J. Spina and Registrant.
10.28A**	Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant.
10.29A**	Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant.

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- 10.30A\*\* Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant.
- 10.31A\*\* License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant.
- 10.32A\*\* Laboratory Services Agreement dated October 15, 1999 between Unilab Corporation and Registrant.
- 10.33 Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc.
- 21.1\*\* Subsidiaries of the Registrant.
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.

\*\*

This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 333-45588) under the same exhibit number, and is incorporated by reference herein.

Confidential treatment requested and received as to certain portions of this agreement.

Indicates a management contract or compensatory arrangement.

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(d) Financial Statement Schedule

Schedule II Valuation and Qualifying Accounts  
Specialty Laboratories, Inc.

Description	Balance at Beginning of Period	Additions Charged to Costs and Expenses	(1) Deductions	Balance at End of Period
<b>Year ended December 31, 2000</b>				
Allowance for bad debts:	\$ 4,016,938	\$ 5,039,817	\$ 5,026,099	\$ 4,030,656
<b>Year ended December 31, 1999</b>				
Allowance for bad debts:	1,806,559	4,307,742	2,097,363	4,016,938
<b>Year ended December 31, 1998</b>				
Allowance for bad debts:	1,952,271	3,765,292	3,911,004	1,806,559

(1) Uncollectible accounts written off, net of recoveries.

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Report of Ernst & Young LLP, Independent Auditors

Board of Directors

Specialty Laboratories, Inc.

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We have audited the accompanying consolidated balance sheets of Specialty Laboratories, Inc. as of December 31, 1999 and 2000, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Specialty Laboratories, Inc. as of December 31, 1999 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

/s/ Ernst & Young LLP

Woodland Hills, California  
January 26, 2001

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### Specialty Laboratories, Inc.

#### Consolidated Balance Sheets

	December 31	
	1999	2000
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 717,297	\$ 75,603,555
Accounts receivable, less allowances for doubtful accounts and contractual allowances of \$4,016,938 in 1999 and \$4,030,665 in 2000	26,774,755	32,775,147
Deferred income taxes	2,680,354	4,238,857
Inventory	1,798,929	1,623,115
Prepaid expenses and other assets	1,276,014	1,496,125
	33,247,349	115,736,799
Property and equipment, net	20,271,587	19,891,132
Deferred income taxes	3,735,601	2,863,427
Other assets	2,604,648	3,513,707
	\$ 59,859,185	\$ 142,005,065
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,118,571	\$ 11,921,443
Accrued liabilities	9,065,874	10,387,764
Income taxes payable	1,298,629	4,638,422
Current portion of long-term debt	9,148,222	
	29,631,296	26,947,629



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December 31

Long-term debt, net of current portion	9,233,977	
Other long-term liabilities	2,712,576	3,259,950
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value:		
Authorized shares none in 1999 and 10,000,000 in 2000		
Issued and outstanding shares none		
Common stock, no par value:		
Authorized shares 100,000,000		
Issued and outstanding shares 16,066,681 in 1999 and 20,937,507 in 2000	4,055,050	89,824,176
Retained earnings	15,430,365	24,102,877
Deferred stock-based compensation	(354,079)	(2,129,567)
Loan to shareholder	(850,000)	
Total shareholders' equity	18,281,336	111,797,486
	\$ 59,859,185	\$ 142,005,065

See accompanying notes.

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Specialty Laboratories, Inc.

Consolidated Statements of Operations

	Year ended December 31		
	1998	1999	2000
Net revenue	\$ 113,842,487	\$ 130,142,532	\$ 153,244,662
Costs and expenses:			
Costs of services	65,097,739	74,783,817	86,855,601
Selling, general and administrative (exclusive of stock-based compensation charges)	42,083,817	46,903,375	49,277,166
Stock-based compensation charges		2,818,039	1,073,009
Write-down of unused facilities		2,208,981	369,494
Total costs and expenses	107,181,556	126,714,212	137,575,270
Operating income	6,660,931	3,428,320	15,669,392
Interest income		(52,762)	(302,622)
Interest expense	1,158,636	1,691,935	1,243,502
Income from continuing operations before income taxes	5,502,295	1,789,147	14,728,512
Provision for income taxes	2,273,000	930,000	6,056,000

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Year ended December 31

Income from continuing operations	3,229,295	859,147	8,672,512
Loss from discontinued operations, net of income tax benefits	(3,060,401)	(2,000,972)	
<b>Net income (loss)</b>	<b>\$ 168,894</b>	<b>\$ (1,141,825)</b>	<b>\$ 8,672,512</b>
Income (loss) per share basic:			
Continuing operations	\$ .21	\$ .05	\$ .54
Discontinued operations	(.20)	(.12)	
<b>Net income (loss)</b>	<b>\$ .01</b>	<b>\$ (.07)</b>	<b>\$ .54</b>
Income (loss) per share diluted:			
Continuing operations	\$ .21	\$ .05	\$ .49
Discontinued operations	(.20)	(.12)	
<b>Net income (loss)</b>	<b>\$ .01</b>	<b>\$ (.07)</b>	<b>\$ .49</b>

See accompanying notes.

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Specialty Laboratories, Inc.

Consolidated Statements of Shareholders' Equity

	Common Stock		Retained Earnings	Deferred Stock Compensation	Loan to Shareholder	Accumulated Other Comprehensive Income (loss)	Total
	Shares	Amount					
Balance, January 1, 1998	15,456,760	\$ 605,551	\$ 16,856,166	\$	\$ (150,000)	\$ (176,770)	\$ 17,134,947
Shares issued for acquisition of interest in affiliate	382,800	1,740	(142,170)				(140,430)
Comprehensive income (loss):							
Foreign currency translation adjustment						(210,309)	(210,309)
Net income			168,894				168,894
Total comprehensive loss							(41,415)
Balance, December 31, 1998	15,839,560	607,291	16,882,890		(150,000)	(387,079)	16,953,102
Proceeds from sale of shares to employees, plus related compensation charge of \$341,814	227,121	617,455					617,455
Compensation charge related to stock options vested at date of grant		1,750,776					1,750,776
Deferred compensation related to stock options		1,079,528		(1,079,528)			

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Common Stock

Amortization of deferred compensation				725,449		725,449
Purchase of 2% interest in Specialty Family Limited Partnership		(310,700)				(310,700)
Loan to shareholder				(700,000)		(700,000)
Comprehensive income (loss):						
Foreign currency translation adjustment					387,079	387,079
Net loss			(1,141,825)			(1,141,825)
<b>Total comprehensive loss</b>						<b>(754,746)</b>
Balance, December 31, 1999	16,066,681	4,055,050	15,430,365	(354,079)	(850,000)	18,281,336
Deferred compensation related to stock option grants, net of forfeitures		2,714,144		(2,714,144)		
Amortization of deferred compensation				938,656		938,656
Proceeds from exercise of stock options	257,575	313,495				313,495
Variable stock-based compensation charges for certain stock options		134,353				134,353
Repayment of loan by shareholder					850,000	850,000
Shares received and cancelled upon redemption of interest in Specialty Family Limited Partnership	(1,136,749)					
Proceeds from sale of common stock, net of \$9,392,865 in related expenses	5,750,000	82,607,134				82,607,134
Net income and comprehensive income			8,672,512			8,672,512
Balance, December 31, 2000	20,937,507	\$ 89,824,176	\$ 24,102,877	\$ (2,129,567)	\$	\$ 111,797,486

See accompanying notes.

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Specialty Laboratories, Inc.

Consolidated Statements of Cash Flows

Year ended December 31

	1998	1999	2000
<b>Operating activities</b>			
Income from continuing operations	\$ 3,229,295	\$ 859,147	\$ 8,672,512
Adjustments to reconcile income from continuing operations to net cash provided by continuing operating activities:			
Depreciation	4,183,355	5,408,763	5,951,290
Deferred income taxes	(1,898,000)	(2,503,000)	(686,329)
Stock-based compensation charges		2,818,039	1,073,009
Write-down of unused facility		2,208,981	369,494

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Year ended December 31

Loss on disposals of property and equipment	1,197	29,396	25,077
<b>Changes in assets and liabilities:</b>			
Accounts receivable, net	(2,615,367)	(4,635,016)	(6,000,392)
Inventory, prepaid expenses and other assets	(557,241)	(1,983,156)	(953,356)
Accounts payable	224,417	437,757	1,802,872
Accrued liabilities	4,203,083	(934,549)	1,321,890
Income taxes payable	155,797	92,517	3,339,793
Other long-term liabilities	426,001	1,516,541	547,374
Net cash provided by continuing operating activities	7,352,537	3,315,420	15,463,234
<b>Investing activities</b>			
Purchases of property and equipment	(5,146,965)	(3,711,842)	(5,967,441)
Proceeds from sales of property and equipment	15,700	15,800	2,035
Net cash used in investing activities	(5,131,265)	(3,696,042)	(5,965,406)
<b>Financing activities</b>			
Net change in revolving bank line of credit	(821,240)	2,314,919	(11,954,275)
Borrowings under bank term loans	4,813,508		6,186,492
Repayment of bank term loans	(1,050,000)	(1,635,583)	(12,614,416)
Repayment of loan by shareholder (loan to shareholder)		(700,000)	850,000
Purchase of interest in Specialty Family Limited Partnership		(310,700)	
Sale of common stock to employees		275,642	
Proceeds from sale of common stock, net of expenses			82,607,134
Proceeds from exercise of stock options			313,495
Net cash provided by (used in) financing activities	2,942,268	(55,722)	65,388,430
<b>Discontinued operating activities</b>			
Net (return from) investment in foreign affiliates	(4,763,463)	284,500	
Net cash (used in) provided by discontinued operating activities	(4,763,463)	284,500	
Net increase (decrease) in cash and cash equivalents	400,077	(151,844)	74,886,258
Cash and cash equivalents at beginning of year	469,064	869,141	717,297
Cash and cash equivalents at end of year	\$ 869,141	\$ 717,297	\$ 75,603,555
<b>Supplemental disclosures of cash flow information:</b>			
Cash paid for:			
Interest	\$ 1,435,000	\$ 1,448,000	\$ 1,293,000
Income taxes	\$ 2,524,000	\$ 2,044,000	\$ 3,562,000

See accompanying notes.

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1. Summary of Significant Accounting Policies

### **Description of Business**

Specialty Laboratories, Inc. (the Company) is a corporation that provides specialized laboratory-testing services to physicians, hospitals, and independent laboratories throughout the United States. The Company's continuing operations are in one reportable segment, the domestic medical laboratory industry.

### **Discontinued Operations**

In August 1999, management of the Company began implementing a plan for the discontinuance of all of the Company's foreign operations which were located in Southeastern Asia, India and Egypt. This plan contemplated the sale or abandonment of each foreign location in which the Company had operations or interests. See Note 3 for additional information on discontinued operations.

### **Principles of Consolidation and Basis of Presentation**

The consolidated financial statements include the accounts of Specialty Laboratories, Inc. and its subsidiary, BVI Specialty Laboratories International, Ltd. (SLIL) (100% owned). All intercompany transactions have been eliminated in consolidation.

In 1998, the Company obtained 100% ownership of SLIL by exchanging 1,740,000 shares of the Company's common stock for the remaining 50% stock of SLIL, which was managed by the Company's chairman. The former 50% owner of SLIL is an affiliate of the majority owners of the Company. Prior to the transaction, SLIL's financial statements were consolidated with the Company's because of the commonality of the ownership of the Company and the 50% of SLIL not owned by the Company.

### **Common Stock Split**

On February 5, 1999, the Board of Directors amended the Company's Articles of Incorporation to effect a 100 for 1 stock split of the shares of common stock, and to increase the authorized number of shares of common stock to 10,000,000. On October 30, 2000, the Company's Board of Directors further amended the Company's Articles of Incorporation to effect a 2.2 for 1 stock split and to increase the authorized number of shares of common stock to 100,000,000. All per share and common share amounts presented in these consolidated financial statements have been adjusted to reflect these stock splits.

### **Foreign Currency Translation**

Balance sheet accounts of the discontinued foreign operations are translated at the current exchange rate as of the end of the accounting period. Income statement accounts are translated at average currency exchange rates. The Company's portion of the resulting translation adjustment is recorded as a component of accumulated other comprehensive income (loss) in shareholders' equity.

### **Cash and Cash Equivalents**

The Company considers highly liquid debt securities with original maturities of 90 days or less to be cash equivalents.

### **Accounts Receivable and Net Revenue**

Accounts receivable and net revenue are recorded net of contractual allowances. The allowance for doubtful accounts represents an estimate of future credit losses.

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### **Inventory**

Inventory consists primarily of laboratory supplies and is stated at the lower of the average cost or market.

### **Property and Equipment**

Property and equipment are stated at cost. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the respective assets as follows:

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Professional equipment	5 - 10 years
Office furniture and equipment	5 - 10 years
Automotive equipment	3 - 5 years
Computer equipment	3 - 5 years
Software	3 years
Leasehold improvements	The lesser of life of asset or lease term

### Revenue Recognition

The company recognizes revenue as services are rendered upon completion of the testing process for a specific customer order for which the Company has no future performance obligations to the customer, the customer is obligated to pay and the fees are non-refundable. The Company's revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101.

Services are provided to certain patients covered by various third-party payor programs including Medicare and Medicaid. Billings for services under third-party payor programs are included in net revenue net of allowances for differences between the amounts billed and estimated receipts under such programs. Adjustments to the estimated payment amounts based on final settlement with the third-party payor programs are recorded upon settlement. In 1998, 1999 and 2000, 4.8%, 5.5% and 5.5%, respectively, of net revenue was reimbursed by Medicare or Medicaid programs.

### Research and Development Expenditures

Research and development expenditures are expensed as incurred. The amounts charged to research and development expense were \$2,392,000, \$2,332,000 and \$2,094,000 in 1998, 1999 and 2000, respectively.

### Concentrations of Credit Risk

The Company's concentration of credit risk with respect to accounts receivable is limited due to the large number of payors comprising its patient base which are spread across the United States. In addition, the Company maintains allowances for potential credit losses and such losses have been within management's expectations. The Company routinely assesses the financial strength of its customers and generally does not require collateral.

No customer accounted for over 10% of net revenue in 1998, 1999 or 2000.

### Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported

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amounts of assets and liabilities and disclosure of contingent assets and liabilities, and the reported amounts of revenues and expenses for the year then ended. The Company routinely estimates amounts to be recovered from third-party payors. Actual results could differ from those estimates.

### Stock-Based Compensation

As permitted by Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS No. 123), the Company accounts for stock options granted to its employees and outside directors using the intrinsic value method. The Company's stock options have generally been granted with exercise prices below the fair value of the Company's common stock as estimated by the Company's management for financial reporting purposes. For stock option grants which were vested at date of grant, the difference between the exercise prices and such estimated fair values was charged to expense as of the date of grant. For stock options not vested at date of grant, the Company has recorded deferred stock compensation for the difference between their exercise prices and such estimated fair values which is being amortized to expense over the stock options' vesting periods in accordance with Financial Accounting Standards Board (FASB) Interpretation No. 28.

For sales of the Company's common stock to employees at a price below such estimated fair value, the difference between the sales price and such estimated fair value was charged to expense as of the date of the sales.

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All outstanding stock options granted by the Company prior to 1999 were canceled in 1999 and were concurrently replaced with newly granted stock options. The exercise price for certain of the newly granted options was lower than the exercise price of the canceled options. These "repriced" options were accounted for as "variable" options effective July 1, 2000 until their exercise in September 2000 in accordance with FASB Interpretation No. 44.

### Income Taxes

The Company utilizes the liability method of accounting for income taxes as set forth in Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes." Under this method, deferred income taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using current tax rates and regulations.

### Fair Value of Financial Instruments

The Company's financial instruments consist mainly of cash, cash equivalents, accounts receivable, accounts payable and its bank credit facility.

The fair value of substantially all financial instruments of the Company approximates their carrying values in the aggregate due to the short-term nature of these instruments. The interest rates on borrowings under the Company's bank credit facilities are adjusted periodically to market rates.

The Company has not used any derivatives or other foreign currency hedging instruments. Accordingly, Statement of Financial Accounting Standards No. 133, "Accounting for Derivative Instruments and Hedging Activities," will have no effect on the Company's financial statements.

### Earnings Per Share

Basic earnings per share is computed by dividing net income by the weighted average number of common shares outstanding. Dilutive earnings per share is computed by dividing net income by the weighted average number of common shares outstanding plus potentially dilutive shares for the portion

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of the year they were outstanding. Potentially dilutive common shares result solely from outstanding stock options.

Basic and diluted earnings per share information was calculated based on the following weighted average shares:

	Year ended December 31		
	1998	1999	2000
Basic weighted average shares	15,458,856	16,044,529	16,100,978
Dilutive effect of outstanding stock options	46,299	959,796	1,537,780
Diluted weighted average shares	15,505,155	17,004,325	17,638,758

In accordance with Statement of Financial Accounting Standards No. 128, "Earnings per Share," the diluted weighted average number of shares for 1999 was used for computing income from operations, loss from discontinued operations and net loss per share even though the effect of including dilutive stock options is anti-dilutive to the loss per share amounts.

## 2. Property and Equipment

Property and equipment consists of the following:

December 31

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	December 31	
	1999	2000
Information technology equipment and systems	\$ 19,784,519	\$ 23,102,531
Professional equipment	7,798,733	9,463,936
Office furniture and equipment	3,923,495	4,095,544
Leasehold improvements	8,114,524	7,962,575
Construction in progress	217,113	614,835
	39,838,384	45,239,421
Less accumulated depreciation and amortization	(19,566,797)	(25,348,289)
	\$ 20,271,587	\$ 19,891,132

### 3. Discontinued Foreign Operations

In fiscal year 1995, the Company started operating internationally by providing routine laboratory services and kit manufacturing as an avenue to create growth. In August 1999, the Company implemented a plan to discontinue all of its foreign operations, due to continued losses incurred with these operations.

A wholly owned subsidiary of the Company owns 60% of Specialty Laboratories Asia Private, Ltd. (SLA) which, in turn, owns 50% of Specialty Ranbaxy, Ltd. (SRL) and 50% of Specialty Medical Laboratories Sdn. Bhd. (SML). During the year ended December 31, 1999, management began implementing a plan to close down the operations of SLA and to dispose of its interests in SRL and SML. As of December 31, 1999, SLA was insolvent. Since the Company has no further obligations nor any plans to fund additional losses of SLA, SRL or SML, the Company has not recorded any additional losses beyond those previously recorded. On July 14, 2000, provisional liquidators of SLA were appointed by an Order of Court in Singapore. See Note 12 for a description of litigation involving SLA.

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In August 1999, the Company began to shut down its Egyptian operations. The net assets of the Egyptian operations were written down to zero, as no net proceeds were anticipated to be received from their disposal. The Company ceased all operations in Egypt prior to December 31, 1999.

The foreign operations each served customers in their local markets by providing routine medical laboratory and health screening services to physicians and corporations, respectively, and differ from the Company's continuing operations, which provide esoteric testing primarily to hospitals and routine laboratories. The operations in Singapore and Malaysia also manufactured routine testing kits for sale to third parties in Asia. Because these business activities differ significantly and were managed separately from the Company's esoteric medical laboratory services, the foreign operations collectively would qualify as a separate business segment of the Company.

There was no income or loss from discontinued operations during the year ended December 31, 2000.

Condensed results of operations for the Company's discontinued foreign operations are as follows:

	Year ended December 31		
	1998	1999	2000
Net revenue	\$ 1,051,426	\$ 643,282	\$
Operating costs and expenses	3,718,479	2,158,099	
	(2,667,053)	(1,514,817)	
Equity in losses of investees	(1,666,621)		
Write-off of uncollectible advances to investees	(616,483)		



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	Year ended December 31		
Disposal of property and equipment		(1,984,429)	
Minority interests	1,056,756	174,274	
Loss before income tax benefits	(3,893,401)	(3,324,972)	
Income tax benefits	833,000	1,324,000	
Loss from discontinued operations	\$ (3,060,401)	\$ (2,000,972)	\$

**4. Write-Down of Unused Facility Costs**

In 1997, the Company leased a building in Memphis, Tennessee, for a potential geographical expansion of its operations. Subsequently, in June 1999, the Company's management decided not to move into the Memphis facility and to sublease it to a third party. As a result, the costs of leasehold improvements related to the facility of \$1,334,761 and the estimated present value of the difference between the Company's lease obligation and the estimated sublease income, which amounted to \$874,220, were recognized as a loss in 1999. The accrual of estimated future lease costs was computed by calculating the present value of the remaining lease payments, offset by the present value of the estimated future sublease income assuming a sub-lease start date of November 2002, using a discount rate of 7%. During 2000, \$271,376 was charged against the liability, which had a balance of \$469,448 at December 31, 2000. The Company's accrual of estimated lease costs is subject to change based on future events. Any future adjustment to the accrual will be classified as a write-down of unused facility costs in the Company's consolidated statement of operations. The facility had not been subleased as of December 31, 2000.

Beginning in 1997, the Company leased on a month-to-month basis a property from a partnership in which the Company's Chairman of the Board and Chief Executive Officer is both a direct and indirect owner. The Company utilized a portion of the property and subleased the remainder. As a

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result of the Company's initial public offering, the lease between the Company and the partnership was terminated on September 1, 2000 on which date the Company had a balance of \$369,494 in unamortized leasehold improvements for this property. Accordingly, a loss was recognized for this amount as of September 1, 2000.

**5. Accrued and Other Long-Term Liabilities**

Accrued liabilities consist of the following:

	December 31	
	1999	2000
Employee compensation related	\$ 5,901,538	\$ 7,052,042
Royalties	3,164,336	3,335,722
	\$ 9,065,874	\$ 10,387,764

The Company has various royalty agreements for technology licensed from third parties which require that royalty fees be paid based upon a percentage of net revenue derived from assays using the licensed technology. Royalty payments are generally made on a semiannual basis.

Other long-term liabilities consist of the following:

	December 31	
	1999	2000
Deferred compensation	\$ 1,768,001	\$ 1,908,057

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	December 31	
Annuity payments due to former employee	545,502	453,164
Non-current portion of accrued rent for unused facility	399,073	232,359
Non-current installment of software acquisition costs		600,000
Other		66,370
	\$ 2,712,576	\$ 3,259,950

**6. Long-Term Debt**

Long-term debt is as follows:

	December 31	
	1999	2000
Revolving line of credit	\$ 11,954,275	\$
Term loan payable to bank, payable in monthly installments of \$83,333 plus interest (8.06% rate at December 31, 1999) through March 2002	2,416,667	
Term loan payable to bank, payable in monthly installments of \$80,225 plus interest (8.32% weighted average rate at December 31, 1999) through February 2004	4,011,257	
	18,382,199	
Less current portion	(9,148,222)	
	\$ 9,233,977	\$

The Company has a bank loan agreement which provides for a revolving line of credit in addition to term loans. The Company's revolving line of credit provides for borrowings of up to \$30,000,000,

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subject to a borrowing base limitation of 75% of eligible accounts receivable as defined in the related loan agreement, and all outstanding borrowings under the line of credit, which may be prepaid at any time without penalty, are payable on September 3, 2002.

An initial term loan was payable over a five-year period with monthly payments of principal of \$83,333 plus interest, and a maturity date of March 31, 2002. A subsequent term loan was payable over a five-year period with monthly payments of principal of \$80,225 plus interest, with a maturity date of February 1, 2004. A third term loan was made in February 2000 in the amount of \$6,186,491 which was used to reduce outstanding borrowings under the revolving line of credit, and was payable with monthly payments of principal of \$128,885 plus interest, with maturity date of January 1, 2004. In December 2000, the Company repaid all of the then outstanding revolving and term loans totaling \$9,233,977.

All borrowings under the bank loan agreement, including the revolving and term loans, bore interest at LIBOR plus a defined rate. At each interest rate reset date, the Company selected the period, ranging from one month to one year, for which the new rate would be effective.

Borrowings under the revolving and term loan facilities are cross collateralized by substantially all of the Company's assets. The bank loan agreement contains certain restrictive covenants, including maintenance of certain levels of financial ratios.

Portions of the revolving note payable to bank carried the following interest rates at December 31, 1999:

Rate	Amount

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	Rate		Amount
The reference rate	8.50%	\$	1,554,275
LIBOR plus 2.2%	8.30%		5,000,000
LIBOR plus 2.2%	7.81%		5,400,000
			11,954,275

Interest expense for 1998, 1999 and 2000 was \$1,158,635, \$1,691,935 and \$1,243,502, respectively.

### 7. Profit Sharing Plan 401(k)

The Company maintains a defined contribution 401(k) profit sharing plan (the 401(k) Plan) covering all employees after minimum eligibility requirements have been met.

In accordance with the 401(k) Plan, eligible employees may contribute up to 15% of their salaries to the 401(k) Plan. The Company will match the employee's contribution at 50 cents per dollar up to 6% of the employee's salary. Matching contributions by the Company to the 401(k) Plan amounted to \$549,000, \$515,000 and \$633,000 in 1998, 1999 and 2000, respectively. Profit sharing contributions to the 401(k) Plan are discretionary and no discretionary contributions were made during 1998, 1999 or 2000.

### 8. Deferred Compensation Program

The Company has a non-qualified deferred compensation program (the Program) for certain executives. Under the Program, employee-designated deferrals of salary are withheld by the Company. An amount equal to the withholding is "invested" at the direction of the employee, in a portfolio of phantom investments selected from the available investments under the Program, which are tracked by

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an administrator. With a portion of the withholding, the Company purchases life insurance policies on each of the participating executives with the Company named as beneficiary of the policies.

Deferred compensation, including gains and losses on phantom investments, amounted to \$1,768,101 and \$1,908,057 at December 31, 1999 and 2000, respectively, and is classified in other long-term liabilities. The cash surrender value of the life insurance policies, which amounted to \$1,428,000 and \$1,408,000 at December 31, 1999 and 2000, respectively, is recorded in other assets.

### 9. Shareholders' Equity

#### Preferred Stock

During 2000, the Company's Board of Directors amended the Company's Articles of Incorporation to authorize 10,000,000 shares of no par value preferred stock. No shares of preferred stock have been issued.

#### Ownership of Common Stock

On August 15, 2000, the Specialty Family Limited Partnership (Partnership) redeemed the Company's interest in the Partnership in exchange for 1,136,749 shares of the Company's common stock, which were then canceled by the Company. Other than the cancellation of the outstanding shares, no other accounting was required for this transaction.

#### Initial Public Offering

On December 8, 2000, the Company completed the initial public offering of 5,000,000 shares of its common stock at a price of \$16.00 per share. The underwriters subsequently exercised their overallotment option by purchasing an additional 750,000 shares of the Company's common stock at a price of \$16.00 per share. After underwriters' discounts, commissions and expenses, the net proceeds of the offering and overallotment exercise to the Company were \$85,560,000. Other expenses of the offering aggregated \$2,952,866.

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**9. Shareholders' Equity (Continued)****Stock Option Plans**

During 1999, the Company's Board of Directors approved the 1999 Stock Option/Stock Issuance Plan (the 1999 Plan) as a comprehensive equity incentive program and granted 1,839,068 options to acquire shares of the Company's common stock to certain employees and the outside directors of the Company. Outstanding stock options previously granted were effectively cancelled and replaced with new options under the 1999 plan. The options granted have an exercise price of \$1.21 or \$1.23 per share and 1,108,171 of such options were vested at their date of grant.

As of January 1, 2000, the Company granted to certain employees of the Company 132,000 options to acquire shares of the Company's common stock at an exercise price of \$1.56 per share. As of July 1, 2000, the Company granted to certain employees of the company 255,200 options to acquire shares of the Company's common stock at an exercise price of \$7.00 per share.

On September 5, 2000, the Company's Board of Directors adopted and the shareholders approved the 2000 Stock Incentive Plan (2000 Plan). The 2000 Plan became effective on the date the underwriting agreement for the initial public offering was signed. Under the 2000 Plan, 4,020,280 shares of the Company's common stock have been authorized for issuance, including shares currently reserved under the 1999 Plan.

As of December 1, 2000, the Company granted to certain employees of the Company 406,060 options to acquire shares of the Company's common stock at an exercise price of \$14.00 per share and 47,000 options to acquire shares of the Company's stock at \$16.00 per share.

The balance of the above options granted vest 25% upon the first anniversary of an employee's employment (33% for the outside directors upon the first anniversary of service as a director) and thereafter ratably in equal monthly installments for the next 36 months (the next 24 months for outside directors). The options have a term of 10 years from the date of grant. The difference between the option exercise price and fair value of the Company's common stock as estimated by the Company's management for financial reporting purposes as of the dates of grant was recorded as deferred stock-based compensation and is being amortized to expense over the vesting periods of the related stock options on an accelerated basis using the graded vesting method.

Changes in options outstanding for the periods indicated were as follows:

	Number of Options	Weighted Average Exercise Price	Range of Exercise Prices
Outstanding at December 31, 1998	147,400	\$ 1.56	\$ 1.23 - \$ 1.76
Options canceled and replaced	(147,400)	\$ 1.56	\$ 1.23 - \$ 1.76
Options granted	1,839,068	\$ 1.21	\$ 1.21 - \$ 1.23
Outstanding at December 31, 1999	1,839,068	\$ 1.21	\$ 1.21 - \$ 1.23
Options exercised	(251,573)	\$ 1.22	\$ 1.21 - \$ 1.23
Options forfeited	(120,923)	\$ 2.37	\$ 1.21
Options granted	840,260	\$ 10.03	\$ 1.56 - \$16.00
Outstanding at December 31, 2000	2,306,832	\$ 5.60	\$ 1.21 - \$16.00
Options exercisable at December 31, 1998	94,380	\$ 1.62	\$ 1.23 - \$ 1.76
Options exercisable at December 31, 1999	1,437,834	\$ 1.21	\$ 1.21 - \$ 1.23
Options exercisable at December 31, 2000	1,413,887	\$ 1.22	\$ 1.21 - \$ 1.56

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There were no options granted during 1998 and none were exercised, forfeited or expired during 1998 or 1999. The weighted average remaining contractual life of outstanding options was 9.26 and 8.78 years at December 31, 1999 and 2000, respectively.

Pro forma net income, as required to be disclosed by SFAS No. 123, determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement, is as follows:

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	Year ended December 31		
	1998	1999	2000
<b>Income from continuing operations:</b>			
As reported	\$ 3,229,295	\$ 859,147	\$ 8,672,512
Pro forma	3,217,295	337,882	8,207,248
<b>Basic income from continuing operations per share:</b>			
As reported	\$ .21	\$ .05	\$ .54
Pro forma	.21	.02	.51
<b>Diluted income from continuing operations per share:</b>			
As reported	\$ .21	\$ .05	\$ .49
Pro forma	.21	.02	.47

These pro forma amounts may not be representative in future disclosures since the estimated fair value of stock options would be amortized to expense over the vesting period, and additional options may be granted in future years.

The fair value for these options was estimated at the date of grant (no options were granted in 1998) using the Black-Scholes option pricing model with the following weighted-average assumptions:

	Year ended December 31	
	1999	2000
Risk-free interest rates	6%	6%
Dividend yields	0%	0%
Weighted-average expected life of option	5 years	5 years
Expected volatility based upon peer companies	.55	.66

### Stock-Based Compensation

In connection with the sales of common stock to certain employees and the granting of stock options to certain employees and the Company's outside directors on February 5, 1999, the amount of related compensation to be recognized was determined by the Company to be the difference between the stock purchase or option exercise price and the fair value of the Company's common stock at that date as estimated by the Company's management for financial reporting purposes. For the common stock sales and the stock options which were vested as of their date of grant, the related compensation was expensed in full as of February 5, 1999. For the stock options which were not vested as of their date of grant, the related compensation was recorded as deferred stock compensation, which is classified as a reduction of shareholders' equity, and is being amortized to expense over the vesting periods of the related stock options.

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The exercise price of stock options granted during 2000 were less than the fair value of the Company's common stock at date of grant as estimated by the Company's management for financial reporting purposes. The differences were recorded as deferred stock compensation which is classified as a reduction of shareholders' equity and is being amortized to expense over the vesting periods of the related stock options.

Stock-based compensation charges were comprised of the following components:

	Year ended December 31	
	1999	2000
<b>Charged to expense on transaction date:</b>		
Stock options vested at date of grant	\$ 1,750,776	\$
Common stock sold to certain employees	341,814	
Amortization of deferred stock compensation	725,449	938,656

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	Year ended December 31	
	-----	
Variable stock-based compensation charges		134,353
	\$ 2,818,039	\$ 1,073,009
	-----	-----

The Company estimates that amortization of deferred stock-based compensation, based upon stock options granted and forfeited during the year ended December 31, 2000 in addition to stock options outstanding at December 31, 2000, will be approximately as follows:

Year ending December 31	
-----	
2001	\$ 1,357,000
2002	520,000
2003	219,000
2004	34,000

**Stock Purchase Plan**

On September 5, 2000, the Company's Board of Directors adopted and the shareholders approved an Employee Stock Purchase Plan (Purchase Plan). The Purchase Plan became effective on the date the underwriting agreement for the offering was signed. Under the Purchase Plan, 330,000 shares of the Company's common stock were reserved for issuance. The share reserve automatically increases on the first trading day of each January by 1% of the total number of shares of the Company's common stock outstanding on the last trading day of each preceding December. The increase in the share reserve is not to exceed 550,000 shares. The shares are available for purchase through overlapping offering periods with a maximum duration of 24 months. The initial offering period began the day the underwriting agreement for the offering was signed and ends in October 2002. Subsequent offering periods begin on the first business day in May and November of each year. Each offering period consists of a series of successive six-month purchasing intervals. Employee share purchases are funded through payroll deductions not to exceed 15% of earnings. The purchase price of shares at each purchase date is the lesser of 85% of the fair market value of the shares on the purchase date or 85% of the fair market value per share on the start date of the offering period. As of December 31, 2000, no shares had been purchased under the Purchase Plan.

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**10. Income Taxes**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial statement purposes and the amounts used for income tax purposes.

Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31	
	1999	2000
	-----	-----
Deferred tax assets:		
Allowances for doubtful accounts and contractual allowances	\$ 1,568,895	\$ 2,484,725
State income taxes	281,180	557,200
Depreciation expense	700,862	
Foreign losses	391,368	
Stock-based compensation charges	986,788	1,329,541
Vacation accrual	332,437	374,068
Other compensation accruals	1,327,470	1,735,961
Write-down of unused facilities	826,955	823,910
	-----	-----
Total deferred tax assets	6,415,955	7,305,405
Deferred tax liability depreciation expense		(203,121)

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	December 31	
	1999	2000
Net deferred tax assets	\$ 6,415,955	\$ 7,102,284

There is no valuation allowance for deferred tax assets as of December 31, 1999 and 2000. The Company believes that it is probable that the results of future operations will generate sufficient taxable income to realize the remaining deferred tax asset.

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The components of the provision (benefit) for income taxes are as follows:

	Year ended December 31		
	1998	1999	2000
<b>Continuing operations:</b>			
Current:			
Federal	\$ 2,663,000	\$ 2,569,000	\$ 7,709,000
State	672,000	864,000	1,592,000
	<u>3,335,000</u>	<u>3,433,000</u>	<u>9,301,000</u>
Deferred:			
Federal	(799,000)	(1,848,000)	(2,644,000)
State	(263,000)	(655,000)	(601,000)
	<u>(1,062,000)</u>	<u>(2,503,000)</u>	<u>(3,245,000)</u>
Total continuing operations	2,273,000	930,000	6,056,000
<b>Discontinued operations:</b>			
Current:			
Federal	124,000	(1,030,000)	
State	(121,000)	(294,000)	
	<u>3,000</u>	<u>(1,324,000)</u>	
Deferred:			
Federal	(771,000)		
State	(65,000)		
	<u>(836,000)</u>		
Total discontinued operations	(833,000)	(1,324,000)	
	<u>\$ 1,440,000</u>	<u>\$ (394,000)</u>	<u>\$ 6,056,000</u>

A reconciliation of the federal statutory rate to the Company's effective tax rate for continuing operations is as follows:

	Year ended December 31		
	1998	1999	2000

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	<u>Year ended December 31</u>		
Tax provision at statutory rate	34.0%	34.0%	35.0%
State and local taxes, net of federal benefit	6.1	7.2	5.8
Non-deductible expenses	1.0	10.4	.2
Other	.2	.4	.1
	<u>          </u>	<u>          </u>	<u>          </u>
Effective tax rate	41.3%	52.0%	41.1%
	<u>          </u>	<u>          </u>	<u>          </u>

**11. Related Party Transactions**

During 1996, the Company loaned the Peter Family Revocable Trust (Trust) \$150,000 without interest. During 1999, the Company loaned to the Trust an additional \$700,000 which bore interest at a rate of 9%, which was paid monthly. Both loans were repaid in March 2000.

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**12. Commitments and Contingencies**

The Company leases certain facilities and equipment under capital and operating leases. Certain leases contain renewal and purchase options. Rental expense was approximately \$1,997,000, \$2,280,000 and \$2,011,400 for 1998, 1999 and 2000, respectively.

The Company leased on a month-to-month basis a facility and parking lot from Santa Monica Properties Partnership (SMPP) which is owned by various shareholders of the Company. Total payments to SMPP were \$219,000, \$205,000 and \$136,380 for 1998, 1999 and 2000, respectively, and are included in the amounts of rent expense shown above. This lease was terminated in September 2000.

Future minimum lease payments under noncancelable operating leases with initial terms of one year or more are as follows:

	<u>Memphis Property</u>	<u>All Others</u>	<u>Total</u>
Year ending:			
2001	\$ 262,440	\$ 2,340,528	\$ 2,602,968
2002	262,440	2,177,013	2,439,453
2003	262,440	1,589,794	1,852,234
2004	262,440	162,331	424,771
2005 and thereafter	721,710		721,710
	<u>          </u>	<u>          </u>	<u>          </u>
Total minimum lease payments	\$ 1,771,470	\$ 6,269,666	\$ 8,041,136
	<u>          </u>	<u>          </u>	<u>          </u>

**Contingencies**

A former employee of SLA has obtained a judgment of \$350,000 against SLA and a default judgment of \$1.95 million in a wrongful termination action against SLA filed in Singapore. The former employee has filed an action against SLA in California to attempt to collect on the Singapore judgment and has obtained a default judgment of \$2.5 million against SLA in California. The former employee has also served discovery upon the Company and certain of its directors and officers, has sought to compel these officers and directors to provide discovery and has requested sanctions in connection with these requests. No overt allegations of any material liability have been made against the Company. The Company's management believes that any claim against the Company or its directors and officers in connection with these judgments, if made, would be without merit and the Company would vigorously defend such action.

In June 1999, the Health Care Financing Administration asserted that the Company was out of compliance with Clinical Laboratory Improvement Amendments regulations pertaining to specific quality assurance functions, and imposed certain fines in connection therewith. After the Health Care Financing Administration's resurvey in June 2000, management indicated the Company was able to satisfy the Health Care Financing Administration that the Company was in compliance with the applicable requirements. The Company appealed the fine imposed by the Health Care Financing Administration and subsequently settled the matter by paying the Health Care Financing Administration the sum of \$87,400. Management believes the Company is presently in compliance with all certified and licensure requirements.



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The Company is from time to time subject to claims arising in the ordinary course of business. These claims have included assertions that the Company's assays infringe existing patents; however, none of the claimants have filed litigation against the Company. The Company intends to defend vigorously any such litigation that may arise and to assert all available defenses to allegations of patent infringement that would be available to the Company. In the opinion of management, the ultimate

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resolution of such proceedings will not have a material adverse effect on the consolidated financial position, results of operations or cash flows of the Company.

### Commitments

In September and October 2000, the Company entered into employment agreements with six employees. The agreements with two of the employees, which provide in the aggregate for annual base salaries of \$886,000, provide that if the employee is terminated other than for cause or if he resigns for good reason during the first five years of his contract, the Company will pay his base salary for a two-year period and his bonus for a one-year period subsequent to his severance. The agreements with the other four employees, which provide in the aggregate for annual base salaries of approximately \$800,000, provide that if the employee is terminated for other than cause during the first three years of his contract, the Company will pay his salary for a one-year period subsequent to his severance. If any of the six employees is terminated for cause, no further payments are due to them under the contracts.

### 13. Quarterly Financial Data (Unaudited)

CY2000	March 31	June 30	September 30	December 31
Net revenue	\$ 35,607,095	\$ 38,556,948	\$ 39,549,843	\$ 39,530,776
Operating income	3,453,523	4,465,619	4,350,468	3,399,782
Income from continuing operations	1,826,417	2,405,585	2,378,031	2,062,479
Net income	1,826,417	2,405,585	2,378,031	2,062,479
Income per share basic	0.11	0.15	0.15	0.12
Income per share diluted	0.10	0.14	0.14	0.11
CY1999	March 31	June 30	September 30	December 31
Net revenue	\$ 30,592,336	\$ 32,574,243	\$ 33,509,081	\$ 33,466,872
Operating income (loss)	(903,839)	(526,165)	2,273,856	2,584,468
Income (loss) from continuing operations	(918,030)	(572,793)	1,118,993	1,230,977
Net income (loss)	(1,342,468)	(813,826)	(216,508)	1,230,977
Income (loss) per share basic	(0.08)	(0.05)	(0.01)	0.08
Income (loss) per share diluted	(0.08)	(0.05)	(0.01)	0.07

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### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Santa Monica, State of California, on the 30th day of March, 2001.

SPECIALTY LABORATORIES, INC.

By: /s/ JAMES B. PETER

Name: James B. Peter  
Title: Chief Executive Officer and  
Chairman of the Board of  
Directors

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, the undersigned hereby constitute and appoint Paul F. Beyer and Frank J. Spina, and each of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite or necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed by the following persons in the capacities and on the dates indicated:

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ JAMES B. PETER</u> James B. Peter, M.D., Ph.D.	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	March 30, 2001
<u>/s/ PAUL F. BEYER</u> Paul F. Beyer	President, Chief Operating Officer and Director	March 30, 2001
<u>/s/ FRANK J. SPINA</u> Frank J. Spina	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2001
<u>/s/ DEBORAH A. ESTES</u> Deborah A. Estes	Secretary and Director	March 30, 2001
<u>/s/ RICHARD E. BELLUZZO</u> Richard E. Belluzzo	Director	March 30, 2001
<u>/s/ DOUGLAS S. HARRINGTON</u> Douglas S. Harrington, M.D.	Director	March 28, 2001
<u>/s/ WILLIAM J. NYDAM</u> William J. Nydam	Director	March 30, 2001
<u>/s/ THOMAS R. TESTMAN</u> Thomas R. Testman	Director	March 30, 2001
<u>/s/ JOHN C. KANE</u> John C. Kane	Director	March 30, 2001

## EXHIBIT INDEX

Number	Description
3.1**	Articles of Incorporation.
3.2**	Form of By-laws.
4.1**	Specimen Common Stock Certificate.
4.2	See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
10.1**	2000 Stock Incentive Plan.
10.2**	2000 Employee Stock Purchase Plan.
10.3**	Loan Agreement dated April 15, 1996 between Union Bank of California and Registrant, as amended and restated on April 7, 1997 and as amended on January 23, 1998, February 17, 1999 and August 30, 1999.
10.4**	Revolving Note dated August 30, 1999 in favor of Union Bank of California.
10.5**	Term Note dated February 17, 1999 in favor of Union Bank of California.
10.6**	Term Note dated January 23, 1998 in favor of Union Bank of California.
10.7**	Term Note dated April 7, 1997 in favor of Union Bank of California.
10.8**	Security Agreement dated April 3, 1996 between Union Bank of California and Registrant.
10.9**	Lease dated June 1996 between Howard Real Property Trust (lessor) and Registrant (lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California.
10.10**	License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property.
10.11**	Lease dated January 26, 2000 between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California.
10.12**	Lease dated July 17, 1993 between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California.
10.13A**	Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant.
10.14**	Agreement dated June 6, 1992, as amended on August 25, 1997 and as amended on January 1, 1997 between Roche Molecular Systems, Inc. and Registrant.
10.15**	Homogeneous PCR Clinical Agreement dated October 5, 1999 between Roche Molecular Systems, Inc. and Registrant.
10.16A**	Services Agreement dated February 1, 1998 between VHA, Inc. (now known as Novation) and Registrant.
10.17**	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant.
10.18A**	Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant.
10.19A**	Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant.
10.20**	Shared Services Health Care letter of confirmation dated June 5, 2000.
10.21A**	Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (sublandlord) and Registrant (subtenant) for the property located at 1620 20th Street, Santa Monica, California.
10.22**	Employment Agreement dated September 1, 2000 between James B. Peter and Registrant.
10.23**	Employment Agreement dated September 1, 2000 between Paul F. Beyer and Registrant.
10.24**	Employment Agreement dated September 1, 2000 between John W. Littleton and Registrant.
10.25**	Employment Agreement dated September 1, 2000 between Bart E. Thielen and Registrant.
10.26**	Employment Agreement dated September 1, 2000 between Thomas E. England and Registrant.
10.27A**	Employment Agreement dated October 12, 2000 between Frank J. Spina and Registrant.
10.28A**	Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant.
10.29**	Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant.
10.30A**	Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant.
10.31A**	License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant.
10.32A**	Laboratory Services Agreement dated October 15, 1999 between Unilab Corporation and Registrant.

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10.33	Asset Purchase Agreement among Registrant, Boston Biomedica, Inc., and BBI Clinical Laboratories, Inc.
21.1**	Subsidiaries of the Registrant.
23.1	Consent of Ernst & Young LLP, independent auditors.

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This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 333-45588) under the same exhibit number, and is incorporated by reference herein.

Confidential treatment requested and received as to certain portions of this agreement.

Indicates a management contract or compensatory arrangement.

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Report of Ernst & Young LLP, Independent Auditors

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