

SPECIALTY LABORATORIES INC  
Form 10-Q  
August 09, 2005

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 10-Q**

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

For the quarterly period ended June 30, 2005

OR

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

For the transition period from to

Commission file number: 001-16217

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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.)

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

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

**Not Applicable**

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(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 August 2, 2005 there were approximately 23,747,092 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**



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This Quarterly Report on Form 10-Q, including the information incorporated herein by reference, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as projects, believes, anticipates, will, estimate, plans, expects, 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 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. 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 elsewhere in this Quarterly Report, and in other filings with the Securities and Exchange Commission made from time to time by Specialty Laboratories, Inc., including our periodic filings on Form 10-K, Form 10-Q and Form 8-K. If any of these risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially adversely affected. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business. Any adverse effect on our business, financial condition or results of operations could result in a decline in the trading price of our common stock and the loss of all or part of your investment.

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

Specialty Laboratories, Inc.

Consolidated Balance Sheets

*(Dollar amounts in thousands)*

	December 31, 2004	June 30, 2005 (Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 18,283	\$ 15,444
Accounts receivable, less allowance for doubtful accounts of \$3,132 as of December 31, 2004 and \$3,189 as of June 30, 2005	26,517	27,922
Receivable from sale of property	3,500	3,500
Refundable income taxes		32
Deferred income taxes	1,155	
Inventory	3,207	3,248
Prepaid expenses and other assets	2,683	1,928
Total current assets	55,345	52,074
Property and equipment, net	32,843	32,435
Long-term investments	21,822	21,687
Deferred income taxes	4,709	
Goodwill, net	5,655	5,655
Other assets	5,768	6,254
	\$ 126,142	\$ 118,105
<b>Liabilities and shareholders equity</b>		
Current liabilities:		
Accounts payable	\$ 9,292	\$ 6,657
Income taxes payable	387	
Facility exit costs accrual	471	
Accrued liabilities	4,297	7,045
Total current liabilities	14,447	13,702
Long-term liabilities	2,161	2,908
Shareholders equity:		
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 23,022,644 as of December 31, 2004 and 23,641,500 as of June 30, 2005	105,224	109,928
Retained earnings (accumulated deficit)	4,486	(8,122)
Accumulated other comprehensive loss	(176)	(311)



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Total shareholders equity		109,534		101,495
	\$	126,142	\$	118,105

*See accompanying notes.*

## Specialty Laboratories, Inc.

## Condensed Consolidated Statements of Operations

(Unaudited)

*(Dollar amounts in thousands except per share data)*

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
Net revenue	\$ 33,216	\$ 38,960	\$ 64,521	\$ 75,678
Costs and expenses:				
Costs of services	22,274	26,220	44,856	52,602
Selling, general and administrative (exclusive of provision for doubtful accounts and stock-based compensation charges)	10,205	13,931	20,380	26,874
Provision for doubtful accounts	1,263	1,135	2,267	2,261
Stock-based compensation	4	177	146	314
Facility exit costs				556
Total costs and expenses	33,746	41,463	67,649	82,607
Operating loss	(530)	(2,503)	(3,128)	(6,929)
Interest income	(177)	(207)	(240)	(396)
Interest expense		111		211
Loss before income taxes	(353)	(2,407)	(2,888)	(6,744)
Provision for income taxes				5,864
Net loss	\$ (353)	\$ (2,407)	\$ (2,888)	\$ (12,608)
Basic loss per common share	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)
Diluted loss per common share	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)

*See accompanying notes.*

## Specialty Laboratories, Inc.

## Condensed Consolidated Statements of Cash Flows

(Unaudited)

*(Dollar amounts in thousands)*

	Six Months Ended June 30,	
	2004	2005
<b>Operating activities</b>		
Net loss	\$ (2,888)	\$ (12,608)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,064	2,957
Loss on disposal of property and equipment		1,550
Write-off of deferred income taxes		5,864
Stock-based compensation	146	314
Changes in assets and liabilities:		
Accounts receivable, net	(3,211)	(1,405)
Inventory, prepaid expenses and other assets	1,053	(20)
Accounts payable	(2,057)	(3,107)
Facility exit costs accrual		(471)
Accrued liabilities	(2,295)	3,219
Income taxes refundable/payable	(2)	(419)
Long-term liabilities	(286)	747
Net cash used in operating activities	(6,476)	(3,379)
<b>Investing activities</b>		
Purchases of property and equipment	(12,966)	(3,851)
Proceeds from sale of property and equipment	27,830	2
Purchase of investments, net	(11,008)	
Net cash provided by (used in) investing activities	3,856	(3,849)
<b>Financing activities</b>		
Borrowings under bank loan, net	119	
Increase in deferred financing cost	(1,650)	
Proceeds from exercise of stock options	423	4,095
Sale of common stock to employees	332	294
Net cash (used in) provided by financing activities	(776)	4,389
Net decrease in cash and cash equivalents	(3,396)	(2,839)
Cash and cash equivalents at beginning of period	27,563	18,283
Cash and cash equivalents at end of period	\$ 24,167	\$ 15,444
<b>Supplemental disclosure of cash flow information:</b>		
Receivable from sale of property	\$ 19,241	\$
Change in unrealized losses on investments	\$ (306)	\$ (135)
Deferred income taxes		
Net change in unrealized losses	\$ (306)	\$ (135)
Interest paid	\$ 10	\$ 120

*See accompanying notes.*



**SPECIALTY LABORATORIES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**June 30, 2005**

**(Unaudited)**

**NOTE 1. BASIS OF PRESENTATION**



*Financial Statement Preparation*





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The accompanying consolidated financial statements of Specialty Laboratories, Inc. (the Company) have been prepared, without audit, in accordance with U.S. generally accepted accounting principles for interim financial reporting and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the consolidated financial statements do not include all of the information and notes required by U.S. 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 of operations and cash flows for the interim periods presented. The results of operations and cash flows for any interim period are not necessarily indicative of results that may be reported for the full fiscal year, nor predictive of results of operations, cash flow or company performance in future periods.

The accompanying consolidated 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, 2004, as filed with the Securities and Exchange Commission.

### **NOTE 2. GOODWILL AND INTANGIBLE ASSETS**



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We allocate 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, we 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) are as follows:*

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	December 31, 2004		June 30, 2005
	(dollar amounts in thousands)		
Customer list related to the acquisition of BBI Clinical Laboratories, Inc. (BBICL)	\$	1,932	\$ 1,932
Other intangible assets		425	425
Less accumulated amortization		(1,039)	(1,184)
Total intangible assets, net	\$	1,318	\$ 1,173

The estimated amortization expense for intangible assets will be \$289,000 for 2005, \$225,000 for 2006, \$193,000 each year from 2007-2010, and \$32,000 in 2011.

**NOTE 3. PROPERTY AND EQUIPMENT**

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Property and equipment consists of the following:

	December 31, 2004	(dollar amounts in thousands)		June 30, 2005
Information technology equipment and systems	\$	16,277	\$	14,364
Professional equipment		11,268		13,592
Leasehold improvements		15,899		15,882
Office furniture and equipment		1,737		2,358
		45,181		46,196
Less accumulated depreciation and amortization		(13,946)		(15,667)
Construction in progress		1,608		1,906
Total property and equipment, net	\$	32,843	\$	32,435

In accordance with the provisions of SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, we recorded a charge in the amount of \$1,539,000 representing the remaining net book value of certain capitalized software costs for a discontinued information technology (IT) program that will provide us with no future benefit. The decision to discontinue this IT program, that was in collaboration with an external technology partner, was made during the second quarter 2005 and we expect to complete our activities related to the cessation of this IT program, and its accompanying customer support, by the end of the first quarter of 2006 (the expected abandonment date). In connection with this decision, we performed an analysis of undiscounted cash flows attributable to this IT program between June 30, 2005 and the expected abandonment date. Based on this analysis, we determined that the entire remaining net book value of the capitalized software attributable to this IT program was impaired as of June 30, 2005. Consequently, we recorded an impairment charge, included in selling, general and administrative expenses for the three and six months ended June 30, 2005, to write-off the remaining net book value of this asset.

**NOTE 4. LONG-TERM DEBT**



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On September 24, 2003, we entered into a \$25 million asset-based credit agreement with CIT Business Credit (CIT), a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds based on the outstanding balance of this asset. The original credit agreement provided us with an initial \$15 million line of credit. On August 13, 2004, we entered into an amendment to the agreement with CIT whereby CIT agreed to assist us in obtaining letters of credit in an aggregate amount of up to \$10.1 million. The aggregate amount of outstanding letters of credit reduces the amount that we can borrow against the \$15.0 million line of credit. On September 14, 2004, CIT assisted us in obtaining a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank in satisfaction of a requirement in our lease agreement for our Valencia facility (Note 6 - Commitments and Contingencies). The principal amount of borrowings under the line of credit 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 December 31, 2004 and June 30, 2005, we had no amounts borrowed against the line of credit.



Interest expense for the first six months of 2005 was \$211,000. During the first six months of 2004, we capitalized approximately \$169,000 of interest related to the Valencia construction.

**NOTE 5. STOCK-BASED COMPENSATION**



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We account 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 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.

We have adopted the disclosure provisions required by SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*. Pro forma net income, as required to be disclosed by SFAS 148, determined as if we had accounted for our employee stock compensation plans under the fair-value method of that Statement, is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
	(dollar amounts in thousands except per share data)			
Net loss, as reported (a)	\$ (353)	\$ (2,407)	\$ (2,888)	\$ (12,608)
Stock-based employee compensation charges/(credits):				
Determined under the intrinsic-value based method	4		146	
Determined under the fair-value based method	(991)	(570)	(2,233)	(1,321)
Net loss, as adjusted	\$ (1,340)	\$ (2,977)	\$ (4,975)	\$ (13,929)
Basic loss per common share:				
As reported	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)
Pro forma	\$ (.06)	\$ (.13)	\$ (.22)	\$ (.60)
Diluted loss per common share:				
As reported	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)
Pro forma	\$ (.06)	\$ (.13)	\$ (.22)	\$ (.60)

(a) On February 28, 2005, we granted an option to purchase 104,000 shares of our common stock to David R. Schreiber, a member of our Board of Directors, in connection with a consulting arrangement for his services. This option vests as follows: 25% on March 1, 2005, 25% on August 30, 2005 and 50% on November 30, 2005. In accordance with the provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, we will record compensation expense for

the fair value of these options, as determined by the Black-Scholes option-pricing model, as a charge to operations over the vesting period. During the first and second quarter 2005, we recorded a charge to stock based compensation expense in the amount of \$137,000 and \$177,000, respectively, related to this option grant. Such expense is included in our net loss as reported. We will record additional amounts to stock based compensation expense in future quarters related to this grant until the final vesting date in the fourth quarter 2005.

These pro forma amounts may not be representative of 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 June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
Risk-free interest rates	3%	4%	3%	4%
Expected dividend yields	0%	0%	0%	0%
Weighted-average expected life of option	5 years	5 years	5 years	5 years
Expected stock price volatility based upon peer companies	.61	.58	.61	.58

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

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123(R) (revised 2004), Share-Based Payment, which is a revision of SFAS No. 123. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. On April 14, 2005, the Securities and Exchange Commission delayed the effective date of SFAS No. 123(R) for public companies. Under the SEC's new rule, SFAS No. 123(R) must be implemented at the beginning of the next fiscal year that begins after June 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We will utilize the modified prospective method, recognizing compensation cost for share-based awards to employees based on their grant-date fair values from the beginning of the year in which the recognition provisions are first applied as if the fair value-based method had been used to account for all employee awards. Under this transition approach, compensation cost will be recognized for all awards granted, modified or settled after the date of adoption as well as to any awards that were not fully vested as of that date. We will adopt SFAS No. 123(R) on January 1, 2006.

The adoption of SFAS No. 123(R)'s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The precise impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on the levels of share-based payments granted in the future. However, had we adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share set forth above in this Note. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), no amounts of operating cash flows were recognized in prior periods for such excess tax deductions in both the first six months of 2004 and 2005.

**NOTE 6. COMMITMENTS AND CONTINGENCIES**



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In January 2003, we elected to utilize a deductible program in connection with our workers' compensation insurance for which our insurance provider, Federal Insurance Company, required a security deposit in the form of a letter of credit. Accordingly, in January 2003, we established a \$680,000 irrevocable letter of credit with the Federal Insurance Company. The letter of credit was increased to \$1,030,000 effective January 2004 and further increased to \$1,330,000 effective January 2005.

The Valencia facility lease requires us to post a security deposit in the form of a letter of credit in connection with the lease agreement for our Valencia facility. On September 14, 2004, we established a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank that names Lexington Lion Clarita L.P. c/o Lexington Corporate Properties Trust (Lexington), our landlord for our Valencia facility, as the beneficiary.

On February 13, 2005, we entered into a separation agreement with Douglas S. Harrington, M.D., then our chief executive officer and a member of our Board of Directors. Pursuant to the separation agreement with Dr. Harrington we paid him \$275,000 following his March 29, 2005 resignation date. In addition to other non-financial items, the separation agreement also required that we pay Dr. Harrington severance payments totaling \$840,000 (equivalent to two years of his base salary), payable bi-weekly, and reimburse him for up to 18 months of COBRA payments for health care coverage.

On February 14, 2005, we entered into a retention agreement with Kevin Sayer, then our Chief Financial Officer, pursuant to which he was entitled to receive an incentive bonus of \$150,000 if he continued employment with the Company through at least May 15, 2005. On April 29, 2005, Mr. Sayer informed us that he intended to resign on May 16, 2005. On May 15, 2005, we paid Mr. Sayer \$150,000 pursuant to the aforementioned retention agreement and on May 16, 2005 Mr. Sayer resigned from the position of CFO. On February 21, 2005 we entered into several incentive agreements with other executive officers entitling them to receive incentive bonuses of varying amounts if they continued employment with the Company through February 20, 2006. These incentive bonuses with other executive officers amount to \$415,000 in aggregate.

On March 28, 2005, we opted to eliminate the positions held by two of our executive officers. Pursuant to the terms of their respective employment contracts, they were both entitled to receive severance payments for being terminated without cause. We will pay severance payments totaling \$414,000 in aggregate to these executive officers representing 12 and 9 months of their respective base salary, and a one-time payment to each of them for health care insurance continuation under COBRA for a specified period of time.

On April 14, 2005, we adopted a new incentive compensation program for executive management that is performance-based and designed to assist in attracting and retaining high quality executive leadership. The program, which applies to the executive officers, includes grants of stock options and restricted stock to certain officers, with a vesting schedule of 25% per year over a 4 year period. The incentive compensation program also includes a bonus component based on the achievement of established Company and individual goals. This incentive bonus component sets a bonus target (Individual Target) for each individual officer, which represents a percentage of the executive's base salary, and a range of Company goals relating to the Company's earnings before interest, income taxes, depreciation and amortization (EBITDA). At the end of the fiscal year, the Individual Target of each executive officer will be multiplied by the percentage of individual goals successfully completed by the officer, and by a factor related to the Company's performance for the year, which can range from 0% to 150% depending on the Company's EBITDA. Options and restricted stock were granted to the Company's officers under the Company's 2000 Stock Incentive Plan.

On May 3, 2005, we entered into an employment agreement with Victoria DiFrancesco as Senior Vice-President of Sales and Marketing, entitling her to a guaranteed bonus of \$58,750 for fiscal year 2005. Also on May 3, 2005, we terminated without cause the employment of our former Senior Vice-President of Sales and Marketing, Mark R. Willig. Pursuant to the terms of his employment contract, Mr. Willig is entitled to receive severance payments totaling approximately \$212,000, representing the equivalent of nine months of base salary and a one-time payment for health care insurance continuation under COBRA for nine months.

A charge of approximately \$1,744,000 is included in the consolidated statements of operations (selling, general and administrative expense) for the first quarter 2005 related to Dr. Harrington's separation agreement, the executive officers' retention and incentive agreements and the termination of two employment contracts. A charge of approximately \$287,000 is included in the consolidated statements of operations (selling, general and administrative expense) for the second quarter 2005 related to a retention agreement and the termination of Mr. Willig's employment contract.

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 has continued to serve various discovery requests upon us and certain of our directors and officers. No action has been brought against Specialty Laboratories, Inc. and we cannot provide an estimate of any loss or potential loss in connection with this matter, and we believe that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit.

In December 2003, we were served with an action in which we were 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, 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 the 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 discuss the coverage issues with the relevant insurance carriers, such carriers have not yet acknowledged coverage of the matter, and several carriers have denied coverage. Because the insurance coverage in this matter has not been finally resolved, and plaintiffs have not provided a specific range or amount of damages sought from us, we are unable to provide any estimates of any loss or potential loss in this matter.

From time to time we are subject to other claims arising in the ordinary course of business. We intend to defend vigorously any such litigation that may arise and to assert all available defenses that would be available to us. Based on current information, we believe any ultimate liability that may arise from these claims would not materially affect our consolidated financial position, results of operations or cash flows. However, our evaluation of the likely impact of these actions could change in the future and an unfavorable outcome, depending upon the amount and timing, could have a material effect on our results of operations or cash flows of a future period.

#### **NOTE 7. EARNINGS PER SHARE**



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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 we reported a net loss for the three and six months ended June 30, 2005, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were anti-dilutive.

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

	Three Months Ended		Six Months Ended	
	2004	2005	2004	2005
	June 30,		June 30,	
	(dollar amounts in thousands except per share data)			
Net loss	\$ (353)	\$ (2,407)	\$ (2,888)	\$ (12,608)
Basic loss per common share	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)
Diluted loss per common share	\$ (.02)	\$ (.10)	\$ (.13)	\$ (.54)
Basic weighted average shares	22,778	23,248	22,743	23,153
Dilutive effect of outstanding stock options				
Diluted weighted average shares	22,778	23,248	22,743	23,153

**NOTE 8. DEFERRED INCOME TAXES**



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At June 30, 2005, we had approximately \$37.3 million and \$45.5 million of federal and state net operating loss carryforwards (NOL s), respectively. The federal NOL s begin expiring in 2024 and the state NOL s begin expiring in 2014. The future realization of the NOL s is dependent on our ability to generate ordinary income in future years.

SFAS No. 109, *Accounting for Income Taxes*, requires that deferred tax assets (DTA s) be reduced by a valuation allowance if it is more likely than not that some portion or all of the DTA s will not be realized. During the six months ended June 30, 2005, we increased our valuation reserve to \$16,982,000 from \$7,211,000 reported as of December 31, 2004. This increase resulted in a non-cash charge of approximately \$5.9 million to our provision for income taxes during the first quarter 2005. The increase in the valuation reserve during the first six months of 2005 is principally due to continued operating losses and our assessment that it is more likely than not that our DTA s will not be realized in the foreseeable future. In making this determination, we considered all available positive and negative evidence and made certain assumptions. These assumptions included, among other things, assumptions regarding the overall business environment, our historical earnings, including our significant pretax losses incurred during the last three years and the first six months of 2005, and our outlook for future years. We performed an analysis as of March 31, 2005 and determined that there was sufficient evidence to conclude that it is more likely than not that our recorded net DTA s, net of the recorded valuation allowance, will not be realized in the foreseeable future. We updated this analysis as of June 30, 2005 and determined that there was still sufficient evidence to conclude that it is more likely than not that our recorded net DTA s, net of recorded valuation allowance, will not be realized in the foreseeable future. We will assess the need for valuation allowances against DTA s on an ongoing basis considering factors such as those mentioned above as well as other relevant criteria. Changes in our assumptions may affect our assessment and allow us to reduce the valuation allowance against DTA s in future periods as our operating results improve.

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





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On February 11, 2004, we entered into an agreement for the sale and leaseback of our Valencia facility with Lexington Corporate Properties Trust (Lexington), 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 \$41.9 million in proceeds, net of \$1.6 million of financing related expenses through June 30, 2005. Receipt of the remaining \$3.5 million balance of proceeds (included in receivable from sale of property) is subject to the completion of certain deliverables to Lexington, which we expect to be completed in the second half of 2005. During the second half of 2004, we relocated substantially all of our administrative functions and laboratory operations from Santa Monica to our Valencia facility and commenced making lease payments to Lexington.

For the first five years, lease payments 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 4.37% at December 31, 2004, the estimated minimum lease payments under the terms of the lease agreement are reflected in the table below. 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. These estimates of minimum lease payments are subject to future changes in the interpolated 15-year Treasury Rate, which has increased slightly since the sale and leaseback transaction was completed, and which can be expected to vary further prior to and during years 6 through 20 of the lease.

	Total	Payments due by Period			2010 and Beyond
		2005-2006	2007 - 2008 (amounts in thousands)	2009	
Operating lease obligations	\$ 90,708	\$ 7,125	\$ 7,125	\$ 3,867	\$ 72,591

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 has been estimated to be approximately \$4.6 million per year.

**NOTE 10. FACILITY EXIT COSTS**



In accordance with the provisions of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities*, we recorded a \$556,000 charge during the first quarter 2005 related to exiting our former facilities in Santa Monica. Exit costs incurred during the first quarter 2005 included actual operating expenses, such as utilities, and the final costs of closing down and restoring our former Santa Monica facilities. This charge is included in facility exit costs in the statement of operations for the first quarter 2005. As of December 31, 2004, we had accrued a liability in our balance sheet related to lease termination costs for our former Santa Monica facilities in the amount of \$471,000. As of June 30, 2005, we had paid substantially all amounts related to our former Santa Monica facilities.



**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 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, 2004, 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 and elsewhere in this Quarterly Report.*

**Overview**

Specialty Laboratories is a leading hospital-focused clinical laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist communities nationwide. We believe we offer one of the most comprehensive menus of specialized assays in the industry, with a test menu comprising thousands of different assays. Specialized assays are used to diagnose, evaluate and monitor patients and offer important clinical value. Because of their complexity, these assays are often performed by highly skilled personnel on technologically sophisticated instruments and are therefore offered by a limited number of clinical laboratories.

Our primary clients are hospitals, independent clinical laboratories and physicians. We have aligned our interests with those of hospitals by generally 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. Through our specialized testing menu and efforts to educate physicians, we also generate significant revenues from other national and regional clinical laboratories and specialized physician practices. 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.

**Relocation to Valencia, California facility**

On February 11, 2004, we entered into an agreement for the sale and leaseback of our newly built Valencia facility with Lexington Corporate Properties Trust (Lexington), 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 \$41.9 million in proceeds, net of \$1.6 million of financing related expenses through June 30, 2005. Receipt of the remaining \$3.5 million balance of proceeds (included in receivable from sale of property) is contingent upon the completion of certain deliverables to Lexington, which we expect to complete in the second half of 2005. During the second half of 2004, we relocated substantially all of our administrative functions and laboratory operations from Santa Monica to our Valencia facility and commenced making lease payments to Lexington. Based on interest rates in effect on December 31, 2004, rent expense for the new facility is expected to be approximately \$4.6 million per year, approximately \$2.0 million higher than comparable costs at our former Santa Monica facilities without any expansion, and includes the effect of scheduled rent increases in future years.

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During the first quarter 2005, we incurred additional expenses associated with the closure of the Santa Monica facilities of approximately \$556,000. These exit costs related to actual operating expenses, such as utilities, and the final costs of closing down and restoring our former Santa Monica facilities. No

material expenses related to the former facilities were incurred during the second quarter 2005 and no material expenses are expected in future periods.

**Other significant developments in the second quarter included:**





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On April 14, 2005, we adopted a new incentive compensation program for executive management that is performance-based and designed to assist in attracting and retaining high quality executive leadership for the Company. The program, which applies to our executive officers, includes grants of stock options and restricted stock to certain officers, with a vesting schedule of 25% per year over a 4 year period. The incentive compensation program also includes a cash bonus component based on the achievement of established Company and individual goals.

On April 14, 2005, we promoted Robert M. Harman from Vice-President & Chief Information Officer to Senior Vice-President & Chief Information Officer, and promoted Nicholas R. Simmons from Vice-President & General Counsel to Senior Vice-President & General Counsel.

On April 14, 2005, we awarded certain performance related bonuses to the following individuals: Michael C. Dugan Vice-President & Laboratory Director; Cheryl G. Gallarda Vice-President, Business Operations; and Nicholas R. Simmons Senior Vice-President & General Counsel.

On May 3, 2005, we announced that Kevin R. Sayer had tendered his resignation as the Company's Executive Vice-President and Chief Financial Officer, effective May 16, 2005. Pursuant to the terms of an incentive agreement with Mr. Sayer, dated February 14, 2005, he received an incentive bonus of \$150,000 following his resignation. Kevin Johnson, the Company's controller, was then appointed as Vice-President of Finance, and is overseeing the Company's financial and accounting functions until a new Chief Financial Officer is identified.

On May 3, 2005, we announced the termination of Mark R. Willig as Senior Vice-President of Sales and Marketing. Pursuant to the terms of his employment agreement, dated September 11, 2003, Mr. Willig will receive severance payments equivalent to nine months of his base salary and a one-time payment representing nine months of health care insurance under COBRA.

On May 3, 2005, we entered into an employment agreement with Victoria DiFrancesco to serve as the Company's new Senior Vice-President, Sales and Marketing. Ms. DiFrancesco's employment was effective May 16, 2005.

### **Critical Accounting Policies**

#### *Revenue Recognition*

We recognize revenue for each customer order when the following fundamental criteria are met: (i) the testing process for a specific customer has been completed; (ii) we have no further performance obligation to the customer; (iii) the customer is obligated to pay for services rendered; and (iv) the related fees are non-refundable. This generally occurs when the assay result is reported to the customer. Our revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101, *Revenue Recognition in Financial Statements*.

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 receivable amounts based on final settlements with the third-party payor



programs are recorded upon settlement. Such adjustments were not material to our quarterly net loss in both the first six months of 2004 and 2005. During the first six months of 2004 and 2005, combined third-party payor programs, including Medicare and Medicaid, comprised 9.5% and 9.4%, of our net revenue, respectively.

#### *Expense Recognition*

Expenses are recognized as incurred and are generally classified between cost of services and selling, general and administrative expenses. The primary components of cost of services are salaries and employee benefits, research and development costs, supplies and reagents, equipment rental costs, courier costs, facilities related costs and depreciation of laboratory equipment and leasehold improvements. Selling, general and administrative expenses include salaries and employee benefits, sales and marketing, information technology, professional fees, insurance, facilities related costs, depreciation and bad debt expense.

#### *Stock-Based Compensation*

Stock-based compensation represents 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, *Accounting for Stock Issued to Employees*, and its related interpretations. In the case of options, we recognize this compensation expense 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 administrative expenses exclude this stock-based compensation, which is reflected as a separate line item.

We have recorded deferred stock-based compensation related to unvested stock options that were granted to employees and directors prior to December 31, 2000. Based on the number of outstanding options granted as of June 30, 2005, we do not expect to amortize any deferred stock-based compensation during the remainder of 2005. We anticipate that the exercise price of the 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.

In accordance with the provisions of SFAS No. 123 we will record compensation expense for the fair value of the option to purchase 104,000 shares of our common stock granted to David R. Schreiber (a member of our Board of Directors, and also currently a serving as a consultant to the Company) on February 28, 2005, as determined by the Black-Scholes option-pricing model, as a charge to operations over the service period. During the first half of 2005, we recorded a charge to stock based compensation expense in the amount of \$314,000 related to this option grant. Such expense is included in our net loss as reported. We will record additional amounts to stock based compensation expense in future quarters related to this grant until the final vesting date in fourth quarter 2005.

#### *Recently Issued Accounting Pronouncements*

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123(R) (revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123, *Accounting for Stock-Based Compensation*. SFAS No. 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends SFAS No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS No. 123(R) is

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similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) *requires* all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an

alternative. On April 14, 2005, the Securities and Exchange Commission (SEC) delayed the effective date of SFAS No. 123(R) for public companies. Under the SEC's new rule, SFAS No. 123(R) must be implemented at the beginning of the next fiscal year that begins after June 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. We will utilize the modified prospective method, recognizing compensation cost for share-based awards to employees based on their grant-date fair values from the beginning of the year in which the recognition provisions are first applied as if the fair value-based method had been used to account for all employee awards. Under this transition approach, compensation cost will be recognized for all awards granted, modified or settled after the date of adoption as well as to any awards that were not fully vested as of that date. We will adopt SFAS No. 123(R) on January 1, 2006.

As permitted by Statement 123, we currently account for share-based payments to employees using APB Opinion No. 25's intrinsic value method and, as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of SFAS No. 123(R)'s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The precise impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share set forth in Note 5 of the notes to the consolidated financial statements. SFAS No. 123(R) also requires the benefits of tax deductions in excess of recognized compensation cost to be reported as a financing cash flow, rather than as an operating cash flow as required under current literature. This requirement will reduce net operating cash flows and increase net financing cash flows in periods after adoption. While we cannot estimate what those amounts will be in the future (because they depend on, among other things, when employees exercise stock options), the amount of operating cash flows recognized in prior periods for such excess tax deductions were \$0 in both of the first six months of 2004 and 2005.

#### **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 our financial condition, changes in the financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources, except for the lease of our Valencia facility. For additional information about the sale and leaseback of our Valencia facility, annual rent expense and scheduled rent payments see Note 9 of the notes to the consolidated financial statements.

**Results of Operations**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2005	2004	2005
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of services	67.1	67.3	69.5	69.5
Selling, general and administrative (exclusive of provision for doubtful accounts and stock-based compensation)	30.7	35.8	31.6	35.5
Provision for doubtful accounts	3.8	2.9	3.5	3.0
Operating loss	(1.6)	(6.4)	(4.8)	(9.2)
Loss before income tax benefit	(1.1)	(6.2)	(4.5)	(8.9)
Net loss	(1.1)	(6.2)	(4.5)	(16.7)

**Quarter Ended June 30, 2005 Compared with Quarter Ended June 30, 2004**





*Net Revenue*

Net revenue of \$39.0 million for the quarter ended June 30, 2005 represents an increase of approximately \$5.8 million, or 17.3%, from the \$33.2 million of net revenue for the prior year second quarter. This increase in revenues resulted primarily from volume growth. Accession volumes increased to approximately 928,000 for the second quarter 2005, increasing approximately 31.4% from the prior year second quarter volume of approximately 706,000. Testing volume for the second quarter 2005 included an increased amount of independent laboratory business which began in the third quarter of 2004 and continued during the first half of 2005. This stream of work, which we continue to believe may be temporary in nature, accounted for approximately 150,000 accessions and \$2.0 million of the \$39.0 million net revenues for the period. Excluding this independent laboratory business, our accession volumes for the second quarter 2005 were approximately 778,000, representing an increase of more than 10.2% over the second quarter 2004 volume. Excluding this increased independent laboratory business, price per accession during the second quarter 2005 increased by approximately 1.0% from the second quarter 2004.

Net revenues in the second quarter 2005 increased from the first quarter of 2005 by approximately \$2.2 million, reflecting an increase of approximately 6.1%. Revenues were impacted by a 4.6% increase in accession volumes from approximately 887,000 in the first quarter 2005 to approximately 928,000 in the second quarter 2005. Excluding the accessions from our increased independent laboratory business, our sequential growth in accession volume from the first quarter 2005 was approximately 3.5%. The accession volume growth came from all areas of our business including the hospital segment and from our many significant independent laboratory customers. Our aggregate average selling price for the second quarter 2005 is slightly higher than that of the first quarter 2005. Excluding the impact of the increased independent laboratory business, our price per accession increased by approximately 2.2% from the first quarter 2005. Both the year-over-year and sequential quarterly improvements in pricing were primarily due to a favorable shift in payor billing mix and test mix that we experienced during the second quarter 2005.

*Cost of Services*

**Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$3.9 million, or 17.7%, to \$26.2 million for the second quarter 2005 from \$22.3 million for the comparable prior year quarter. This cost increase is a result of higher accession volumes, which increased approximately 31.4% year-over-year, and increased operating expenses related to the new Valencia facility. The first quarter 2005 was the first quarter that operating costs related to the Valencia facility were recorded in costs of services. As a percentage of revenue, costs of services remained stable from 67.1% in the second quarter 2004 to 67.3% in the second quarter 2005.**



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**In comparing the second quarter of 2005 to the first quarter of 2005, costs of services decreased approximately \$162,000 or 0.6%. This decrease in costs of services, both in absolute terms and as a percentage of revenue, is the result of a more favorable test mix and the recent implementation of significant cost reduction initiatives from which we realized reduced spending levels during the second quarter 2005 on several expense categories including, but not limited to, salaries and employee benefits and royalty obligations. As a percentage of revenue, cost of services decreased to 67.3% in the second quarter 2005 from 71.9% in the first quarter 2005.**

In comparing the second quarter of 2005 to the first quarter of 2005, costs of services decreased approximately \$162,000 or 0.6%.



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*Selling, General and Administrative Expenses (Exclusive of Provision for Doubtful Accounts and Stock-Based Compensation)*

**Selling, general and administrative expenses increased by \$3.7 million, or 36.5%, to \$13.9 million for the second quarter 2005 from \$10.2 million for the second quarter 2004. This year-over-year increase in selling, general and administrative costs is a result of several factors including approximately \$1.5 million in charges related to the write-off of certain fixed assets (primarily capitalized software costs for a discontinued information technology program that will provide us with no future benefits); approximately \$287,000 in expenses related to severance payments for executive officers who departed the company in the second quarter 2005 as part of a management reorganization effort; increased operating expenses related to our Valencia operations; increased administrative fees paid under the terms of our new GPO contractual arrangements; and increased variable selling expenses attributable to higher sales volume. As a percentage of revenue, selling, general and administrative expenses increased to 35.8% during the second quarter 2005 from 30.7% during the comparable prior year quarter.**

Selling, general and administrative expenses increased by \$3.7 million, or 36.5%, to \$13.9 million for the second qu





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Selling, general and administrative expenses in the second quarter 2005 increased \$988,000, or 7.6%, from the first quarter 2005. This sequential increase is a result of increased operating expenses related to our Valencia operations; increased administrative fees paid under the terms of our new GPO contractual arrangements; and increased variable selling expenses attributable to higher sales volume. As a percentage of revenue, selling, general and administrative expenses increased slightly to 35.8% during the second quarter 2005 from 35.2% during the first quarter 2005.

### *Provision for Doubtful Accounts*

Provision for doubtful accounts decreased approximately \$128,000, or 10.1%, to \$1.1 million for the second quarter 2005 from \$1.2 million for the comparable prior year quarter. On a sequential quarterly basis, provision for doubtful accounts remained relatively flat between the first and second quarters of 2005. Our bad debt performance, as measured as a percentage of net revenue, was 2.9% for the second quarter 2005 as compared to 3.8% for the second quarter 2004 and 3.1% for the first quarter 2005.

*Stock-Based Compensation*

Stock-based compensation increased from approximately \$4,000 to \$177,000 from the second quarter 2004 to the second quarter 2005. Stock-based compensation increased by \$40,000 from the first quarter 2005 to the second quarter 2005. Stock-based compensation recorded during the first half of 2005 represents the estimated fair value compensation related to stock options we granted to Mr. Schreiber in connection with a consulting arrangement on February 28, 2005. We anticipate recording additional stock based compensation expense related to Mr. Schreiber's stock option grant during the remainder of 2005. For additional information about this stock option grant see Note 5 of the notes to the consolidated financial statements.

*Interest (Income) Expense, Net*

Net interest income decreased from approximately \$177,000 for the second quarter 2004 to \$96,000 for the second quarter 2005. The decrease in net interest income reflects an increase in interest expense related to our letters of credit during the second quarter 2005 whereas interest expense was capitalized during the second quarter 2004 in connection with the construction of our Valencia facility. The impact of increased interest expense on net interest income was partially offset by higher interest rates earned on investment balances during the second quarter 2005. Net interest income increased from \$89,000 for the first quarter 2005 to \$96,000 for the second quarter 2005.

*Provision for Income Taxes*

We did not record any additional benefits for income taxes related to current operations during the second quarter of both 2004 and 2005. Please see Risk Factor Our effective tax rate may fluctuate and we may not be able to fully realize all or a portion of our deferred tax assets.

*Net Loss*

A net loss of \$2.4 million was recorded for the second quarter 2005 compared to a net loss of \$353,000 for the comparable prior year quarter. While our net revenue increased by \$5.7 million, our total costs and expenses increased by \$7.7 million. Our net loss decreased from \$10.2 million for the first quarter 2005 to \$2.4 million for the second quarter 2005, a decrease of \$7.8 million. As a percentage of revenue, a net loss of 6.2% was recorded for the second quarter 2005 as compared to a net loss of 1.1% for the comparable prior year quarter.

**Six Months Ended June 30, 2005 Compared with Six Months Ended June 30, 2004**



*Net Revenue*

Net revenue of \$75.7 million for the six months ended June 30, 2005 represents an increase of approximately \$11.2 million, or 17.3%, from the \$64.5 million of net revenue for the six months ended June 30, 2004. This increase in revenues resulted from a combination of volume growth, including the increased independent laboratory business which began in the third quarter of 2004. Accession volumes increased to approximately 1,815,000 for the first six months of 2005, increasing approximately 31.9% from the first six months of 2004 volume of approximately 1,376,000. Testing volume for the first six months of 2005 included an increased amount of independent laboratory business. This stream of work, which we continue to believe may be temporary in nature, accounted for approximately 285,000 accessions and \$3.8 million of the \$75.7 million net revenues for the period. Excluding this increased independent laboratory business, our accession volumes for the first six months of 2005 were approximately 1,530,000, representing an increase of nearly 11.2% over the first six months of 2004

volume. Excluding this increased independent laboratory business, price per accession during the first six months of 2005 remained relatively flat with that of the first six months of 2004.

*Cost of Services*

**Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$7.7 million, or 17.3%, to \$52.6 million for the first six months of 2005 from \$44.9 million for the comparable prior year period. This cost increase is a result of higher accession volumes, which increased approximately 31.9% year-over-year, and increased operating expenses related to the new Valencia facility. The first quarter 2005 was the first quarter that costs related to the Valencia facility were recorded in costs of services. As a percentage of revenue, cost of services remained stable at 69.5% for the first six months of 2004 and 2005.**



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### *Selling, General and Administrative Expenses (Exclusive of Provision for Doubtful Accounts and Stock-Based Compensation)*

Selling, general and administrative expenses increased by \$6.5 million, or 31.9%, to \$26.9 million for the first six months of 2005 from \$20.4 million for the first six months of 2004. This year-over-year increase in selling, general and administrative expenses is a result of several factors including approximately \$2.1 million in expenses related to severance and ongoing organizational changes; \$1.5 million in charges related to the write-off of certain fixed assets (primarily capitalized software costs for a discontinued information technology program that will provide us with no future benefits); increased operating expenses related to our Valencia operations; increased administrative fees paid under the terms of our new GPO contractual arrangements; and increased variable selling expenses attributable to higher sales volume. As a percentage of revenue, selling, general and administrative expenses increased to 35.5% during the first six months of 2005 from 31.6% during the comparable prior year period.

### *Provision for Doubtful Accounts*

Provision for doubtful accounts remained stable at approximately \$2.3 million for both the first six months of 2004 and 2005. Our bad debt performance, as measured as a percentage of net revenue, was 3.0% for the first six months of 2005 as compared to 3.5% for the first six months of 2004.

### *Stock-Based Compensation*

Stock-based compensation increased from approximately \$146,000 to \$314,000 from the first six months of 2004 to the first six months of 2005. Stock-based compensation recorded during the first half of 2004 primarily relates to the separation of our former Chief Financial Officer, Frank Spina and a related modification of his stock option award. Stock-based compensation recorded during the first half of 2005 represents the estimated fair value compensation related to stock options we granted to Mr. Schreiber in connection with a consulting arrangement on February 28, 2005. We anticipate recording additional stock based compensation expense related to Mr. Schreiber's stock option grant during the remainder of 2005. For additional information about this stock option grant see Note 5 of the notes to the consolidated financial statements.

### *Facility Exit Costs*

Our statement of operations includes a separate line item for facility exit costs that are not included in costs of services or selling, general and administrative. The total facility exit costs were approximately \$556,000 for the first six months of 2005, with no comparable charge for the first six

months of 2004. These costs relate to actual operating expenses, such as utilities, and the final costs associated with closing down and restoring our former Santa Monica laboratory.

#### *Interest (Income) Expense, Net*

Net interest income decreased from approximately \$240,000 for the first six months of 2004 to \$185,000 for the first six months of 2005. The decrease in net interest income reflects an increase in interest expense related to our letters of credit during the first half of 2005 whereas interest expense was capitalized during the first half of 2004 in connection with the construction of our Valencia facility. The impact of increased interest expense on net interest income was partially offset by higher interest rates earned on investment balances during the first six months of 2005.

#### *Provision for Income Taxes*

We did not record any additional benefits for income taxes related to current operations during the first six months of both 2004 and 2005. In addition, we performed an analysis as of March 31, 2005 and determined that there was sufficient evidence pertaining to cumulative losses in recent years (including a recently projected net loss for 2005) to conclude that it is more likely than not that our net deferred tax assets will not be realized in the foreseeable future. Consequently, we recorded a \$5.9 million income tax charge during the first quarter 2005 to fully reserve against our net deferred tax assets included in the balance sheet. Please see Risk Factor Our effective tax rate may fluctuate and we may not be able to fully realize all or a portion of our deferred tax assets.

#### *Net Loss*

A net loss of \$12.6 million was recorded for the first six months of 2005 compared to a net loss of \$2.9 million for the comparable prior year period. While our net revenue increased by \$11.2 million, our total costs and expenses increased by \$15.0 million. As a percentage of revenue, a net loss of 16.7% was recorded for the first six months of 2005 as compared to a net loss of 4.5% for the comparable prior year period.

#### **Liquidity and Capital Resources**

Our cash and cash equivalents combined with long-term investments totaled approximately \$37.1 million as of June 30, 2005 as compared to \$40.1 million as of December 31, 2004. This \$3.0 million decrease is a result of capital expenditures of approximately \$3.9 million, as reflected in investing activities and \$3.4 million of cash used in operating activities, offset by \$4.1 million in proceeds from stock option exercises, as reflected in financing activities during the first six months of 2005. Our long-term investments, accounting for \$21.7 million, are almost entirely in U.S. government and corporate debt securities.

During 2004 we received \$41.9 million in proceeds, net of \$1.6 million in deferred financing fees, from our sale and leaseback agreement for our Valencia facility. Receipt of the \$3.5 million balance of proceeds is subject to the completion of certain deliverables to our landlord, including completion of remaining construction items and leasehold improvements. The \$3.5 million balance of proceeds has been recorded as a



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receivable in our balance sheet as of June 30, 2005, and we expect to receive the proceeds in the second half of 2005.

Operating activities for the first six months of 2005 used net cash of approximately \$3.4 million. The use of cash from operating activities was driven by our \$12.6 million net loss that was partially offset by a \$5.9 million decrease in net deferred tax assets and depreciation and amortization of \$3.0 million.

For the first six months of 2004, operating activities used net cash of approximately \$6.5 million. The net decrease in the combined accounts payable and accrued liabilities used cash of approximately \$4.4 million, primarily for severance, payroll and vendor payments. The increase in accounts receivable resulted in the use of cash of \$3.2 million. The net loss of \$2.9 million was offset by depreciation and amortization of \$3.1 million and a \$1.1 million reduction in inventory and prepaid assets.

Investing activities for the first six months of 2005 used cash of \$3.9 million primarily related to capital expenditures. Investing activities for the first six months of 2004 provided cash of \$3.9 million as we received \$27.8 million in proceeds from the sale of our Valencia facility prior to the payment of \$1.6 million in financing costs, which is reflected in financing activities. This receipt was partially offset by \$13.0 million of capital expenditures as we resumed construction of the Valencia facility and also repositioned \$11.0 million of cash and cash equivalents to long-term investments.

Net cash provided by financing activities was \$4.4 million for the first six months of 2005 as compared to cash used in financing activities of \$776,000 for the first six months of 2004. During the first half of 2005, we received \$4.1 million from the exercise of employee stock options and \$294,000 from the sale of common stock to employees. For the first six months of 2004, we paid \$1.6 million in financing related expenses associated with the sale and leaseback of our Valencia facility that was partially offset by the combined receipt of \$755,000 from the exercise of stock options and the sale of common stock to employees.

On September 24, 2003, we entered into a \$25 million asset-based credit agreement with CIT Business Credit (CIT), a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds based on the outstanding balance of this asset. The original credit agreement provided us with an initial \$15 million line of credit. On August 13, 2004, we entered into an amendment to the agreement with CIT whereby CIT agreed to assist us in obtaining letters of credit in an aggregate amount of up to \$10.1 million. The aggregate amount of outstanding letters of credit reduces the amount that we can borrow against the \$15.0 million line of credit. On September 14, 2004, CIT assisted us in obtaining a \$9.0 million irrevocable letter of credit with JPMorgan Chase Bank in satisfaction of a requirement in our lease agreement for our Valencia facility. The principal amount of borrowings under the line of credit 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 December 31, 2004 and June 30, 2005, we had no amounts borrowed against the line of credit.

We expect existing cash and cash equivalents, long-term investments and the balance of proceeds from the sale and leaseback arrangement will be sufficient to fund our operations, meet our capital requirements to upgrade our IT infrastructure and support our current growth 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 more stock 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 provide assurances 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. For more information, please see Risk Factors We may need or elect to raise additional funds to fund our operations and activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies.

**Contractual Obligations**



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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, 2004.

### **Subsequent Events**

On July 21, 2005, we entered into an employment agreement with David C. Weavil to serve as our Chief Executive Officer, effective July 22, 2005. Under the terms of the agreement, Mr. Weavil will receive a base salary of \$400,000 and is eligible for annual incentive bonus, at the discretion of the Board of Directors, of up to 60% of his base salary, based on the Company's financial performance and his achievement of management targets and goals. In addition, Mr. Weavil has been granted an option to purchase 425,000 shares of the Company's common stock, with a grant date of July 22, 2005 and exercise price of \$8.67. In the event that his employment with the Company is terminated without cause, Mr. Weavil will be paid severance equal to one year of his base salary.

## **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 number of both large and small 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. We also have a compliance committee in place to proactively monitor all aspects of our operations to assist in complying with these laws. However, we cannot guarantee that such procedures can prevent all aspects of non-compliance or that they will prevent future investigations into our billing practices. In the event of such an investigation, or any adverse findings from such an investigation, our business and reputation could be materially damaged.

### *Federal and State Clinical Laboratory Licensing*

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

In June and October 2001, we underwent unannounced inspections by CDHS representing both the State of California and acting as agent of CMS under CLIA. Based upon these inspections, and findings that we were permitting unlicensed personnel to perform and supervise clinical

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laboratory testing in violation of California law, in 2002 CDHS and CMS separately imposed sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed, and civil money penalties.

After filing supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, CDHS conducted additional unannounced inspections, and we provided additional documentation supporting our compliance with CDHS requirements. CDHS subsequently indicated that we were in substantial compliance with California clinical laboratory law, and CMS also notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA. CDHS and CMS assessed civil money penalties in excess of \$700,000, and we did not challenge the penalties. Following the announcement of the sanctions imposed by CDHS and CMS, and despite the speedy resolution of the violations, our business suffered and our reputation in the industry and with our clients was materially damaged.

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. Any such findings of non-compliance could significantly harm our business and our ability to continue operations. 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 pre-market approval. Our existing and future assays may be subject to federal regulatory approval similar to the pre-marketing approval process that the FDA applies to drugs and medical devices, or may be subject to other increased regulatory standards, which could have a negative effect on our business. If the FDA seeks to regulate in-house genetic testing, depending the nature and scope of such regulation, it could have a detrimental effect on our business. We cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require pre-marketing clearance. Hence, we might be subject in the future to greater regulation, or different regulations that could have a material effect on our finances and operations.

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

#### *Fee-Splitting*

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

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

Because of uncertainty surrounding the sanctions imposed on us by CMS in 2002, questions about our clients' ability to bill for services we performed for them, and a reduction in the number of assays we offer, some of our clients suspended or stopped sending us specimens for testing. As a result, our total accessions declined in 2002 and 2003. While our accession volumes rose in 2004 and the first six months of 2005, 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. In addition, we are currently receiving a large number of accessions from one independent laboratory client for one particular test. We believe that such referral business is temporary in nature, and could end at any time if the client chose to send the testing work to another laboratory or internalized the testing. We cannot provide assurances that our overall 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 future prospects.

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

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

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

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

large commercial enterprises, such as Quest Diagnostics, or Quest, and Laboratory Corporation of America, or LabCorp, that offer a wide test and product menu on a national scale;

smaller niche laboratories like Prometheus Laboratories or Athena Diagnostics that focus on a narrow segment of the market for specialized testing; and

institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or ARUP, that are affiliated with large medical centers or universities.

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

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

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

The clinical laboratory industry is intensely competitive and fragmented. Our current competitors include large national laboratories that offer a wide test and product menu on a national scale as well as smaller niche and regional organizations. Some of our large competitors have expanded, and may continue to expand, their competitive product offerings through acquisitions. For example, Quest, the nation's leading provider of diagnostic testing and related services for the healthcare industry, acquired American Medical Laboratories Incorporated, a national provider of esoteric testing to hospitals and specialty physicians, Clinical Diagnostic Services, Inc., a provider of routine and esoteric testing, and Unilab Corporation, a leading clinical testing laboratory. LabCorp acquired Dianon Systems Inc., a leading U.S. provider of anatomic pathology and oncology testing services. More recently, LabCorp announced the acquisition of U.S. Labs, a cancer testing provider, and Esoterix, Inc, a provider of specialized testing services. Acquisitions among existing and future competitors may allow them to compete with us more effectively.

In addition, some of our current customers refer assays to us that they cannot perform themselves and cannot efficiently refer to our competitors. These customers may no longer need to refer assays to us if these competitors internally develop assays similar to us, or through the acquisition of other esoteric laboratories, begin offering assays we currently perform. A loss of business and customers from such acquisitions could materially adversely affect our business, financial condition, results of operations and future prospects.

Because of the highly competitive nature of the laboratory industry in recent years, there has been increasing pressure on us from clients and payors to provide more competitive pricing for the tests we offer. If we are unable to meet the pricing expectations of current or prospective clients, we may lose

such business. While we provide other benefits to our customers, including high quality customer service and competitive turnaround times for the testing we offer, we cannot provide assurances that we will not be adversely impacted by intense competition and consolidation in our industry forcing us to offer more competitive pricing.

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

Our quarterly operating results have varied significantly in the past and may vary significantly in the future. If our quarterly net revenue and operating results fall below the expectations of securities analysts and investors, the market price of our common stock could fall substantially. Operating results vary depending on a number of factors, many of which are outside our control, including, but not limited to:

demand for our testing and ancillary services;

loss of a significant customer or group purchasing organization contract;

new assay introductions by competitors;

changes in our pricing policies or those of our competitors;

the hiring and retention of key personnel;

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

changes in healthcare laws and regulations;

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

costs related to acquisitions of technologies or businesses;

the impacts of possible service disruptions; and

the effect of litigation.

Due to these and other factors, results of operations and quarterly revenues are difficult to forecast, and we believe that period-to-period comparisons of our operating results are not predictive of future performance. In one or more future quarters our results of operations may fall below the expectations of securities analysis and investors. In that event, the trading price of our common stock would likely decline.

In addition, the trading price of our common stock may materially decline regardless of our operating results and performance. The market price of our common stock has been subject to significant fluctuations since our initial public offering in December 2000. The stock market has experienced significant price and volume fluctuations that have affected the market prices of securities, including securities of clinical laboratory, biotechnology and other health care service companies. Furthermore, because the number of share of common stock held by public shareholders is relatively small, and our common stock has generally traded thinly in recent years, a relatively small volume of purchases or sales

of our common stock can cause relatively large percentage changes in our stock price. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. As previously announced, such securities claims were filed against us in 2002 and have since been settled. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurance that we will not face any similar future actions.

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

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

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

There has been and will continue to be significant efforts by both federal and state agencies to reduce costs in government healthcare programs and otherwise implement government control of healthcare costs. In addition, increasing emphasis on managed care in the U.S. may continue to put pressure on the pricing of healthcare services. Uncertainty exists as to the reimbursement status of new assays. Third party payors, including state payors and Medicare, are challenging the prices charged for medical products and services. Government and other third party payors increasingly are limiting both coverage and the level of reimbursement for our services. Third party insurance coverage may not be available to patients for any of our existing assays or assays we discover and develop. In 2002, 2003 and 2004, third party payors accounted for approximately 6.6%, 8.3% and 9.3%, respectively, of our net revenue. However, a substantial portion of the testing for which we bill our hospital and laboratory clients is ultimately paid by third party payors and we do not know the percentage of our net revenue that is indirectly derived from these payors. Any pricing pressure exerted by these third party payors on our customers may, in turn, be exerted by our customers on us. If government and other third party payors do not provide adequate coverage and reimbursement for our assays, our net revenue may decline.

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

Proposals have been made in recent years to require competitive bidding procurement of laboratory testing services for which reimbursement is provided by Medicare and Medicaid. The Centers for Medicare and Medicaid Services (CMS) has recently selected a vendor to begin a demonstration project of a Medicare competitive bidding for clinical laboratory services, although the project has not yet begun. A competitive Medicaid bidding proposal was made in Florida (and later withdrawn) that would permit only one laboratory to provide services as the sole vendor under the contract. It is possible that other future competitive Medicare and Medicaid bidding demonstration projects may also award the contract to a sole-source vendor. We can provide no assurances that we will be able to compete successfully for the Medicare or Medicaid contracts in any future competitive bidding process. In the event that we are not successful in the competitive bidding process, or are otherwise not allowed to participate in such awarded competitive bidding contracts, we may not be reimbursed for testing we perform for patients covered by the competitive bidding process. Any restriction on our ability to do testing for Medicare or Medicaid patients, or be reimbursed for testing we perform for such patients, could materially affect our revenue and business. Any restriction on our ability to do testing for Florida Medicaid patients could also significantly negatively affect the amount of business we receive from our





Florida clients, as such clients might be less inclined to divide the work they send to outside reference laboratories. Loss of business from our Florida clients could materially affect our revenue and business.

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

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

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

At June 30, 2005, we had approximately \$37.3 million and \$45.5 million of federal and state net operating loss carryforwards (NOLs), respectively. Statement of Financial Accounting Standards No. 109, *Accounting for Income Taxes*, requires that deferred tax assets (DTAs) be reduced by a valuation allowance if it is more likely than not that some portion or all of the DTAs will not be realized. For the first six months of 2005, we concluded that there was sufficient evidence to determine that it is more likely than not that our recorded net DTAs will not be realized in the foreseeable future. Consequently, we increased our valuation allowance to approximately \$17.0 million at June 30, 2005 to fully reserve against our DTAs. The future realization of the NOLs is dependent on our ability to generate approximately \$37.3 million of federal and \$45.5 million of state ordinary income in future years. We cannot provide any assurances that such NOLs will be realized. The federal NOLs begin expiring in 2024 and the state NOLs begin expiring in 2014.

**Recent changes in our senior management team may negatively affect our business.**

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

On February 14, 2005 we announced the departure of Douglas S. Harrington, M.D., our chief executive officer and laboratory director, effective March 29, 2005. On May 3, 2005 we announced that Kevin R. Sayer had tendered his resignation as the company's Executive Vice-President and Chief Financial Officer, effective May 16, 2005, and the termination of Mark R. Willig as Senior Vice-President of Sales and Marketing.

We also recently opted to eliminate the positions of Senior Vice-President of Strategic Business Development and Vice-President & Chief Science Officer.

While we appointed a new Chief Executive Officer and Senior Vice-President of Sales and Marketing, we have not yet identified a new chief financial officer.

These recent changes in our senior management, and any delay in filling open positions in management, may have a significant negative impact on our business, as such changes and uncertainty in our leadership may cause our customers to delay or cancel their decisions to utilize our services. Current customers may also opt to choose other providers of testing services. In addition, these changes in our management team may create uncertainty in the company's employees, and we may be unable to retain or attract other key employees, including mid-level managers and California licensed laboratory scientists.

If current and potential customers seek laboratory testing elsewhere, or delay their decisions to sending us specimens for testing, it could negatively affect our accessions, our revenue, and our ability to attain future profitability. In addition, if we are unable to recruit and retain key employees due to the uncertainty of the composition of our senior management team, it may substantially impair our ability to maintain our level of services and grow our business.

We can provide no assurances that we will be able to attract and retain suitable and effective members of senior management and other key employees, and our failure to do so may negatively affect our business. Despite incentive bonus agreements put in place in the first half of 2005, there is no guarantee that our remaining members of senior management will choose to remain with the company. Changes and uncertainty in senior management may also cause the market price of our common stock to fluctuate or significantly decrease.

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

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, accounting and finance, and customer service personnel at our new laboratory and operational headquarters facility in Valencia, California, which is at the north end of the Los Angeles metropolitan area, approximately 30 miles from our former laboratory location in Santa Monica, California.

Any failure to retain and attract necessary personnel, including executive officers and other senior management, could hurt our business and impair our growth strategy.

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

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

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

(now affiliated with MedAssets HSCA). We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at various times from 2005 to 2009.

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

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

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

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

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

Legislation governing the dissemination and use of medical information is continually being proposed and enacted at both the state and federal levels. For example, the Health Insurance Portability and Accountability Act of 1996, known as HIPAA, and regulations promulgated under HIPAA require certain healthcare providers and holders or users of electronically transmitted patient health information to implement measures to maintain the security and privacy of such information. Ultimately, this and other legislation may even affect the dissemination of medical information that is not individually identifiable. Physicians and other persons providing patient information to us are also required to comply with these laws and regulations. If a patient's privacy is violated, or if we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties. The HIPAA regulations required that covered entities (including us) be in compliance with the privacy regulations on or before April 14, 2003, and new HIPAA regulations covering the electronic and physical security of patient information took effect in the first half of 2005.

The commercialization of our electronic ordering and result reporting products including Outreach Express®, DataPassportMD®, and DataPassport Clinical Trials are strictly governed by state



and federal laws and regulations, including the regulations under HIPAA. We have implemented certain encryption technology to protect patient medical information, but use of encryption technology does not guarantee the privacy and security of confidential information.

We believe that we are in material compliance with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information. However, differing interpretations of existing laws and regulations, or the adoption of new laws and regulations, could reduce or eliminate our ability to obtain or use patient information which, in turn, could limit our ability to use our information technology products for electronically transmitting patient data. While we believe we are in compliance in all material respects with the applicable HIPAA regulations, our failure to comply could subject us to fines and penalties, and have a detrimental effect on our business.

We may be subject to inspections or investigations by state or federal regulatory entities that enforce privacy laws and regulations, and we can provide no assurances that we will be found fully compliant with HIPAA or other privacy laws and regulations. Any findings of non-compliance with HIPAA or other privacy laws and regulations could significantly harm our client's confidence in our processes relating to the confidentiality, dissemination and use of medical record information, and could significantly harm our business.

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

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

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

Our average selling price has fluctuated, and may go down depending on the ordering patterns of our clients. 96





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As our clients internalize some tests we perform for them, or as they find alternative sources of testing, they may change the mix of testing sent to us. If our clients send us fewer higher-priced tests, the average selling prices for our assays could drop, and our revenue could be negatively affected. In addition, competitive pressures in the industry may require us to offer our assays to our clients at lower prices. 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 maintain or grow our average selling price.

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

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

competitive disadvantage in the industry, and it may become more difficult to retain existing clients and obtain new 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® and Data PassportMD® suite of products, and our laboratory information system. Sustained or repeated system failures that interrupt our ability to process assay orders, deliver assay results or perform assays in a timely manner would reduce significantly the attractiveness of our products to our customers. Our business, financial condition, results of operations, or cash flows could be materially and adversely affected by any damage or failure that interrupts or delays our operations, or that reduces the attractiveness of our products to our customers.

Our computer systems are vulnerable to damage from a variety of sources, including telecommunications failures, malicious human acts and natural disasters. Moreover, despite reasonable security measures we have implemented (including recent measure to comply with the HIPAA security regulations which took effect in the first half of 2005), 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 fully 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.

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

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



this occurs, we may lose this competitive advantage, and as a result, may be unable to maintain or increase our business growth.

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

A significant portion of our net revenue is derived from 59 of the more than 2,000 assays we offer. Net revenue from these 59 assays comprised approximately 47% of our total net revenue for the year ended December 31, 2004. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

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

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

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

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

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

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. For example, in response to a patent infringement

allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease.

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

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

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

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

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

redesign or reengineer our assays.

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

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





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

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

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

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

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

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

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

Our specimen processing facilities, our clinical laboratory, and our corporate offices may be affected by catastrophes such as fires, earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because our current clinical laboratory facilities are located in Valencia, California, an earthquake-prone area. While our Valencia facility was designed specifically to withstand a major earthquake, no major earthquakes have occurred in the area since the facility was completed. 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 the design of the facility and the precautions we have undertaken, 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. In addition, the regional effects of a major earthquake or other disaster on transportation systems and other infrastructure could interrupt our ability to receive specimens from our clients, thus materially harming our business.

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

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

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

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

revenues and costs, impede our ability to continue to grow our business and may result in the volatility of the market price of our common stock and on the future price of our common stock.

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

Our principal shareholder is the Specialty Family Limited Partnership, whose sole managing general partner, James B. Peter, M.D., Ph.D., is our founder and currently a member of our board of directors. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 59% 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 our principal shareholder may differ significantly 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. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS**

At any time, fluctuations in interest rates could affect 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 June 30, 2005, 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 June 30, 2005, we had cash and cash equivalents of \$15.4 million, which had a weighted average yield of 2.71% per annum. At June 30, 2005, our long-term investment balance of \$21.7 million consisted of investments in U.S. government and agency obligations with maturity dates in excess of one year, a weighted average yield per annum of 2.87% and an average of 23.1 months until maturity.

**ITEM 4. CONTROLS AND PROCEDURES**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and principal financial/accounting officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and principal financial/accounting officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the quarter covered by this report. Based on the foregoing, our Chief Executive Officer and principal financial/accounting officer concluded, as of that time, that our disclosure controls and procedures were effective at the reasonable assurance level.

There has been no material change in our internal controls over financial reporting during the most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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In addition to the California state and federal investigations described in 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, including:

*Specialty Laboratories Asia:* Specialty Laboratories Asia Pte. Ltd., a Singapore corporation, (SLA), is 60% owned by our wholly-owned subsidiary, Specialty Laboratories International Ltd., a British Virgin Islands corporation (SLIL). SLA was headquartered in Singapore but, in early 1999, SLA ceased all operations and is currently insolvent. A former employee of SLA has obtained a judgment for \$350,000 against SLA and a default judgment of approximately \$1.95 million in a wrongful termination action against SLA filed by him in Singapore. The former employee has filed an action against SLA in San Diego Superior Court to attempt to collect on the Singapore judgment and has obtained a default judgment of approximately \$2.5 million against SLA in California. The former employee has continued to serve various discovery request upon us and certain of our directors and officers. No action has been brought against Specialty Laboratories, Inc. and we believe that any claim against us or our directors and officers in connection with these judgments, if made, would be without merit, and we would vigorously defend any such action.

*Singapore Litigation:* In December 2003, we were served with an action in which we are named as a defendant, together with certain of our former officers, SLIL, and multiple other parties located in Singapore and India, in a lawsuit brought in the High Court of the Republic of Singapore by Dragon Investment Company (Dragon), one of the shareholders in SLA 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 discuss the coverage issues with the relevant insurance carriers, such carriers have not yet acknowledged coverage of the matter, and several carriers have denied coverage. Because the insurance coverage in this matter has not been finally resolved, and plaintiffs have not provided a specific range or amount of damages sought from us, we are unable to provide any estimates of any loss or potential loss in this matter

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

### **ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS**

None.

**ITEM 3.        DEFAULTS UPON SENIOR SECURITIES**

None.

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

The Company's Annual Meeting of Shareholders was held on May 12, 2005. The matters voted on at the annual meeting and the tabulation of votes on such matters are as follows:

a) Election to the Company's Board of Directors:

The following seven directors were elected for a one-year term.

	<b>Number Voting</b>	<b>For</b>	<b>Against or Withheld</b>
Richard K. Whitney	21,962,628	21,652,061	310,567
Deborah A. Estes	21,962,628	21,904,384	58,244
Michael T. DeFreece	21,962,628	21,649,861	312,767
Hubbard C. Howe	21,962,628	21,652,361	310,267
William J. Nydam	21,962,628	21,711,260	251,368
James B. Peter	21,962,628	20,853,090	1,109,538
David R. Schreiber	21,962,628	21,903,110	59,518

**ITEM 5. OTHER INFORMATION**

None.

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



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(a) Exhibits.

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

- 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)
- 10.22000 Employee Stock Purchase Plan. (1)
- 10.3 Lease dated June 1996, as amended on October 24, 2002, between Howard Real Property Trust (Lessor) and Registrant (Lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California. (7)
- 10.4 Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (Sublandlord) and Registrant (Subtenant) for the property located at 1620 20th Street, Santa Monica, California. (1) (Superceded by Exhibit 10.38)
- 10.5 Lease dated January 26, 2000, as amended on November 22, 2002, between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California. (7)
- 10.6 Lease dated July 17, 1993, as amended on October 24, 2002, between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California. (7)

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- +10.7 Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant. (1)
- +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) 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)
- +10.19 Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant. (1)
- +10.20 License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant. (1)
- 10.21 Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002. (5)
- 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)
- 10.25 Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant. (9)
- 10.26 Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant. (9)
- 10.27 Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant. (9)
- 10.28 Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant. (9)
- 10.29 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant. (9)
- 10.30 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant. (9)
- 10.31 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant. (9)
- 10.32 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant. (9)
- 10.33 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant. (9)
- +10.34 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant. (9)
- +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. (11)
- 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. (11)
- 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. (11)
- 10.42 Separation Agreement dated March 14, 2004 between Frank J. Spina and Registrant. (11)
- 10.43 Employment Agreement dated April 12, 2004 between Kevin R. Sayer and Registrant. (11)
- 10.44 First Amendment to Lease dated June 2, 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.

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- 10.45 First amendment to credit agreement dated August 13, 2004 between CIT Group/Business Credit, Inc. and Registrant. (13)
- ±10.46 Agreement effective November 1, 2004 between Novation and Registrant. (13)
- 10.47Retention Agreement dated February 14, 2005 between Kevin R. Sayer and Registrant. (14)
- 10.48Incentive Agreement dated February 21, 2005 between Michael C. Dugan, M.D. and Registrant. (14)
- 10.49Incentive Agreement dated February 21, 2005 between Cynthia K. French, Ph.D. and Registrant. (14)
- 10.50Incentive Agreement dated February 21, 2005 between Cheryl G. Gallarda and Registrant. (14)
- 10.51Incentive Agreement dated February 21, 2005 between Robert M. Harman and Registrant. (14)
- 10.52Incentive Agreement dated February 21, 2005 between Maryam Sadri and Registrant. (14)
- 10.53Incentive Agreement dated February 21, 2005 between Nicholas R. Simmons and Registrant. (14)
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- \*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.
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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.

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**EXHIBIT INDEX**

- 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.
- 10.1 2000 Stock Incentive Plan. (1)
- 10.2 2000 Employee Stock Purchase Plan. (1)
- 10.3 Lease dated June 1996, as amended on October 24, 2002, between Howard Real Property Trust (Lessor) and Registrant (Lessee) for the property located at 1752-1756 Cloverfield, Santa Monica, California. (7)
- 10.4 Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (Sublandlord) and Registrant (Subtenant) for the property located at 1620 20th Street, Santa Monica, California. (1) (Superseded by Exhibit 10.38)
- 10.5 Lease dated January 26, 2000, as amended on November 22, 2002, between WDI Santa Monica LLC (Lessor) and Registrant (Lessee) for the property located at 1756 22nd Street, Santa Monica, California. (7)
- 10.6 Lease dated July 17, 1993, as amended on October 24, 2002, between Oscar & Ethel Salenger Trust (Landlord) and Registrant (Tenant) for the property located at 2211 Michigan Avenue, Santa Monica, California. (7)
- +10.7 Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant. (1)
- +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) 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)
- +10.19 Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant. (1)
- +10.20 License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant. (1)
- 10.21 Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002. (5)
- 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)
- 10.25 Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant. (9)
- 10.26 Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant. (9)
- 10.27 Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant. (9)
- 10.28 Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant. (9)
- 10.29 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant. (9)



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- 10.30 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant. (9)
- 10.31 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant. (9)
- 10.32 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant. (9)
- 10.33 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant. (9)
- +10.34 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant. (9)
- +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. (11)
- 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. (11)
- 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. (11)
- 10.42 Separation Agreement dated March 14, 2004 between Frank J. Spina and Registrant. (11)
- 10.43 Employment Agreement dated April 12, 2004 between Kevin R. Sayer and Registrant. (11)
- 10.44 First Amendment to Lease dated June 2, 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. (12)
- 10.45 First amendment to credit agreement dated August 13, 2004 between CIT Group/Business Credit, Inc. and Registrant. (13)
- ±10.46 Agreement effective November 1, 2004 between Novation and Registrant. (13)
- 10.47 Retention Agreement dated February 14, 2005 between Kevin R. Sayer and Registrant. (14)
- 10.48 Incentive Agreement dated February 21, 2005 between Michael C. Dugan, M.D. and Registrant. (14)
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