

SPECIALTY LABORATORIES INC  
Form 10-Q  
May 12, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2004

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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**Not Applicable**

(Former name, former address and former fiscal year, if changed since last report)

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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  No

As of April 30, 2004, there were approximately 22,737,125 shares of Common Stock outstanding, no par value.

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**SPECIALTY LABORATORIES, INC.**

**FORM 10-Q QUARTERLY REPORT**

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**CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This Quarterly Report on Form 10-Q (the "Quarterly Report") includes information incorporated herein by reference and 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. These forward-looking statements are based on the current expectations, assumptions, estimates and projections about Specialty Laboratories, Inc. and the esoteric clinical laboratory industry. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. These forward-looking statements involve risks and uncertainties. Our actual results could differ materially from those discussed in these forward-looking statements as a result of certain factors, including those described in this Quarterly Report. All forward-looking statements attributable to Specialty Laboratories, Inc. are expressly qualified in their entirety by the cautionary statements of this Quarterly Report and by the discussion of Risk Factors included in this Quarterly Report, and in other filings with the Securities and Exchange Commission ("SEC") made from time to time by Specialty Laboratories, Inc., including our periodic reports on Form 10-K and Form 10-Q and our current reports on Form 8-K. If any of these risks actually occur, our business, financial condition, results of

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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.

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

Specialty Laboratories, Inc.

Condensed Consolidated Balance Sheets

*(Dollar amounts in thousands)*

	December 31, 2003	March 31, 2004 (Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,563	\$ 40,572
Short-term investments	9,104	9,067
Accounts receivable, less allowance for doubtful accounts of \$2,720 as of December 31, 2003 and \$2,566 as of March 31, 2004	22,239	23,846
Receivable from sale of property		16,241
Refundable income taxes	126	128
Deferred income taxes	1,155	1,155
Inventory	2,729	3,009
Prepaid expenses and other assets	2,680	2,102
Total current assets	65,596	96,120
Property and equipment, net	61,535	21,183
Long-term investments		3,000
Deferred income taxes	5,029	5,029
Goodwill, net	5,655	5,655
Other assets	4,738	6,112
	\$ 142,553	\$ 137,099
<b>Liabilities and shareholders equity</b>		
Current liabilities:		
Accounts payable	\$ 8,834	\$ 7,334
Accrued liabilities	6,261	4,559
Total current liabilities	15,095	11,893
Long-term debt	5,019	5,082
Other long-term liabilities	1,939	1,812
Commitments and contingencies		
Shareholders equity:		

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Preferred stock, no par value:			
Authorized shares	10,000,000		
Issued and outstanding shares none			
Common stock, no par value:			
Authorized shares	100,000,000 shares		
Issued and outstanding shares	22,570,256 as of December 31, 2003 and 22,732,502 as of March 31, 2004	103,005	103,385
Retained earnings		17,436	14,901
Deferred stock-based compensation		(13)	(5)
Accumulated other comprehensive income		72	31
Total shareholders equity		120,500	118,312
		\$ 142,553	\$ 137,099

*See accompanying notes.*

Specialty Laboratories, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

(Dollar amounts in thousands except per share data)

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2004</b>
Net revenue	\$ 30,300	\$ 31,304
Costs and expenses:		
Costs of services	21,785	22,582
Selling, general and administrative (exclusive of stock-based compensation charges)	10,914	11,178
Stock-based compensation charges	24	142
Total costs and expenses	32,723	33,902
Operating loss	(2,423)	(2,598)
Interest income	(211)	(63)
Interest expense	34	
Loss before income tax benefit	(2,246)	(2,535)
Income tax benefit	(764)	
Net loss	\$ (1,482)	\$ (2,535)
Basic loss per common share	\$ (.07)	\$ (.11)
Diluted loss per common share	\$ (.07)	\$ (.11)

See accompanying notes.

## Specialty Laboratories, Inc.

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

*(Dollar amounts in thousands)*

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2004</b>
<b>Operating activities</b>		
Net loss	\$ (1,482)	\$ (2,535)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,688	1,531
Tax benefits related to employee stock options	217	
Deferred income taxes	(188)	
Stock-based compensation charges	24	142
Changes in assets and liabilities:		
Accounts receivable, net	585	(1,607)
Inventory, prepaid expenses and other assets	183	480
Accounts payable	1,708	(1,500)
Accrued liabilities	(974)	(1,702)
Income taxes refundable/payable	(791)	(2)
Long-term liabilities	(505)	(127)
Net cash provided by (used in) operating activities	465	(5,320)
<b>Investing activities</b>		
Purchases of property and equipment	(7,368)	(5,156)
Proceeds from sale of property and equipment		27,830
Purchase of investments, net	(1,972)	(3,004)
Net cash (used in) provided by investing activities	(9,340)	19,670
<b>Financing activities</b>		
Borrowings under bank loans		63
Increase in deferred financing cost		(1,650)
Proceeds from exercise of stock options	90	246
Net cash provided by (used in) financing activities	90	(1,341)
Net (decrease) increase in cash and cash equivalents	(8,785)	13,009
Cash and cash equivalents at beginning of period	22,405	27,563
Cash and cash equivalents at end of period	\$ 13,620	\$ 40,572
<b>Supplemental disclosure of cash flow information:</b>		
Receivable from sale of property		\$ 16,241
Change in unrealized losses on investments	\$ (34)	\$ (41)



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Deferred income taxes		(18)		
Net change in unrealized losses	\$	(16)	\$	(41)
Interest paid	\$	29	\$	62

*See accompanying notes.*

**SPECIALTY LABORATORIES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 2004**

**(Unaudited)**

**NOTE 1. BASIS OF PRESENTATION**

*Financial Statement Preparation*

The accompanying financial statements of Specialty Laboratories, Inc. (the Company) have been prepared, without audit, in accordance with generally accepted accounting principles for interim financial reporting and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. In the opinion of management, such interim financial statements contain all adjustments (consisting of normal recurring items) considered necessary for a fair presentation of our financial position, results for operations and cash flows for the interim periods presented. The results of operations and cash flows for any interim periods are not necessarily indicative of results that may be reported for the full year.

The accompanying financial statements should be read in conjunction with the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission.

**NOTE 2. GOODWILL AND INTANGIBLE ASSETS**

The Company allocates the excess of the purchase price over the fair value of the net assets acquired to goodwill and identifiable intangible assets. Identifiable intangible assets include customer lists and license agreement fees, which are amortized evenly over periods of 10 and 4.5 years, respectively. Effective January 1, 2002, the Company ceased amortization of goodwill in accordance with the provisions of Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*.

*Intangible Assets (included in other assets)*

	<b>December 31, 2003</b>	<b>March 31, 2004</b>
	<b>(amounts in thousands)</b>	
<b>Intangible assets are as follows:</b>		
Customer list related to the acquisition of BBICL	\$ 1,932	\$ 1,932

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Other intangible assets	425	425
Less accumulated amortization	(750)	(823)
Total intangible assets, net	\$ 1,607	\$ 1,534

The estimated amortization expense for intangible assets will be \$289,000 per year through December 31, 2005, \$225,000 for 2006, \$193,000 per year for 2007 through 2010, and \$32,000 for 2011.

**NOTE 3. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

	December 31, 2003		March 31, 2004
	(amounts in thousands)		
Information technology equipment and systems	\$ 36,061	\$	36,346
Professional equipment	14,248		14,957
Office furniture and equipment	4,223		4,223
Land	8,701		
Leasehold improvements	8,846		8,924
	72,079		64,450
Less accumulated depreciation and amortization	(44,380)		(45,817)
Construction in progress (See Note 9)	33,836		2,550
Total property and equipment, net	\$ 61,535	\$	21,183

**NOTE 4. LONG-TERM DEBT**

On September 24, 2003, the Company entered into a \$25 million asset-based credit agreement with CIT Business Credit, a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds being commensurate with this asset. The credit agreement provides the Company with an initial \$15 million line of credit. The principal amount of borrowings is due three years from the closing date, the date the line of credit matures. Interest is computed and payable monthly. Interest is based on the Chase Bank rate plus one-half percent (0.5%) per annum. As of March 31, 2004, the Company had borrowed approximately \$5,082,000 against the line of credit.

**NOTE 5. STOCK-BASED COMPENSATION**

The Company accounts for stock options under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Compensation cost for stock options is reflected in net income and is measured as the excess of the market price of the Company's stock at the date of grant over the amount an employee must pay to acquire the stock. Compensation cost for fixed awards subject to vesting is recognized pro rata over the vesting period.

The Company has adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*. Pro forma net income, determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement, follows:

**NOTE 5. STOCK-BASED COMPENSATION**



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	Three Months Ended March 31,	
	2003	2004
	(amounts in thousands except per share data)	
Net loss, as reported	\$ (1,482)	\$ (2,535)
Stock-based employee compensation charges (credits), net of related tax effects in 2003 only:		
Determined under the intrinsic-value based method	16	142
Determined under the fair-value based method	(916)	(1,376)
Net loss, as adjusted	\$ (2,382)	\$ (3,769)
Basic loss per common share:		
As reported	\$ (.07)	\$ (.11)
Pro forma	\$ (.11)	\$ (.17)
Diluted loss per common share:		
As reported	\$ (.07)	\$ (.11)
Pro forma	\$ (.11)	\$ (.17)

These pro forma amounts may not be representative and vary 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 using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended March 31,	
	2003	2004
Risk-free interest rates	3%	3%
Expected stock dividend yields	0%	0%
Weighted-average expected life of option	5 years	5 years
Expected stock price volatility based upon peer companies	.71	.65

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

Effective March 19, 2004, our senior vice president and chief financial officer resigned. We agreed to extend the period in which he can exercise his vested stock options in exchange for the provision of certain nonsubstantive services through the filing of Form 10-Q for the period ended March 31, 2004. This modification resulted in a charge of approximately \$134,000 for the excess of the intrinsic value on the separation date over the original intrinsic value at the stock option grant date.

**NOTE 6. COMMITMENTS AND CONTINGENCIES**

In January 2003, the Company established a \$680,000 irrevocable Letter of Credit with the Federal Insurance Company, our workers compensation insurance provider for 2003. The Letter of Credit was increased to \$1,030,000 effective January 2004. The Company elected to utilize a deductible program for 2003 and 2004 for which Federal Insurance Company required a security deposit in the form of a Letter of Credit. The Company has accrued an estimate for claim deductibles under its worker compensation programs.

In May and June, 2002, we were named as a defendant, together with certain of our current or former board members and officers, in four substantially identical class-action lawsuits filed in the United States District Court for the Central District of California. The lawsuit purports to state claims on behalf of an alleged class of investors who bought our stock in the open market between December 8, 2000 and April 15, 2002 ( Class Period ). The lawsuit alleges that the market price of our stock was artificially inflated during the Class Period as a result of alleged misrepresentations made in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with our initial public offering of common stock and subsequent public disclosures. The lawsuit alleges, among other things, false and misleading statements about our compliance with certain regulatory requirements imposed by the California Department of Health Services and the federal Centers for Medicare & Medicaid Services. Plaintiffs seek compensatory damages, including interest, costs and expenses, attorneys fees, and other relief. Plaintiffs have filed several amended complaints, and we in turn have filed motions to dismiss these complaints. The court ruled on these motions, dismissing some claims and not dismissing others, and allowed plaintiffs to proceed with their claims against the Company and several current and former officers and directors for alleged violations of both the Securities Act of 1933 and the Securities Exchange Act of 1934. We have provided notice to our directors and officer s insurers, and believe that we have insurance applicable to the defense of the lawsuits. We also believe that the claims against us and our current and former officers and directors are without merit, and intend to defend the lawsuits vigorously.

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

In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company ( Dragon ), one of the shareholders in SLA. Dragon has also brought the lawsuit in the name of SLA as a derivative action. The lawsuit alleges, among other things, that SLA and Dragon suffered damages as a result of the winding up of the affairs of SLA and disposition of its assets. The lawsuit also alleges that certain of the defendants breached certain written agreements to allow Dragon to acquire more shares of SLA, that certain of our former officers conspired to run down and dissipate the assets of SLA, and that they fraudulently concealed their actions from Dragon and the other minority shareholder of SLA. We have provided notice to the applicable insurance carriers. While we believe that we have insurance applicable to the defense of the lawsuits, and continue to work with the relevant insurance

carriers on the coverage issue, such carriers have not yet acknowledged coverage of the matter. We also believe that the claims against us, SLIL, and our former officers are without merit, and intend to defend the lawsuits vigorously.

#### NOTE 7. EARNINGS PER SHARE

Basic earnings (loss) per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding for the respective periods. Diluted earnings (loss) per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options that were outstanding during the respective periods presented. Since the Company reported a net loss for the quarter ending March 31, 2004, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were anti-dilutive.

Basic and diluted loss per share for the respective periods are set forth in the table below:

	Three Months Ended March 31,	
	2003	2004
	(amounts in thousands except per share data)	
Net loss	\$ (1,482)	\$ (2,535)
Basic loss per common share	\$ (.07)	\$ (.11)
Diluted loss per common share	\$ (.07)	\$ (.11)
Basic weighted average shares	22,096	22,663
Dilutive effect of outstanding stock options		
Diluted weighted average shares	22,096	22,663

#### NOTE 8. DEFERRED INCOME TAXES

The Company reported \$6,184,000 of net deferred tax assets (current and long-term) in the March 31, 2004 balance sheet, with approximately \$9,026,000 of this amount related to federal and state net operating loss carryforwards (NOL s). Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax assets will not be realized. The Company's valuation allowance totaled approximately \$1.9 million at March 31, 2004. Realization of the NOL s generated through March 31, 2004 is dependent on the Company's ability to generate approximately \$19.5 million of federal and \$27.0 million of state ordinary income in future years. Inability to generate the necessary ordinary income could have a material adverse effect on the Company's results of operations in future years. The federal NOL s begin expiring in 2024 and the state NOL s begin expiring in 2014.



**NOTE 9. SALE AND LEASEBACK OF BUILDING**

On February 11, 2004, the Company entered into an agreement for the sale and leaseback of our Valencia facility with Lexington Corporate Properties Trust, a real estate investment trust. Lexington agreed to purchase the existing facility for \$47.0 million. The closing of the sale was completed on March 18, 2004 and we received approximately \$26.2 million in proceeds, net of \$1.6 million of financing related expenses. The proceeds will be used to finance \$3.0 million of construction costs required by buyer under the sale agreement, and approximately \$12.0 million of Company owned leasehold improvements prior to the rent commencement date. Receipt of the approximately \$19.2 million balance of proceeds is expected by the fourth quarter of 2004, contingent upon the completion of the construction project and the commencement of lease payments to Lexington. Of the \$19.2 million, \$16.2 million has been recorded as a receivable on our balance sheet as of March 31, 2004, with the remaining \$3.0 million to be recorded over the next three to five months as the construction is completed.

Lease payments are expected to begin in the third quarter of 2004. For the first five years will be fixed at an annual rate of approximately \$3.5 million and will be adjusted every five years. Lease payments for years 6 through 10 will be the amount necessary to fully amortize the total project cost over 15 years at an interest rate equal to the sum of the then interpolated 15-year U.S. Treasury Bond rate plus 75 basis points. Payments will be increased 10% for years 11 through 15 with an additional 10% increase scheduled for years 16 through 20. The primary term for the lease is twenty years. There are three options to extend the term of the lease: two renewal options of five years each and a third renewal option for four years and six months.

Based on an interpolated 15-year Treasury Rate of 4.08% at March 31, 2004, the estimated minimum lease payments under the terms of the related lease agreement are reflected in the table. For 2004, the lease payments are anticipated to begin in August 2004. Actual lease payments for years 6 through 20 will be determined at least sixty days prior to the first day of the sixth lease year.

	Total	Payments due by Period			2009 and Beyond
		2004	2005 - 2006	2007 - 2008	
			(amounts in thousands)		
Operating lease obligations	\$ 90,487	\$ 1,484	\$ 7,125	\$ 7,125	\$ 74,753

The lease payments will be accounted for under FASB Technical Bulletin 85-3, *Accounting for Operating Leases with Scheduled Rent Increases*, which requires minimum lease payments with scheduled rent increases to be accounted for on a straight-line basis over the lease term. Rent expense for the facility is expected to be approximately \$4.5 million per year.

**ITEM 2. 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 Quarterly Report and the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2003, as filed with the Securities and Exchange Commission. This section includes forward-looking information that involves risks and uncertainties. See Cautionary Statement Regarding Forward-Looking Statements . Our actual results could differ materially from those anticipated by forward-looking statements due to factors discussed under Risk Factors , Business and elsewhere in this Quarterly Report.*

**Overview**

We are a leading hospital-focused clinical reference laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist communities nationwide. We believe we offer one of the most comprehensive menu of esoteric assays in the industry, with a test menu comprising thousands of different assays. Many of our tests 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 ordering and results reporting with these customers.

Through the execution of our hospital-focused strategy, we grew rapidly in recent years. For the three years 1999 through 2001, our net revenue grew at a compounded annual growth rate of 16%. This growth was supplemented with the acquisition of BBI Clinical Laboratories, Inc. (BBICL), in the first quarter of 2001. BBICL, founded in 1989, was a leading esoteric clinical reference laboratory specializing in infectious disease testing, such as Lyme disease and viral hepatitis. BBICL's primary customers included hospitals, physician specialists, pharmaceutical and diagnostic companies, and other clinical and research laboratories.

On April 2, 2002, Quest Diagnostics, Inc. announced that they had entered into a definitive agreement to acquire Unilab Corporation. Unilab, our largest customer, comprised approximately 10% and 8% of our net revenue for the years ended December 31, 2002 and 2001, respectively. As a result, Unilab did not renew the three-year agreement with us, which expired in October of 2002, and we experienced a significant decline in testing volumes sent to us from Unilab after expiration of the contract. In October 2002, we entered into a new agreement with Unilab which allowed for a more orderly reduction of the remaining test volumes. With the completion of Unilab's acquisition in February 2003 by Quest Diagnostics, we were provided notice that Unilab would stop sending us certain higher priced tests covered under the new agreement, and these test volumes ended in early April 2003. For the year ended December 31, 2003, Unilab contributed less than 3% of our net revenue.

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As previously reported, in December 2001, we purchased a 13.8 acre site in Valencia, California and began construction during the second quarter of 2002 of a 198,000 square foot facility which would enable us to consolidate all of our laboratory and administrative functions in one location. In October 2002, we announced that we would postpone the move to our new facility in Valencia until the second half of 2004. Accordingly, the construction of the new facility was suspended at completion of the Core and Shell of the facility, which was substantially completed in January 2003. This postponement allowed us to focus on rebuilding client confidence and stabilizing our business by minimizing any disruptions in

service to our clients based on planning and executing a move to a new facility during this rebuilding period. We resumed construction of the Valencia facility in early 2004, and on February 11, 2004, we signed an agreement for the sale and leaseback of the Valencia facility with Lexington Corporate Properties Trust, a real estate investment trust. Under the terms of the agreement, Lexington purchased the existing facility for \$47.0 million. We will complete the construction project and enter a twenty-year lease for use and occupancy of the facility. The sale and leaseback transaction was completed on March 18, 2004. Lease payments are expected to begin in the third quarter of 2004. Rent expense for the new facility is expected to be approximately \$4.5 million per year. With construction planned for completion in the third quarter of 2004, the move from the facilities in Santa Monica to Valencia will be conducted in stages beginning in the third quarter of 2004 and completing by the second quarter of 2005. We do expect to incur incremental costs of approximately \$2.5 million to \$3.0 million for overlapping rents and relocation expenses during the phased relocation process. For more information, please see Risk Factors - Our planned move to Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers.

Other significant developments in the last quarter included:

On March 19, 2004, Frank J. Spina, Senior Vice President and Chief Financial Officer, left the company to pursue other professional opportunities. On April 12, 2004, we announced the appointment of Kevin R. Sayer as Executive Vice President and Chief Financial Officer of the Company.

### **Critical Accounting Policies**

#### *Revenue Recognition*

Revenue is recognized as services are rendered upon completion of the testing process for a specific customer order for which we have no future performance obligation to the customer, the customer is obligated to pay and the fees are non-refundable. Our 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.

#### *Expense Recognition*

Expenses are recognized as incurred and are generally classified as cost of services or selling, general and administrative expenses. Components of cost of services include salaries and employee benefits, research and development costs, supplies and reagents, courier costs, depreciation of laboratory equipment and leasehold improvements. Selling, general and administrative expenses include salaries and employee benefits, sales and marketing, information technology, 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 March 31, 2004, we

expect to amortize approximately \$5,000 of deferred stock-based compensation during the remainder of 2004. We anticipate that the exercise price of stock options granted after the calendar year of 2000 will be at the reported market price of our common stock, and therefore no deferred stock-based compensation will result from these grants.

### Off-Balance Sheet Arrangements

There are no off-balance sheet transactions, arrangements or obligations (including contingent obligations) that have, or are reasonably likely to have a material effect on the Company's financial condition, changes in the financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

### Results of Operations

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

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2004</b>
Net revenue	100.0%	100.0%
Cost of services	71.9	72.1
Selling, general and administrative (exclusive of stock-based compensation charges)	36.0	35.7
Operating loss	(8.0)	(8.3)
Loss from operations before income taxes (benefits)	(7.4)	(8.1)
Net loss	(4.9)	(8.1)

### Quarter Ended March 31, 2004 Compared with Quarter Ended March 31, 2003

#### *Net Revenue*

Net revenue increased by \$1.0 million, or 3.3%, to \$31.3 million for the quarter ended March 31, 2004 from \$30.3 million for the quarter ended March 31, 2003. This increase in revenue resulted primarily from an increase in accession volumes from approximately 616,000 in the first quarter of 2003 to approximately 670,000 in the first quarter of 2004, an increase of nearly 9%. The year-over-year increase in accession volume reflects the increase in business from hospital clients and regional laboratories. The net revenues for the quarter ended March 31, 2004 include the loss of business from Unilab Corporation, previously our largest customer, when the acquisition of Unilab by Quest Diagnostics was completed in February 2003. Revenues from Unilab, compared to the prior year period, declined approximately \$2.0 million in the first quarter of 2004. Revenues for the first quarter of 2004 also were impacted by a year-over-year reduction of approximately 5% in the aggregate average selling price due primarily to new client volume of lower-priced, routine-esoteric tests and the loss of higher-priced tests received from Unilab in the first quarter of 2003.

Sequentially, net revenues increased from the fourth quarter of 2003 by approximately \$845,000, reflecting an increase of approximately 7% in accession volumes from approximately 628,000 in the fourth quarter of 2003 to approximately 670,000 in the first quarter of 2004. In addition, the first quarter of 2004 aggregate average selling price declined nearly 4% from the fourth quarter of 2003 due to a higher volume of lower-priced routine tests being performed in the first quarter of 2004. The growth of new business activity remains sound and as a result, we expect accession volumes for the second quarter of 2004 to exceed 690,000. For second quarter of 2004, we estimate our aggregate average selling price will remain consistent with our first quarter pricing.

*Cost of Services*

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$797,000, or 3.7%, to \$22.6 million for the first quarter of 2004 from \$21.8 million for the comparable prior year quarter. This increase is due primarily to higher accession volumes, and resultant increases in reagents, laboratory labor costs, and distribution costs, and some additional reagent costs associated with the start up of new tests. As a percentage of revenue, cost of services increased slightly to 72.1% for the quarter ended March 31, 2004 from 71.9% from the comparable prior year quarter.

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of approximately \$983,000, or 4.6%, on an approximately 7% higher accession volume. This sequential increase is the result of increased reagents, royalties and laboratory labor costs related to the higher accession volumes in the first quarter of 2004. As a percentage of revenue, cost of services increased to 72.1% from 70.9% for quarter ended December 31, 2003. For the second quarter of 2004, cost of services as a percentage of revenue is expected to improve over the first quarter levels.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased approximately \$264,000, or 2.4%, to \$11.2 million for the first quarter of 2004 from \$10.9 million for the first quarter of 2003. This increase is primarily due to approximately \$430,000 of certain charges related to previously disclosed legal matters, the separation of our former chief financial officer and the hiring of our new chief financial officer, and other employee severance expenses. As a percentage of revenue, selling, general and administrative expenses decreased to 35.7% for the quarter ended March 31, 2004 from 36.0% from the comparable prior year quarter.

Sequentially, selling, general and administrative expenses increased approximately \$1.2 million from the fourth quarter of 2003. This increase is the result of higher expenditures on sales and marketing, information technology, and related programs to support new business growth and the \$430,000 of certain charges related to previously disclosed legal matters, the separation of our former chief financial officer and the hiring of our new chief financial officer, and other employee severance expenses. As a percentage of revenue, selling, general and administrative expenses increased to 35.7% from 32.9% for the quarter ended December 31, 2003. We expect to see a modest decline in selling, general and administrative costs for the second quarter of 2004 as compared to the first quarter of 2004 costs.

*Stock-Based Compensation Charges*

Stock-based compensation charges increased from \$23,700 to approximately \$142,000 from the first quarter of 2003 to the first quarter of 2004. The increase in the first quarter of 2004 is primarily due to a charge related to the separation of our former chief financial officer on March 19, 2004 and a related modification of his stock option award (see Consolidated Financial Statements Note 5).

*Interest (Income) Expense, Net*

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 24



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Net interest income decreased from approximately \$177,000 to \$63,000 from the first quarter of 2003 to the first quarter of 2004. This reduction reflects a lower level of investments, as cash was utilized for capital expenditures for the new Valencia facility and IT infrastructure, and proceeds from the sale and leaseback of the Valencia facility were received in the latter half of March 2004.

### *Provision for Income Taxes (Benefits)*

For the first quarter of 2004, we did not record any additional benefits for income taxes due to the size of deferred tax assets currently recorded on our balance sheet as of March 31, 2004. For the first quarter of 2003, we did record a benefit for income taxes of \$764,000. We do not expect to record any additional benefits for income taxes should they be available. If our loss narrows and we return to profitability, the effective tax rate could fluctuate significantly depending on the exact nature of the

operating results. Please see Risk Factor Our effective tax rate may fluctuate and we may not be able to fully realize a portion of our deferred tax assets.

### *Net Income*

A net loss of \$2.5 million was recorded for the quarter ended March 31, 2004 compared to a net loss of \$1.5 million for the comparable prior year quarter, an increase of approximately \$1.0 million. While our net revenue increased by approximately \$1.0 million for the first quarter of 2004 as compared to the first quarter of 2003, our total costs and expenses increased by approximately \$1.2 million. This increase in costs is related to higher accession volumes and certain charges of \$430,000 recorded in the first quarter of 2004 related to previously disclosed legal matters, the separation of our former chief financial officer and the hiring of our new chief financial officer, and other employee severance expenses. In addition, we did not record any benefits for income taxes in the first quarter of 2004 as compared to the benefit of \$764,000 recorded in the first quarter of 2003. As a percentage of revenue, a net loss of 8.1% was recorded for the quarter ended March 31, 2004 as compared to a net loss of 4.9% for the comparable prior year quarter.

### **Liquidity and Capital Resources**

Our cash and cash equivalents combined with short-term and long-term investments totaled \$52.6 million as of March 31, 2004 as compared to \$36.7 million as of December 31, 2003. This \$15.9 million increase is primarily related to the receipt of proceeds, net of \$1.6 million in financing related expenses, of \$26.2 million from the sale of our Valencia facility to Lexington Corporate Properties Trust, partially offset by capital expenditures of \$5.2 million as we resumed the construction of our Valencia facility, as reflected in investing activities during the first quarter of 2004.

Operating activities for the quarter ended March 31, 2004 used net cash of approximately \$5.3 million. The net decrease in the combined accounts payable and accrued liabilities used cash of approximately \$3.2 million, primarily for severance and vendor payments. The increase in accounts receivable resulted in the use of cash of \$1.6 million. The net loss of \$2.5 million was partially offset by depreciation and amortization of \$1.5 million. For the quarter ended March 31, 2003, operating activities provided cash of \$465,000. This cash was generated primarily by an increase of approximately \$734,000 in accounts payable and accrued liabilities, \$585,000 of cash provided by accounts receivable collections, and the net loss of \$1.5 million was offset by depreciation and amortization of \$1.7 million. These were somewhat offset by a \$505,000 reduction in long-term liabilities and a \$791,000 increase to our tax benefits, as reflected in income taxes refundable.

Investing activities for the quarter ended March 31, 2004 provided net cash of \$19.7 million as we received \$27.8 million in proceeds from the sale of our Valencia facility. This receipt was partially offset by \$5.2 million of capital expenditures as we resumed construction of the Valencia facility and also repositioned \$3.0 million of cash and cash equivalents to long-term investments. For the first quarter of 2003, we used net cash of \$9.3 million which included approximately \$7.4 million in funds to complete the Core and Shell phase of our Valencia facility and purchase additional information technology equipment, and we repositioned \$2.0 million of cash and cash equivalents to long-term investments.

Net cash used in financing activities was \$1.3 million for the quarter ended March 31, 2004 as compared to cash provided by financing activities of \$90,000 for the quarter ended March 31, 2003. For the first quarter of 2004, we paid \$1.6 million in financing related expenses associated with the sale and leaseback of our Valencia facility which were partially offset by the receipt of \$246,000 from the exercise of stock options. For the first quarter of 2003, net cash was provided from financing activities from the exercise of stock options of \$90,000.

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 26

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On February 11, 2004, the Company entered into an agreement for the sale and leaseback of our Valencia facility with Lexington Corporate Properties Trust, a real estate investment trust. Lexington purchased the existing facility for \$47.0 million. The closing of the sale was completed on March 18, 2004 and we received approximately \$26.2 million in proceeds, net of \$1.6 million of financing related expenses. The proceeds will be used to finance \$3.0 million of construction costs required by buyer

under the sale agreement, and approximately \$12.0 million of Company owned leasehold improvements prior to the rent commencement date. Receipt of the approximately \$19.2 million balance of proceeds is expected by the fourth quarter of 2004, contingent upon the completion of the construction project and the commencement of lease payments to Lexington. Of the \$19.2 million, \$16.2 million has been recorded as a receivable on our balance sheet as of March 31, 2004, with the remaining \$3.0 million to be recorded over the next three to five months as the construction is completed. With construction planned for completion in the third quarter of 2004, the move from the facilities in Santa Monica to Valencia will be conducted in stages beginning in the third quarter of 2004 and completing by the second quarter of 2005. We do expect to incur incremental costs of approximately \$2.5 million to \$3.0 million for overlapping rents and relocation expenses during the phased relocation process which will be expensed as incurred.

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

### Contractual Obligations

There have been no material changes to the contractual obligations described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2003 except as follows. On February 11, 2004, the Company entered into an agreement for the sale and leaseback of our Valencia facility with Lexington Corporate Properties Trust, a real estate investment trust. Lease payments are expected to begin in the third quarter of 2004. For the first five years will be fixed at an annual rate of approximately \$3.5 million and will be adjusted every five years. Lease payments for years 6 through 10 will be the amount necessary to fully amortize the total project cost over 15 years at an interest rate equal to the sum of the then interpolated 15-year U.S. Treasury Bond rate plus 75 basis points. Payments will be increased 10% for years 11 through 15 with an additional 10% increase scheduled for years 16 through 20. The primary term for the lease is twenty years. There are three options to extend the term of the lease: two renewal options of five years each and a third renewal option for four years and six months. (Please see our Consolidated Financial Statements Note 9 and Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources for further discussion.)

In the table below, we set forth our estimated operating lease obligations as of March 31, 2004 related to this new lease agreement. For 2004, lease payments are anticipated to begin in August 2004. Some of the figures we include in this table are based on management's estimates and assumptions about these obligations, including their duration, the possibility of renewal, anticipated actions by third parties, and other factors. Because these estimates and assumptions are necessarily subjective, the contractual obligations we will actually pay in future periods may vary from those reflected in the table.

	Total	2004	Payments due by Period			2009 and Beyond
			2005 - 2006	2007 - 2008		
Operating lease obligations	\$ 90,487	\$ 1,484	\$ 7,125	\$ 7,125	\$ 74,753	

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 26

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 20%

## **Risk Factors**

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

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

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

### *Fraud and Abuse*

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

### *Federal and State Clinical Laboratory Licensing*

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

In June and October 2001, we underwent unannounced inspections by CDHS representing both the State of California and acting as agent of CMS under CLIA. As a result, we were cited by CDHS with 20 deficiencies under California law and CLIA. A separate statement indicating 12 overlapping deficiencies under CLIA was issued by CMS in February 2002 based upon the same inspections. We subsequently submitted responses and corrective action plans to CDHS and CMS, although CDHS and CMS ultimately found these plans to not constitute credible

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 30

allegations of compliance.

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

CMS separately imposed certain sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed, imposing a civil money penalty of \$3,000 per day for each day during the sanction period, and imposing a directed plan of correction by which CMS could notify our customers of our non-compliance and the

nature and effective date of any sanctions imposed.

After filing supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, CDHS conducted additional unannounced inspections, and we provided additional documentation supporting our compliance with CDHS requirements.

By letter dated June 28, 2002, and amended on July 18, 2002, CDHS indicated that we were in substantial compliance with California clinical laboratory law. CDHS also imposed sanctions of a civil money penalty of \$1,000 per day for 344 days (i.e., \$344,000), plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections. We did not appeal these imposed sanctions.

On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's right to bill Medicare and Medicaid for its testing services was reinstated as of June 19, 2002, and that all actions against our CLIA certificate were rescinded. We also did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day during the sanction period. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services performed from February 22, 2002 through June 19, 2002 did not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly.

In May 2003, CDHS conducted an unannounced monitoring inspection of our laboratory facilities in conjunction with the imposed onsite monitoring for three years. The CDHS inspection found no material deficiencies related to the issues we faced in 2002, and found that we continued to maintain condition level compliance with state laboratory law.

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

#### *Food & Drug Administration*

Neither the FDA nor any other governmental agency currently fully regulates the new assays we internally develop. Although the FDA previously asserted that its jurisdiction extends to tests generated in a clinical laboratory, it has allowed these tests to be run and the results commercialized without FDA premarket approval. In January 2003, the U.S. Department of Health and Human Services (HHS) indicated it is still assessing the feasibility of regulating in-house genetic testing, and HHS recently created a new committee, the Secretary's Advisory Committee on Genetics, Health and Society, to take over and expand on the role of the former Secretary's Advisory Committee on Genetic Testing (SACGT). Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. If the FDA seeks to regulate in-house genetic testing, depending the nature and scope of such regulation, it could have a detrimental effect on our business. We cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require premarketing clearance. Hence, we might be subject in the future to greater

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of



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regulation, or different regulations, that could have a material effect on our finances and operations.

The FDA has also asserted that its jurisdiction includes the ability to inspect our facilities in connection with certain testing we do for blood donation and collection centers. An inspector from the FDA conducted an unannounced site inspection of our laboratory facilities in July and August 2003 in connection with this testing for blood centers. The FDA inspector's report of this inspection did not indicate any material issues or deficiencies of our facilities. However, we will likely be subject to future

FDA inspections, and no assurances can be given that our facilities will satisfactorily pass all such inspections. Any inability to comply with applicable FDA regulations could result in substantial monetary penalties, revocation of our FDA registration, suspension or cancellation of our ability to conduct testing for blood donation and collection centers, and could divert a substantial amount of management's time and resources, and any such action could materially harm our business.

#### *Anti-Kickback Regulations*

Existing federal laws governing Medicare and Medicaid and other similar state laws impose a variety of broadly described restrictions on financial relationships among healthcare providers, including clinical laboratories. These laws include federal anti-kickback laws which prohibit clinical laboratories from, among other things, making payments or furnishing other benefits intended to induce the referral of patients for tests billed to Medicare, Medicaid or certain other federally funded programs. In addition, they also include self-referral prohibitions which prevent us from accepting referrals from physicians who have non-exempt ownership or compensation relationships with us as well as anti-markup and direct billing rules that may apply to our relationships with our customers. Sanctions for violations of these laws may include exclusion from participation in Medicare, Medicaid and other federal healthcare programs, and criminal and civil fines and penalties.

#### *Fee-Splitting*

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

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

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

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

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Some of our customers, such as Quest, LabCorp, Mayo and ARUP, also compete with us by providing esoteric testing services. They often refer assays to us that they either cannot or elect not to perform themselves. During 2002, we saw a significant decline in test volumes referred to us from our competitors. Sales to our competitors were approximately 4% of our net revenue for the years ended December 31, 2003 and 2002. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours, and we may experience a further decline in our net revenues from these competitors. For example, in April 2002, Quest announced that they had entered into a definitive agreement to acquire Unilab Corporation. Unilab, our largest customer, comprised approximately 10% and 8% of our net revenue for the years 2002 and 2001, respectively. As a result, Unilab did not renew the three-year agreement with us, which expired in October 2002. We experienced a significant decline in testing volumes sent to us from Unilab after expiration of the contract. In February 2003, with the completion of Unilab's acquisition by Quest, we received notice that Unilab would stop sending us certain higher priced tests and these tests volumes ended in early April 2003. For

2003, Unilab contributed less than 3% of our net revenue. We experienced a significant reduction in volume from Quest, LabCorp, Mayo and ARUP in 2002 and 2003, and if these or other laboratories decide to reduce or discontinue purchases of our assays for competitive or other reasons, it will reduce the number of our accessions and reduce our net revenue.

**The 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 ARUP, that are affiliated with large medical centers or universities.

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

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

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

The clinical laboratory industry is intensely competitive and highly fragmented. Our current competitors include large national laboratories that offer a wide test and product menu on a national scale as well as smaller niche and regional organizations. Some of our large competitors have expanded, and may continue to expand, their competitive product offerings through acquisitions. For example, Quest, the nation's leading provider of diagnostic testing and related services for the healthcare industry, recently acquired American Medical Laboratories Incorporated, a

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of

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national provider of esoteric testing to hospitals and specialty physicians, Clinical Diagnostics Services, Inc., a provider of routine and esoteric testing, and Unilab Corporation, a leading clinical testing laboratory. LabCorp recently acquired Dianon Systems Inc., a leading U.S. provider of anatomic pathology and oncology testing services. Acquisitions among existing and future competitors may allow them to rapidly gain greater market share. In addition, some of our customers refer assays to us that they cannot perform themselves. These customers may no longer need to refer assays to us if they develop assays similar to us through the acquisition of other esoteric laboratories. A loss of market share and customers from such acquisitions could materially adversely affect our business, financial condition, results of operations and prospects.

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

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

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

demand for our 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;

our ability, and that of our clients, to bill Medicare and Medicaid programs for our services;

changes in healthcare laws and regulations;

costs of reagents and supplies, as well as other operating costs;

costs related to acquisitions of technologies or businesses; and

the effect of litigation.

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

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 38

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In addition, the trading price of our common stock may materially decline regardless of our operating results and performance. The market price of our common stock has been subject to significant fluctuations since our initial public offering in December 2000. The stock market has experienced significant price and volume fluctuations that have affected the market prices of securities, particularly securities of clinical laboratory, biotechnology and other health care service companies. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. As previously announced, such securities claims were filed against us in May and June 2002. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurance that we will be successful in defending these actions. For more detailed description of the purported class-action securities claims recently filed against us, please see Part II. Item 1. Legal Proceedings Below.

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, financial condition, results of operations, or cash flows could be materially harmed and operating results in a given quarter could be worse than expected.

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

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

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

medical products and services. Government and other third party payors increasingly are limiting both coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. In 2001, 2002 and 2003, third party payors accounted for approximately 6.9%, 6.6% and 8.3%, respectively, of our net revenue. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payors and we do not know the percentage of our net revenue that is indirectly derived from these payors. Any pricing pressure exerted by these third party payors on our customers may, in turn, be exerted by our customers on us. If government and other third party payors do not provide adequate coverage and reimbursement for our assays, our net revenue may decline.

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

Proposals have been made to require competitive bidding procurement of Medicare laboratory testing services. CMS is required to complete five Medicare bidding demonstrations involving various types of medical services and CMS is expected to include a clinical laboratory demonstration project in a metropolitan statistical area. At least one state competitive Medicaid bidding proposal underway in Florida may permit only one laboratory to provide services as the sole vendor under the contract, and it is possible that other future competitive bidding demonstration projects may also award the contract to a sole-source vendor. We can provide no assurances that future competitive bidding processes will allow us to compete successfully for the Medicare/Medicaid contracts. In the event that we are not successful in the competitive bidding process, including in the current competitive bidding process underway in Florida, or are otherwise not allowed to participate in such awarded competitive bidding contracts, we may not be reimbursed for testing we perform for Medicaid patients in these states. Any restriction on our ability to do testing for Medicare/Medicaid patients, or be reimbursed for testing we perform for such patients, could materially affect our revenue and business. Any restriction on our ability to do testing for Florida Medicaid patients could also significantly negatively affect the amount of business we receive from our Florida clients, as such clients might be less inclined to divide the work they send to outside reference laboratories. Loss of business from our Florida clients could materially affect our revenue and business.

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

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

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of 40



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

We reported \$6,184,000 of deferred income taxes (current and long-term) in the March 31, 2004 balance sheet, with approximately \$9,026,000 of this amount related to federal and state net operating loss carryforwards (NOL s). Statement of Financial Accounting Standards No. 109, *Accounting for Income*

*Taxes*, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. The Company's valuation allowance totaled approximately \$1.9 million at March 31, 2004. Realization of the NOLs generated through March 31, 2004 is dependent on Specialty's ability to generate approximately \$19.5 million of federal and \$27.0 million of state ordinary income in future years. However, we cannot provide any assurances that the NOLs will be realized. Inability to generate the necessary ordinary income, and our inability to realize the NOLs, could have a material adverse effect on our results of operations in future quarters. The federal NOLs begin expiring in 2024 and the state NOLs begin expiring in 2014.

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

We depend substantially on the continued services and performance of our senior management, particularly Douglas S. Harrington, M.D., our chief executive officer and laboratory director, and certain other key personnel. The loss of the services of any of these executive officers or other key employees could hurt our business.

We have employment agreements with our executive officers, including Dr. Harrington. However, most members of our current senior management group have been recruited and hired over the past three years. These individuals may not be able to fulfill their responsibilities adequately and may not remain with us.

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

**Our planned move to a new facility in Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers.**

As we previously reported, we are constructing a 198,000 square foot facility in Valencia, California that will enable us to consolidate our laboratory and administrative functions in one location. The location of the new facility is approximately 30 miles from our current location in Santa Monica, California.

Moving our entire laboratory and administrative functions to a new location is a time-consuming and complicated process, and includes physically moving and setting up delicate and complex laboratory equipment over a short period of time, transferring specimens and reagents from one facility to another, changing processes and procedures for delivery of testing specimens, ensuring that we have adequate staffing of laboratory and administrative personnel at the new facility, and continuing to conduct our testing of specimens during the process. While we have announced a phased relocation to minimize client disruption, if we are unable to execute the move to Valencia effectively and efficiently, it could result in service disruptions that would negatively affect our business and could reduce our revenue. Such service disruptions could also

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of

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result in customer dissatisfaction, and could materially hurt our business if our customers decided not to purchase our services any longer as a result of the service disruptions. Furthermore, planning for the move of our facility is also expected to divert the attention of key management personnel, as state laboratory licensing regulations in California make a phased relocation more complicated from a licensing perspective than moving the entire laboratory at once.

We can provide no assurances that key management will not be distracted by planning for the facility move. We can also provide no assurances that we will be able to complete the move to the new Valencia facility efficiently or effectively, or on time, or that we will not experience service disruptions, loss in customers, or decreased revenue as a result of the move. Because the new Valencia facility is

located 30 miles away from our current headquarters, some of our key employees may choose not to remain employed with us after the move. The occurrence of any of the foregoing events affecting or resulting from our move could harm our business.

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

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

Our participation in group purchasing organizations constitutes one aspect of our overall strategy to attract new hospital customers. We have contracts with several group purchasing organizations: AmeriNet, MedAssets HSCA (formerly Health Services Corporation of America), Managed Healthcare Associates (MHA), Shared Services Healthcare (now affiliated with MedAssets HSCA), and Consorta. We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at various times from 2004 to 2006.

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

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

The 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 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.

**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.

In comparing the first quarter of 2004 to the fourth quarter of 2003, costs of services show a sequential increase of

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

HIPAA regulations required that covered entities (including us) be in compliance with the privacy regulations on or before April 14, 2003.

The commercialization of our Internet products including Outreach Express®, DataPassportMD®, and DataPassport Clinical Trials is strictly governed by state and federal laws and regulations, including the regulations under HIPAA. We have implemented encryption technology to protect patient medical information, 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. While we believe we are in compliance in all material respects with the applicable HIPAA regulations, our failure to comply could subject us to fines and penalties, and have a detrimental effect on our business.

We may be subject to inspections or investigations by state or federal regulatory entities that enforce privacy laws and regulations, and we can provide no assurances that we will be found fully compliant with HIPAA or other privacy laws and regulations.

**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.

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

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

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

In order to maintain our margins and benefit from the premium prices that we typically charge for our newly introduced 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.

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

**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 competitors' assays, and our net revenue may decrease.

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

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

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

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

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

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

**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.**

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



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A significant portion of our net revenue is derived from 30 assays. Net revenue from these 30 assays comprised approximately 45% of our total net revenue for the year ended December 31, 2003. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

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

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

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

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

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

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. 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 also received letters from Chiron Corporation ( Chiron ) in February 1998, and the National Institute of Health (NIH) in 2000-2003 claiming that some of our assays may violate their patents. In August 2003 we reported that we had entered into a letter agreement with Chiron that called for us to make payments to Chiron for alleged past infringement of Chiron patents by certain Hepatitis C Virus ( HCV ) and Human Immunodeficiency Virus ( HIV ) testing performed by us, and Chiron agreed not to assert its patent rights, or bring any claim against Specialty for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. We cannot provide any assurances that the NIH or other patent holders will not bring suit against us in the future for alleged patent infringement. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us. Such suits could be expensive to defend and could divert management's time and resources, regardless of the merit or validity of any such suit. Furthermore, we cannot provide any assurances that we would be successful in defending any such suit, and there can be no assurance that there will be no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and such litigation, or the threat of such litigation, could force us to do one or more of the following:

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

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

redesign or reengineer our assays.

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

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

We have made in the past and we may continue to make acquisitions of complementary businesses, products or technologies. For example, we acquired BBI Clinical Laboratories, Inc. in February 2001. If we identify any additional appropriate acquisition candidates, we may not be successful in negotiating acceptable terms of the acquisition, financing the acquisition, or integrating the acquired business, products or technologies into our existing business and operations. Further, completing an acquisition and integrating an acquired business will significantly divert management time and resources. The diversion of management attention and any difficulties encountered in the transition and integration process could harm our business. If we consummate any significant acquisitions using stock or other securities as consideration, our shareholders' equity could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results.

**We may 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, and a specimen splitting system, known as the Harmonized Assignment of Nanoliter Aliquots, or HANA. In addition, we plan to develop and implement other automated systems to enhance our testing procedures. We will need to develop sophisticated software to support these other automated procedures, analyze the data generated by these tests and report the results. Further, as we attempt to increase the number of patient samples we process, throughput or quality-control problems may arise.

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

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business which may increase our costs.

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

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

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

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

Our specimen processing facilities, our clinical laboratory, and our corporate offices are located in Santa Monica, California and we have been planning to move our operations to Valencia, California. California is still in an energy crisis that could disrupt our operations and increase our expenses. In the event power reserves for the state of California fall to critically low levels, California may implement rolling power blackouts throughout the state. The state of California has already experienced such occasional power blackouts. We currently have 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.

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

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

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

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

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Our principal shareholder is the Specialty Family Limited Partnership, whose sole general managing partner, James B. Peter, M.D., Ph.D., is a member of our board of directors. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 62% of the

outstanding shares of our common stock. Accordingly, the Specialty Family Limited Partnership along with Dr. Peter will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including election of directors, mergers, consolidations and the sale of all or substantially all of our assets. Our principal shareholder will also have the power to prevent or cause a change in control. The interests of this shareholder may differ from other shareholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a change in control and could deprive other shareholders of an opportunity to receive a premium for their common stock as part of a sale of our business.

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

We have taken a number of actions that could have the effect of discouraging a takeover attempt. For example, provisions of our amended and restated articles of incorporation and amended and restated bylaws could make it more difficult for a third party to acquire us, even if doing so would be beneficial to our shareholders. These provisions also could limit the price that certain investors might be willing to pay in the future for shares of our common stock.

These provisions include:

limitations on who may call special meetings of shareholders;

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

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



**ITEM 3.  
RISKS**

**QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET**

At any time, fluctuations in interest rates could effect interest earnings on our cash and cash equivalents and interest expense on our existing line of credit. We believe that the effect, if any, of reasonably possible near term changes in interest rates on our financial position, results of operations, and cash flows would not be material. Currently, we do not hedge these interest rate exposures. The primary objective of our investment activities is to preserve capital. We have not used derivative financial instruments in our investment portfolio.

At March 31, 2004, 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 March 31, 2004, we had cash and cash equivalents of \$40.6 million, which had a weighted average yield of 1.09% per annum. At March 31, 2004, our short-term investment balance of \$9.0 million, consisting of government securities with maturity dates less than one year, had a weighted average yield per annum of 2.6% and an average of 133.5 days until maturity. At March 31, 2004, our long-term investment balance of \$3.0 million consisted of government securities with maturity dates beyond one year had a weighted average yield per annum of 2.1% and an average of 30 months until maturity.

**ITEM 4.**

**CONTROLS AND PROCEDURES**

As of the end of the period covered by this report, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

There were no significant changes in our internal controls over financial reporting, identified in connection with the evaluation of such internal controls that occurred during our last fiscal quarter that have materially affected, or are likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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

As previously reported, in May and June 2002, we were named as a defendant, together with certain of our current or former board members and officers, in four substantially identical class-action lawsuits filed in the United States District Court for the Central District of California. The lawsuit purports to state claims on behalf of an alleged class of investors who bought our stock in the open market between December 8, 2000 and April 15, 2002 ( Class Period ). The lawsuit alleges that the market price of our stock was artificially inflated during the Class Period as a result of alleged misrepresentations made in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with our initial public offering of common stock and subsequent public disclosures. The lawsuit alleges, among other things, false and misleading statements about our compliance with certain regulatory requirements imposed by the California Department of Health Services and the federal Centers for Medicare & Medicaid Services. Plaintiffs seek compensatory damages, including interest, costs and expenses, attorneys fees, and other relief. Plaintiffs have filed several amended complaints, and we in turn have filed motions to dismiss these complaints. The court ruled on these motions, dismissing some claims and not dismissing others, and allowed plaintiffs to proceed with their claims against the Company and several current and former officers and directors for alleged violations of both the Securities Act of 1933 and the Securities Exchange Act of 1934. We have provided notice to our directors and officer s insurers, and believe that we have insurance applicable to the defense of the lawsuits. We also believe that the claims against us and our current and former officers and directors are without merit, and intend to defend these lawsuits vigorously.

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

In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company ( Dragon ), one of the shareholders in SLA. Dragon has also brought the lawsuit in the name of SLA as a derivative action. The lawsuit alleges, among other things, that SLA and Dragon suffered damages as a result of the winding up of the affairs of SLA and disposition of its assets. The lawsuit also alleges that certain of the defendants breached certain written agreements to allow Dragon to acquire more shares of SLA, that certain of our former officers conspired to run down and dissipate the assets of SLA, and that they fraudulently concealed their actions from Dragon and the other minority shareholder of SLA. We have provided notice to the applicable insurance carriers. While we believe that we have insurance applicable to the defense of the lawsuits, and continue to work with the relevant insurance carriers on the coverage issue, such carriers have not yet acknowledged coverage of the matter.

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From time to time, we receive letters alleging infringement of patent or other intellectual property rights. Our management believes that these letters generally are without merit and intend to contest them

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

**ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5. OTHER INFORMATION**

None.

**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K**

(a) Exhibits.

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

## Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

- 3.1 Articles of Incorporation. (1)
- 3.2 Form of By-laws. (1)
- 4.1 Specimen Common Stock Certificate. (1)
- 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.
- 10.12000 Stock Incentive Plan. (1)
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- +10.8 Expanded PCR Diagnostics Services Agreement dated August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant. (6)
- +10.9 Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended. (3)
- +10.10 Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant. (1)
- +10.11 Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant. (1)
- +10.12 Shared Services Health Care letter of confirmation dated June 5, 2000. (1)
- 10.13 License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee)

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- regarding Santa Monica Service Center property. (1)
- 10.14 Employment Agreement dated May 15, 2002 between Douglas S. Harrington and Registrant. (8)
- 10.15 James B. Peter, M.D., Ph.D. severance agreement dated June 7, 2002. (5)
- 10.16 Paul F. Beyer severance agreement dated June 6, 2002. (5)
- +10.17 Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant. (1)
- +10.18 Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant. (1)
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- +10.20 License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant. (1)
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- 10.22 Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc. (2)
- 10.23 Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended. (4)
- 10.24 Employment Agreement dated January 28, 2003 between Thomas E. England and Registrant. (8)
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- 10.33 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant. (9)
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- ++10.35 Agreement dated August 15, 2003 between Chiron Corporation and Registrant. (9)
- 10.36 Agreement dated September 24, 2003 between CIT Group/Business Credit, Inc. and Registrant. (9)
- 10.37 Employment Agreement dated December 10, 2003 between Maryam Sadri and Registrant. (10)
- 10.38 Lease dated January 12, 2004 between Water Garden Company L.L.C. (Landlord) and Registrant (Tenant) for the property located at 1620 26<sup>th</sup> Street, Santa Monica, California. (10)
- \*10.39 Agreement for Sale and Leaseback dated February 22, 2004 between Lexington Corporate Properties Trust (Buyer) and Registrant (Seller) for property located at 27027 Tourney Road, Santa Clarita, California.
- \*10.40 Construction Funding Agreement dated March 11, 2004 between Lexington Lion Clarita L.P. (Owner) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California.
- \*10.41 Lease dated March 18, 2004 between Lexington Lion Clarita L.P. (Landlord) and Registrant (Tenant) for property located at 27027 Tourney Road, Santa Clarita, California.
- \* 10.42 Separation Agreement dated March 14, 2004 between Frank J. Spina and Registrant.
- \* 10.43 Employment Agreement dated April 12, 2004 between Kevin R. Sayer and Registrant.
- \*31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- \*31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934.
- \*32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002.
- 99.1 California Department of Health Services Letter dated June 28, 2002. (6)
- 99.2 Center for Medicare and Medicaid Services Letter dated July 17, 2002. (6)
- 99.3 California Department of Health Services Letter dated July 18, 2002. (6)

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\* Filed herewith.

Indicates a management contract or compensatory agreement.

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

++ Confidential treatment requested as to certain portions of this agreement.

(1) 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) and is incorporated by reference herein.

(2) This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2000 with the Securities & Exchange Commission on March 30, 2001 and is incorporated by

reference herein.

(3) This exhibit was originally filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 and an amendment was filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 on August 10, 2001 and is incorporated by reference herein.

(4) This exhibit was previously filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2001 with the Securities & Exchange Commission on August 10, 2001 and is incorporated by reference herein.

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(b) Reports on Form 8-K:

On February 12, 2004, the Company filed a report on Form 8-K (Items 5 and 7) to report that it had announced that the Company had entered into an agreement for the sale and lease-back of its future headquarters and laboratory facility in Valencia, California, with Lexington Corporate Properties Trust, attaching a related press release.

On February 18, 2004, the Company filed a report on Form 8-K (Items 7, 9 and 12) with respect to its results of operations for the quarter and year ended December 31, 2003, attaching a copy of a press release containing financial statements for such periods.

On March 19, 2004, the Company filed a report on Form 8-K (Items 5 and 7) to report that it had announced the completion of the sale/lease-back of its future headquarters and laboratory facility in Valencia, California with an affiliate of Lexington Corporate Properties Trust, attaching a related press release.

On March 22, 2004, the Company filed a report on Form 8-K (Items 5 and 7) to report that it had announced that Frank J. Spina, senior vice president and chief financial officer, left the Company effective March 19, 2004 to pursue other professional opportunities, attaching a related press release.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Quarterly Report on Form 10-Q to be signed on its behalf by the undersigned, thereunto duly authorized.

SPECIALTY LABORATORIES, INC.,  
a California corporation

Dated: May 10, 2004

By: /s/ Douglas S. Harrington  
Name: Douglas S. Harrington  
Title: *Chief Executive Officer and Director*

Dated: May 10, 2004

By: /s/ Kevin R. Sayer  
Name: Kevin R. Sayer  
Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

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