

SPECIALTY LABORATORIES INC  
Form 10-Q  
November 14, 2003

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

---

**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 September 30, 2003

OR

o

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-16217

---

**SPECIALTY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

**95-2961036**  
(IRS Employer Identification No.)

**2211 Michigan Avenue  
Santa Monica, California 90404**  
(Address of principal executive offices, including zip code)

Registrant's Telephone Number, Including Area Code: **(310) 828-6543**

**Not Applicable**

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

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

---

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 October 31, 2003, there were approximately 22,385,805 shares of Common Stock outstanding, no par value.

---

**SPECIALTY LABORATORIES, INC.**

**FORM 10-Q QUARTERLY REPORT**

**TABLE OF CONTENTS**

		<b>Page</b>
<b><u>PART I.</u></b>	<b><u>FINANCIAL INFORMATION</u></b>	
<u>ITEM 1.</u>	<u>FINANCIAL STATEMENTS</u>	<u>1</u>
<u>ITEM 2.</u>	<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>11</u>
<u>ITEM 3.</u>	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>39</u>
<u>ITEM 4.</u>	<u>CONTROLS AND PROCEDURES</u>	<u>39</u>
<b><u>PART II.</u></b>	<b><u>OTHER INFORMATION</u></b>	
<u>ITEM 1.</u>	<u>LEGAL PROCEEDINGS</u>	<u>40</u>
<u>ITEM 2.</u>	<u>CHANGES IN SECURITIES AND USE OF PROCEEDS</u>	<u>40</u>
<u>ITEM 3.</u>	<u>DEFAULTS UPON SENIOR SECURITIES</u>	<u>41</u>
<u>ITEM 4.</u>	<u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS</u>	<u>41</u>
<u>ITEM 5.</u>	<u>OTHER INFORMATION</u>	<u>41</u>
<u>ITEM 6.</u>	<u>EXHIBITS AND REPORTS ON FORM 8-K</u>	<u>42</u>

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

Specialty Laboratories, Inc.

Consolidated Balance Sheets

*(Dollar amounts in thousands)*

	December 31, 2002	September 30, 2003 (Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,405	\$ 27,510
Short-term investments	9,247	10,078
Accounts receivable, less allowance for doubtful accounts of \$2,922 as of December 31, 2002 and \$2,829 as of September 30, 2003	22,597	21,677
Refundable income taxes	8,491	1,729
Deferred income taxes	1,870	1,522
Inventory	1,893	2,230
Prepaid expenses and other assets	2,410	2,707
Total current assets	68,913	67,453
Property and equipment, net	55,152	60,734
Long-term investments	9,222	4,094
Deferred income taxes	168	3,758
Goodwill, net	5,655	5,655
Other assets	4,197	4,521
	\$ 143,307	\$ 146,215
<b>Liabilities and shareholders equity</b>		
Current liabilities:		
Accounts payable	\$ 8,052	\$ 12,194
Accrued liabilities	9,313	7,309
Total current liabilities	17,365	19,503
Long-term debt		5,000
Other long-term liabilities	2,208	1,728
Commitments and contingencies		
Shareholders equity:		
Preferred stock, no par value:		
Authorized shares 10,000,000		
Issued and outstanding shares none		
Common stock, no par value:		

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

Authorized shares	100,000,000		
Issued and outstanding shares	22,023,392 as of December 31, 2002 and 22,374,930 as of September 30, 2003	99,790	101,706
Retained earnings		23,797	18,194
Deferred stock-based compensation		(94)	(25)
Accumulated other comprehensive income		241	109
Total shareholders' equity		123,734	119,984
		\$ 143,307	\$ 146,215

*See accompanying notes.*

## Specialty Laboratories, Inc.

## Consolidated Statements of Operations

(Unaudited)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2003	2002	2003
Net revenue	\$ 32,505	\$ 29,858	\$ 110,265	\$ 89,194
Costs and expenses:				
Costs of services	26,331	21,342	81,647	64,497
Selling, general and administrative (exclusive of stock-based compensation charges)	11,568	11,888	39,777	33,440
Stock-based compensation charges	49	17	(9)	52
Restructuring charge	468		4,066	
Charge related to regulatory matters			1,853	
Total costs and expenses	38,416	33,247	127,334	97,989
Operating loss	(5,911)	(3,389)	(17,069)	(8,795)
Interest income	(391)	(156)	(1,390)	(549)
Interest expense	46	11	185	46
Loss before income taxes (benefits)	(5,566)	(3,244)	(15,864)	(8,292)
Provision for income taxes (benefits)	(2,243)	(973)	(6,395)	(2,689)
Net loss	\$ (3,323)	\$ (2,271)	\$ (9,469)	\$ (5,603)
Basic loss per common share	\$ (0.15)	\$ (0.10)	\$ (0.44)	\$ (0.25)
Diluted loss per common share	\$ (0.15)	\$ (0.10)	\$ (0.44)	\$ (0.25)

*See accompanying notes.*

## Specialty Laboratories, Inc.

## Consolidated Statements of Cash Flows

(Unaudited)

*(Dollar amounts in thousands)*

	Nine Months Ended September 30,	
	2002	2003
<b>Operating activities</b>		
Net loss	\$ (9,469)	\$ (5,603)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	5,232	4,989
Tax benefits related to employee stock options	2,565	1,090
Deferred income taxes	(2,439)	(3,147)
Stock-based compensation charges	(9)	52
Changes in assets and liabilities:		
Accounts receivable, net	8,338	920
Inventory, prepaid expenses and other assets	99	(969)
Accounts payable	2,036	4,142
Accrued liabilities	312	(2,004)
Income taxes refundable/payable	(7,353)	6,762
Long-term liabilities	(213)	(480)
Net cash (used in) provided by operating activities	(901)	5,752
<b>Investing activities</b>		
Purchases of property and equipment	(21,092)	(10,354)
Sale (purchase) of short-term investments, net	22,486	(764)
Sale of long-term investments, net	12,315	4,834
Net cash provided by (used in) investing activities	13,709	(6,284)
<b>Financing activities</b>		
Borrowings under bank loan	4,609	5,000
Increase in deferred financing cost		(206)
Proceeds from exercise of stock options	635	510
Sale of common stock to employees	623	333
Net cash provided by financing activities	5,867	5,637
Net increase in cash and cash equivalents	18,675	5,105
Cash and cash equivalents at beginning of period	15,183	22,405
Cash and cash equivalents at end of period	\$ 33,858	\$ 27,510

*See accompanying notes.*





**SPECIALTY LABORATORIES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2003**

**(Unaudited)**

**NOTE 1. BASIS OF PRESENTATION**

*Financial Statement Preparation*

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

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

The accompanying financial statements should be read in conjunction with the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2002, as filed with the Securities and Exchange Commission.

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

*When we acquire a business, we allocate the excess of the purchase price over the fair value of the net assets acquired to goodwill and identified intangible assets. Identifiable intangible assets include customer lists and license agreement fees. We amortize customer lists and license agreement fees evenly over periods of 10 and 4.5 years, respectively. Prior to 2002, we amortized goodwill and intangible assets evenly over periods ranging from 10 to 20 years. Under the guidance of Statement of Financial Accounting Standards No. 142, we concluded that there was no impairment of goodwill for the nine-month period ended September 30, 2003.*

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

Intangible assets (included in other assets) are as follows:

	December 31, 2002	September 30, 2003
	(dollar amounts in thousands)	
Customer list related to the acquisition of BBICL	\$ 1,932	\$ 1,932
Other intangible assets	425	425
Less accumulated amortization	(461)	(678)
Total intangible assets, net	\$ 1,896	\$ 1,679

Under the new rules, intangible assets will continue to be amortized over their useful lives. The estimated amortization expense for intangible assets will be \$72,000 per quarter or \$288,000 per year for the next three years and \$197,000 per year for the subsequent five years.

**NOTE 3. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

	December 31, 2002	September 30, 2003
	(dollar amounts in thousands)	
Information technology equipment and systems	\$ 29,435	\$ 32,085
Professional equipment	13,055	13,772
Leasehold improvements	8,843	8,843
Land	8,657	8,701
Office furniture and equipment	4,223	4,223
	64,213	67,624
Less accumulated depreciation and amortization	(38,438)	(43,210)
Construction in progress	29,377	36,320
Total property and equipment, net	\$ 55,152	\$ 60,734

**NOTE 4. LONG TERM DEBT**

On September 24, 2003, the Company entered into a \$25 million asset-based credit agreement with CIT Business Credit, a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds being commensurate with this asset. The credit agreement provides the Company with an initial \$15 million line of credit. The principal amount of borrowings is due three years from the closing date, the date the line of credit matures. Only interest is due and payable monthly. As of September 30, 2003, the Company had \$5 million in outstanding borrowings against the line of credit.

**NOTE 5. STOCK-BASED COMPENSATION**



The Company accounts for stock options under the recognition and measurement principles (the intrinsic-value method) prescribed in Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. Compensation cost for stock options is reflected in net income and is measured as the excess of the market price of the Company's stock at the date of grant over the amount an employee must pay to acquire the stock. SFAS No. 123, *Accounting for Stock-based Compensation*, established accounting and disclosure requirements using a fair-value based method of accounting for stock-based employee compensation plans.

In December 2002, SFAS No. 148, *Accounting for Stock-Based Compensation - Transition and Disclosure*, was issued. SFAS No. 148 amends SFAS No. 123 to provide alternative methods of transition to SFAS No. 123's fair-value method of accounting for stock-based employee compensation. It also amends and expands the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting*, to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. While SFAS No. 148 does not require companies to account for employee stock options using the fair-value method, the disclosure provisions of SFAS No. 148 are applicable to all companies with stock-based employee compensation, regardless of

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

whether they account for that compensation using the fair-value method of SFAS No. 123 or the intrinsic-value method of APB Opinion No. 25. The Company adopted the disclosure requirements of SFAS No. 148 in the fourth quarter of 2002.

Pro forma net income determined as if the Company had accounted for its employee stock options under the fair-value method of that Statement, is as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2002		2003		2002		2003	
	(dollar amounts in thousands except per share data)							
Net loss, as reported	\$	(3,323)	\$	(2,271)	\$	(9,469)	\$	(5,603)
Stock-based employee compensation, net of related tax effects:								
Determined under the intrinsic-value based method		29		12		(5)		35
Determined under the fair-value based method		(1,031)		(806)		(2,591)		(2,582)
Net loss, as adjusted	\$	(4,325)	\$	(3,065)	\$	(12,065)	\$	(8,150)
Basic loss per common share:								
As reported	\$	(.15)	\$	(.10)	\$	(.44)	\$	(.25)
Pro forma	\$	(.20)	\$	(.14)	\$	(.55)	\$	(.37)
Diluted loss per common share:								
As reported	\$	(.15)	\$	(.10)	\$	(.44)	\$	(.25)
Pro forma	\$	(.20)	\$	(.14)	\$	(.55)	\$	(.37)

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

The fair value for these options was estimated at the date of grant using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2003	2002	2003
Risk-free interest rates	4%	3%	4%	3%
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	.71	.66	.71	.66



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

**NOTE 6. CHARGE RELATED TO REGULATORY MATTERS**

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

By letter dated April 12, 2002, the federal Centers for Medicare & Medicaid Services (CMS) notified the Company that it concluded the Company's February 2002 response to deficiencies detected in the June and October 2001 inspections conducted by the California Department of Health Services (CDHS) did not constitute a credible allegation of compliance. As a result, CMS imposed certain sanctions, including notice of revocation of the Company's Clinical Laboratory Improvement Act (CLIA) certificate, canceling the Company's approval to receive Medicare and Medicaid payments for services performed on or after February 22, 2002, imposing a civil money penalty of \$3,000 per day for each day during the sanction period, and imposing a directed plan of correction by which CMS could notify the Company's customers of the Company's non-compliance and the nature and effective date of any sanctions imposed. The Company filed an appeal to the CMS action on April 17, 2002.

On April 26, 2002, we filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS. In May and June 2002, CDHS conducted additional unannounced inspections, and we provided additional documentation supporting our compliance with CDHS requirements. By letter dated June 28, 2002, and amended on July 18, 2002, CDHS indicated that we were in substantial compliance with California clinical laboratory law. CDHS imposed sanctions of a civil money penalty of \$344,000, plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections.

On July 17, 2002, CMS notified the Company that it had deemed the Company in compliance with all condition level requirements of CLIA and, that the Company's ability to bill Medicare and Medicaid for its testing services had been reinstated, effective June 19, 2002, and that all actions against the Company's CLIA certificate had been rescinded. The Company withdrew the appeal of the sanctions the Company filed with CMS on April 17, 2002 and paid a monetary fine of \$351,000.

The Company recorded a charge in the first quarter of 2002 of approximately \$1,241,000 to reserve for Medicare and Medicaid services earned and billed and a civil money penalty, all pertaining to the period February 22, 2002 to March 31, 2002. During the second quarter of 2002, the Company did not recognize any net revenue related to Medicare and Medicaid services and recorded a charge of approximately \$612,000 for additional civil money penalties, costs for inspections, and incremental legal costs related to the CDHS and CMS regulatory actions. Beginning July 1, 2002, with the resolution of sanctions imposed by CMS, the Company resumed the recognition of net revenue related to Medicare and Medicaid services performed. In pursuing patient collections, subsequent information was provided by the patient or client that the services provided were covered by Medicare or Medicaid during the period of February 22 through June 19, 2002, resulting in the Company writing off these receivables. These write-offs along with additional reserves, totaled \$400,000, and were recorded as a charge during fourth quarter of 2002.

**NOTE 7. RESTRUCTURING CHARGE**



In March 2002, the Company entered into a 6.5 year lease agreement to finance the construction of our new laboratory and headquarters facility in Valencia, California. BNP Paribas and a syndication of banks arranged our lease, which was initially structured as an off balance sheet financing arrangement, sometimes referred to as a synthetic lease. Construction of the new facility was to be completed in the second half of 2003, and the move from our existing Santa Monica facilities was scheduled shortly thereafter. In October 2002, the Company announced the postponement of our move to the new Valencia facility, and suspended construction of the facility after the completion of the core and shell of the building, which was substantially completed in January 2003. As a result of our decision to pause construction of the Valencia facility and our desire to have on balance sheet financing, we exercised our purchase option in the fourth quarter of 2002 under the lease finance agreement, paying off the debt in order to obtain title to the ground lease and facility improvements, thus ending the synthetic lease. Construction costs incurred through September 30, 2003 were \$33,608,000, which we financed with investments and cash generated from operations.



In March 2002, the Company also obtained a bank loan agreement that provided for a revolving line of credit up to \$40,000,000. The bank group led by BNP Paribas also provided this loan agreement. We had no borrowings under this bank loan agreement and terminated the loan agreement in the fourth quarter of 2002.

In January 2003, the Company established a \$680,000 irrevocable Letter of Credit for Federal Insurance Company, our workers' compensation insurance provider for 2003. The Company elected to utilize a deductible program for 2003 for which Federal Insurance Company required a security deposit in the form of a Letter of Credit.

In 2001, one of our former officers filed an action in federal district court in Los Angeles against us and two of our officers alleging violations of federal and state securities laws and other causes of action in connection with the sale of our common stock by the former officer and our application of our insider trading policy. Our motion to compel arbitration was granted, and one of the individual defendants was subsequently dropped from plaintiff's claims. The matter was submitted to binding arbitration before a former federal judge, and was scheduled for a hearing on July 28, 2003. However, the matter was settled amicably by the parties prior to conclusion of the hearing. We expect our defense costs, and most or all of the agreed-upon settlement amount to be covered under one or more of our insurance policies.

On August 15, 2003, we entered into a letter agreement with Chiron Corporation, of Emeryville, California, and a separate Settlement and License Agreement with the Diagnostics Division of Bayer Healthcare LLC of Tarrytown, New York. The agreements call for us to make payments to Bayer and to Chiron for alleged past infringement of several Chiron patents by certain Hepatitis C Virus ( HCV ) and Human Immunodeficiency Virus ( HIV ) testing performed by us. We denied infringing any intellectual property rights of Bayer or Chiron. We believe the amount of these payments is immaterial to the Company's cash position and ongoing operations.

Under the agreement with Chiron, Chiron agreed not to assert its patent rights, or bring any claim against us for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. In the agreement with Bayer, Bayer agreed to indemnify us in the event Chiron brings such a suit or claim against us for infringement of Chiron's patent rights with respect to HCV and HIV testing during this period. Bayer also provided us with a royalty-bearing non-exclusive sublicense to perform laboratory-developed HCV and HIV nucleic acid assays.

Separately, we agreed to modify our supply agreement with Bayer to convert to using Bayer products, which are licensed under certain Chiron patent rights, for HCV and HIV genotyping. The supply agreement called for the conversion to Bayer licensed products to be completed on or before October 15, 2003.

**NOTE 9. EARNINGS PER SHARE**

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

Basic earnings (loss) per share are computed by dividing net income (loss) by the weighted average number of common shares outstanding for the respective periods. Diluted earnings (loss) per share, calculated using the treasury stock method, gives effect to the potential dilution that could occur upon the exercise of certain stock options that were outstanding during the respective periods presented. Since the Company reported a net loss for the three and nine-month periods ended September 30, 2002 and 2003, these potentially dilutive common shares were excluded from the diluted loss per share calculation because they were anti-dilutive.

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2002		2003		2002		2003	
	(dollar amounts in thousands except per share data)							
Net loss	\$	(3,323)	\$	(2,271)	\$	(9,469)	\$	(5,603)
Basic loss per common share	\$	(.15)	\$	(.10)	\$	(.44)	\$	(.25)
Diluted loss per common share	\$	(.15)	\$	(.10)	\$	(.44)	\$	(.25)
Basic weighted average shares		21,903		22,331		21,755		22,188
Dilutive effect of outstanding stock options								
Diluted weighted average shares		21,903		22,331		21,755		22,188

**NOTE 10. DEFERRED INCOME TAXES**

The Company reported \$5,280,000 of deferred income taxes (current and long-term) in the September 30, 2003 balance sheet, with approximately \$4,916,000 related to federal and state net operating loss carryforwards (NOL s). Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. Management believes that there is not sufficient uncertainty regarding the realizability of the NOL s and therefore has not established a valuation allowance. Realization of the NOL s incurred through September 30, 2003 is dependent on the Company s ability to generate approximately \$13,000,000 of ordinary income in future years. The inability to generate the necessary ordinary income, or an unfavorable outcome in the realization of the NOL s, could have a material adverse effect on the Company s results of operations in future quarters.

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

*For purposes of the following discussion, EBITDA is defined as income (loss) from operations before interest, income taxes, depreciation and amortization. EBITDA should not be considered a measure of financial performance under generally accepted accounting principles (GAAP). Items excluded from EBITDA are significant components in understanding and assessing financial performance. We present EBITDA, which is a non-GAAP measure, to enhance the understanding of our operating results. EBITDA should not be considered in isolation or as an alternative to net income, cash flows generated by operations, investing or financing activities, or other financial statement data presented in the consolidated financial statements as an indicator of financial performance or liquidity. Because EBITDA is not a measurement determined in accordance with GAAP and is thus susceptible to varying calculations, EBITDA as presented may not be comparable to other similarly titled measures of other companies.*

### Overview

Specialty Laboratories is a leading hospital-focused clinical laboratory, performing highly advanced, clinically useful testing services for hospitals, laboratories and physician specialist communities nationwide. We believe we offer the most comprehensive menu of esoteric assays in the industry, with a test menu of more than 2,500 assays. Many of our tests have been developed through our internal research and development efforts. Esoteric assays are complex, comprehensive or unique tests used to diagnose, evaluate and monitor patients. These assays are often performed on sophisticated instruments by highly skilled personnel and are therefore offered by a limited number of clinical laboratories.

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

Through the execution of our hospital-focused strategy, we grew rapidly in the three years 1999 through 2001, when our net revenue grew at a compounded annual growth rate of 16% from approximately \$130 million to approximately \$175 million. This growth was supplemented with the acquisition of BBI Clinical Laboratories, Inc., in the first quarter of 2001. BBI Clinical Laboratories, a private company founded in 1989, was a leading esoteric clinical reference laboratory specializing in infectious disease testing, such as Lyme disease and viral hepatitis. BBI Clinical Laboratories' primary customers included hospitals, physician specialists, pharmaceutical and diagnostic companies, and other clinical and research laboratories.

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

While the core hospital-focus strategy remains the same, the calendar year 2002 was marked by two significant events – the regulatory actions taken by the California Department of Health Services (CDHS) and the federal Centers for Medicare & Medicaid Services (CMS) in March and April 2002, and

the announcement of the acquisition of Unilab Corporation, our largest customer, by Quest Diagnostics Inc., one of our competitors. As a result of these events, we experienced a significant reduction in revenues in 2002 and into the first nine months of 2003. These events are discussed below.

By letter dated March 28, 2002, CDHS notified us of its intent to impose sanctions of a directed plan of correction, random onsite monitoring, and a civil money penalty based upon deficiencies cited on November 28, 2001 following laboratory inspections conducted during June and October 2001. The sanctions were based on findings that we were permitting unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law. After we filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, and additional inspections by CDHS, CDHS notified us that by letter dated June 28, 2002, and amended on July 18, 2002, that we were in substantial compliance with California clinical laboratory law. CDHS imposed sanctions of a civil money penalty of \$344,000 plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections.

By letter dated April 12, 2002, CMS notified the Company that it concluded our February 2002 response to deficiencies detected in the June and October 2001 inspections conducted by CDHS did not constitute a credible allegation of compliance. As a result, CMS imposed certain sanctions, including notice of revocation of our Clinical Laboratory Improvement Act (CLIA) certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed on or after February 22, 2002, imposing a civil money penalty of \$3,000 per day for each day during the sanction period, and imposing a directed plan of correction by which CMS could notify our customers of our non-compliance and the nature and effective date of any sanctions imposed. We filed an appeal to the CMS action on April 17, 2002. On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's ability to bill Medicare and Medicaid for its testing services had been reinstated as of June 19, 2002, and that all actions against our CLIA certificate were rescinded. We withdrew the appeal of the sanctions we filed with CMS on April 17, 2002 and paid a monetary fine of \$351,000.

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

As a result of these significant events on our business, on June 18, 2002, we announced a reduction in workforce of approximately 10% as part of an overall restructuring plan. The plan involved all areas and levels of the company. In connection with the restructuring effort, we recorded a charge of approximately \$3.6 million in the second quarter of 2002. The charge was comprised of severance payments and related obligations for employees whose positions were eliminated. During September 2002, as a result of further business review and the refinement of our core strategic business, we eliminated some employee positions primarily in the area of our clinical trials department. We recorded a restructuring charge of approximately \$468,000 in the third quarter of 2002. The charge was comprised of severance payments for employees whose positions were eliminated and the write-off of certain assets related to our clinical trials business. In November 2002, in our continuing efforts to manage costs and align our staff with current business levels, we had a reduction in workforce focused primarily on the laboratory. We recorded a restructuring charge of approximately \$984,000 in the fourth quarter of 2002, which was comprised of severance payments for employees whose positions were eliminated and for the write-off of certain capitalized costs associated with the delayed move to our new Valencia facility and

the related termination of the synthetic lease financing arrangement with the banking group led by BNP Paribas.

As previously reported, in December 2001, we purchased a 13.8-acre site in Valencia, California and began construction during the second quarter of 2002 of a 195,000 square foot facility which would enable us to consolidate all of our laboratory and administrative functions in one location. In October 2002, we announced that we would postpone the move to our new facility in Valencia until the second half of 2004. Accordingly, the construction of the new facility was suspended at completion of the Core and Shell of the facility, which was substantially completed in January 2003. This postponement will allow us to focus on rebuilding client confidence and stabilizing our business by minimizing any disruptions in service to our clients based on planning and executing a move to a new facility during this rebuilding period. Upon restart of the facility construction, we plan to fund completion with new financing. We expect to decide whether and when to recommence the facility's construction sometime by the end of 2003. However, we can provide no assurances that we will be able to obtain financing on favorable terms to fund construction of the new facility, that we will have the ability to complete a move to a new facility without incurring disruptions in service to our customers and loss of client confidence, or that we will need a larger facility for our operations in light of our reduced testing volume and employee headcount. Based on these and other factors, it is possible that we may never recommence construction of the new facility in Valencia, or decide to recommence construction after December 31, 2003. If we do not provide notice of our intent to resume construction prior to that date, the agreement for construction of the facility will be deemed terminated, and we could be subject to substantial termination costs and penalties, which could be in excess of \$2.5 million. For more information, please see Risk Factors - Our planned move to Valencia, California may divert management attention and may lead to disruptions in our operations and service to our customers and Risk Factors - We may decide to further postpone or cancel our planned move to a new location in Valencia, which could create financial liabilities.

In March 2002, we completed a \$100 million financing transaction. This credit facility had two components: first, we entered into a 6.5 year lease to finance construction of our new laboratory and headquarters facility in Valencia, California, sometimes referred to as a synthetic lease, with a total cost, including financing costs, of up to \$60 million, and second, we entered into a \$40 million revolving line of credit with the same lenders that provided the lease financing, with proceeds available for general corporate purposes. This credit facility, arranged by BNP Paribas, included Union Bank, US Bank, First Union National Bank, as co-syndication agents, and Allied Irish Banks, Manufacturers Bank, and Bank Leumi, USA, as participants. As a result of our decision to pause construction of the Valencia facility and our desire to have on balance sheet financing, we exercised our purchase option in the fourth quarter of 2002 under the lease finance agreement, paying off the debt in order to obtain title to the ground lease and facility improvements, thus ending the synthetic lease. Subsequently, we also terminated our line of credit with this bank group.

On May 1, 2002, we announced that Novation, a national purchasing group for hospitals, discontinued its service agreement with us. The termination of the agreement was without cause and was effective on July 29, 2002. The original agreement was initiated on May 1, 2001 and provided Novation members with access to discounted clinical laboratory services from us. While we have experienced some loss of Novation clients, the exact consequences of the agreement's termination are difficult to predict, particularly since the termination of the contractual relationship with Novation does not prevent its members from using our services, and it may take a significant period of time before any individual Novation member decides to stop utilizing our services.

Other significant developments in the last twelve months included:

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

On June 18, 2003, we announced that Consorta, Inc., a leading group purchasing and resource management company representing more than 400 acute care facilities, had signed a three-year agreement with us for clinical reference testing. The agreement, effective July 1, 2003, provides Consorta members



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

access to our comprehensive menu of more than 2,500 assays, proprietary client connectivity applications and turnaround time schedules.

On July 1, 2003, we announced the appointment of Cynthia K. French, Ph.D. to the position of Vice President and Chief Science Officer. Dr. French has more than 15 years experience as a researcher and business executive in the diagnostic and clinical laboratory industry, and more recently served as Senior Scientist at Quest Diagnostics, Center for Applied Technologies until joining Specialty. Dr. French will oversee our research and development program.

In addition, on July 1, 2003, we announced the formation of a Scientific Advisory Board and the appointment of Michael G. Douglas, Ph.D. as its chairperson. Dr. Douglas currently serves as Vice President and Chief Science Officer of Novactyl Biopharmaceuticals, Inc. of St. Louis, Missouri, and Associate Vice Chancellor and Director of the Center of Technology Management, Washington University in St. Louis. Dr. Douglas will be responsible for assembling the Advisory Board and enlisting a panel of experts to advise Specialty on its research and assay development efforts.

On July 30, 2003, we announced the signing of a three-year service agreement, as the primary reference laboratory, with the University of Maryland Medical System (UMMS) and began receiving patient specimens and testing orders from member hospitals on August 4, 2003. UMMS is a regional health network comprised of the University of Maryland Medical Center, community and specialty hospitals and outpatient sites for primary and secondary care in the Maryland area, with more than 1,600 licensed beds.

On August 15, 2003, we announced that we entered into a letter agreement with Chiron Corporation, of Emeryville, California, and a separate Settlement and License Agreement with the Diagnostics Division of Bayer Healthcare LLC of Tarrytown, New York. The agreements call for us to make payments to Bayer and to Chiron for alleged past infringement of several Chiron patents by certain Hepatitis C Virus ( HCV ) and Human Immunodeficiency Virus ( HIV ) testing performed by us. We denied infringing any intellectual property rights of Bayer or Chiron. We believe the amount of these payments is immaterial to the company's cash position and ongoing operations.

Under the agreement with Chiron, Chiron agreed not to assert its patent rights, or bring any claim against us for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. In the agreement with Bayer, Bayer agreed to indemnify us in the event Chiron brings such a suit or claim against us for infringement of Chiron's patent rights with respect to HCV and HIV testing during this period. Bayer also provided us with a royalty-bearing non-exclusive sublicense to perform laboratory-developed HCV and HIV nucleic acid assays. Separately, we agreed to modify our supply agreement with Bayer to convert to using Bayer products, which are licensed under certain Chiron patent rights, for HCV and HIV genotyping. The supply agreement called for the conversion to Bayer licensed products to be completed on or before October 15, 2003.

On September 16, 2003, we announced the resignation of Terrance H. Gregg as a member of our Board of Directors. Mr. Gregg, a member of the Board of Directors since June 2002, cited personal and philanthropic commitments for his decision to resign from the board. The resignation was effective immediately. Our Board of Directors now consists of a total of seven members, including four independent directors.

On September 24, 2003, we entered into a \$25 million asset-based credit agreement with CIT Business Credit, a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds being commensurate with this asset. The credit agreement provides us with an initial \$15 million line of credit. The principal amount of borrowings is due three years from the closing date, the date the line of credit matures. We drew \$5 million under this line of credit and added this amount to cash and investments on hand.



**Recent Developments**

On October 22, 2003, we announced the commercial availability of our next generation Outreach Express ®, a proprietary, Web-based laboratory test order and result reporting system. Outreach Express ® gives hospital organizations a cost-effective tool for strengthening the laboratory services they provide to physician offices, medical groups and affiliated healthcare organizations.

### **Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses for each period. The following represents a summary of our critical accounting policies, defined as those policies that we believe are: (a) the most important to the portrayal of our financial condition and results of operations, and (b) that require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

#### *Revenue Recognition*

Revenue is recognized as services are rendered upon completion of the testing process for a specific customer order for which we have no future performance obligation to the customer, the customer is obligated to pay and the fees are non-refundable. Our revenue recognition policies are in compliance with Securities and Exchange Commission Staff Accounting Bulletin No. 101.

Services are provided to certain patients covered by various third-party payor programs including Medicare and Medicaid. Billings for services under third-party payor programs are included in net revenue net of allowances for differences between the amounts billed and estimated receipts under such programs. Adjustments to the estimated payment amounts based on final settlement with the third-party payor programs are recorded upon settlement.

#### *Expense Recognition*

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

#### *Stock-Based Compensation Charges*

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

We have recorded deferred stock-based compensation related to unvested stock options granted to employees and directors. Based on the number of outstanding options granted as of September 30, 2003, we

expect to amortize approximately \$25,000 of deferred stock-based compensation in future periods. We expect to amortize this deferred stock-based compensation approximately as follows: \$13,000 during the remainder of 2003 and \$12,000 during 2004. We anticipate that the exercise price of the majority of stock options granted in the future will be at the market price of our common stock on the date of grant, and therefore no deferred stock-based compensation will result from these grants.

*Goodwill and Intangible Assets*

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 are amortized evenly over 10 years.

Under Statement of Financial Accounting Standards No. 142, *Goodwill and Other Intangible Assets*, goodwill is no longer amortized but is subject to annual impairment tests in accordance with the statements. Other intangible assets will continue to be amortized over their useful lives. We concluded that there was no impairment of goodwill for the three and nine-month periods ended September 30, 2003 since our fair value exceeded the book equity value.

**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 September 30,		Nine Months Ended September 30,	
	2002	2003	2002	2003
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of services	81.0	71.5	74.0	72.3
Selling, general and administrative (exclusive of stock-based compensation charges)	35.6	39.8	36.1	37.5
Restructuring charge	1.4		3.7	
Charge related to regulatory matters			1.7	
Operating loss	(18.2)	(11.4)	(15.5)	(9.9)
Loss before income taxes (benefits)	(17.1)	(10.9)	(14.4)	(9.3)
Net loss	(10.2)	(7.6)	(8.6)	(6.3)
EBITDA (1)	(12.6)	(6.0)	(10.7)	(4.3)

(1) The following is a reconciliation of net loss to EBITDA as a percentage of net revenue:

Net loss	(10.2)	(7.6)	(8.6)	(6.3)
Interest income, net	(1.1)	(0.5)	(1.1)	(0.6)
Provision for income taxes (benefits)	(6.9)	(3.3)	(5.8)	(3.0)
Depreciation and amortization	5.6	5.4	4.8	5.6
EBITDA	(12.6)	(6.0)	(10.7)	(4.3)

The following table sets forth the reconciliation of net loss to EBITDA in dollars.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2003	2002	2003
	(dollar amounts in thousands)			
Net loss	\$ (3,323)	\$ (2,271)	\$ (9,469)	\$ (5,603)
Interest income, net	(345)	(145)	(1,205)	(503)
Provision for income taxes (benefits)	(2,243)	(973)	(6,395)	(2,689)
Depreciation and amortization	1,806	1,612	5,232	4,989
EBITDA	\$ (4,105)	\$ (1,777)	\$ (11,837)	\$ (3,806)





**Quarter Ended September 30, 2003 Compared with Quarter Ended September 30, 2002**

*Net Revenue*

Net revenue of \$29.9 million for the quarter ended September 30, 2003 is a decline of approximately \$2.6 million, or 8.1%, from the \$32.5 million for the prior year third quarter. This year-over-year decline is due primarily to \$3.7 million less revenue in the third quarter of 2003 from Unilab Corporation, our largest customer in 2002, when compared to the prior year third quarter. This reduction in revenue is a result of Quest Diagnostics' acquisition of Unilab, completed in February 2003, and the resultant reduction in accessions being sent to us by Unilab. In addition, we experienced residual business loss due to our regulatory matters that were resolved in the third quarter of 2002. Our loss of business from Unilab is somewhat offset by new business growth from new and existing clients. In total, our accession volumes were approximately 630,000 for the third quarter of 2003, down more than 8% from the prior year third quarter volume of approximately 685,000. The aggregate average selling price for the third quarter of 2003 remained essentially flat compared to the year ago quarter.

Sequentially, net revenues for the third quarter of 2003 increased from the second quarter of 2003 by approximately \$0.8 million or 2.8%, as accession volume grew to approximately 630,000 from nearly 612,000 in the second quarter of 2003. This increased accession volume is the direct result of growth in business from new and existing clients. The aggregate average selling price for the third quarter of 2003 remained relatively stable with the second quarter of 2003. We anticipate growth in new client business activity in the fourth quarter of 2003, but this growth will be offset as the fourth quarter is historically a slower quarter due to year-end holidays. As a result, we expect accession volumes for the fourth quarter of 2003 to be similar to third quarter 2003 levels, and the aggregate average selling price for the fourth quarter of 2003 to remain consistent with third quarter levels.

*Cost of Services*

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, decreased by approximately \$5.0 million, or nearly 19%, to \$21.3 million for the third quarter of 2003 from \$26.3 million for the comparable prior year quarter. This decrease is due primarily to lower accession volume in the third quarter of 2003, which declined more than 8% year-over-year, and resultant reductions in costs for reagents and royalties, laboratory labor, and distribution. In addition, our outsourced testing costs decreased more than \$1.8 million in the third quarter of 2003 when compared to the prior year quarter. As a percentage of revenue, cost of services decreased to 71.5% for the quarter ended September 30, 2003 from 81.0% for the comparable prior year quarter.



Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

**In comparing the third quarter of 2003 to the second quarter of 2003, costs of services remained essentially flat, while testing volumes increased approximately 3%. This reflects our continued emphasis on cost management. As a percentage of revenue, cost of services decreased to 71.5% in the third quarter of 2003 from 73.6% for the second quarter of 2003. While we remain focused on managing costs, we expect cost of services to increase in connection with future business growth.**

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased by approximately \$300,000, or 2.8% to \$11.9 million for the third quarter of 2003 from \$11.6 million for the third quarter of 2002. This increase is primarily due to one-time charges in the third quarter of 2003 of nearly \$2.0 million for legal settlement costs and charges for the Valencia facility. This increase is partially offset by a decrease in selling, general and administrative expenses as we continue to control our staffing and discretionary expenditures. As a percentage of revenue, selling, general and administrative expenses increased to 39.8% for the quarter ended September 30, 2003 from 35.6% from the comparable prior year quarter.

Sequentially, selling, general and administrative expenses in the third quarter of 2003 increased by nearly \$1.3 million, or 11.8%, from the second quarter of 2003, as a result of one-time charges of nearly \$2.0 million for legal settlement costs and charges for the Valencia facility partially offset by continued control of staffing and discretionary expenditures. When selling, general and administrative expenses are adjusted for the one-time charges of \$2.0 million, our adjusted ongoing expense is approximately \$9.9 million, reflecting a sequential decline from the second quarter of 2003 of approximately 7%. We expect to see a modest increase in this adjusted level of selling, general and administrative spending in the fourth quarter of 2003. In addition, during our Valencia construction postponement period, we will continue to incur the ongoing facility support costs, to provide security, insurance, maintenance, and fund taxes. The facility support costs are estimated to be between \$100,000 and \$200,000 per quarter.

In comparing the third quarter of 2003 to the second quarter of 2003, costs of services remained essentially flat, wh

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

### *Stock-Based Compensation Charges*

Stock-based compensation charges decreased from approximately \$49,000 to \$17,000 from the third quarter of 2002 to the third quarter of 2003, respectively. This decline is a result of normal amortization coupled with forfeited stock options resulting from the 2002 reductions in workforce that had the effect of reducing amortization expense.

### *Restructuring Charge*

We had no restructuring charge in the third quarter of 2003. During September 2002, as a result of further business review and the refinement of our core strategic business, we eliminated some employee positions primarily in the area of our clinical trials department. We recorded a charge of approximately \$468,000 in the third quarter of 2002. The charge was comprised of \$199,000 of severance payments for employees whose positions were eliminated and a \$269,000 write-off of certain assets related to our clinical trials business.

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

Net interest income decreased from approximately \$345,000 to \$145,000 from the third quarter of 2002 to the third quarter of 2003, respectively. This reduction directly reflects lower invested balances as cash was utilized for capital expenditures for the new Valencia facility construction and an information technology infrastructure upgrade for our existing facilities.

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

Provision for income taxes (benefits) was a benefit of \$973,000 for the third quarter of 2003 as compared to a \$2.2 million benefit for the comparable prior year quarter. Our effective tax rate reflects a 30% benefit for the third quarter of 2003, as compared to 40.3% benefit for the third quarter of 2002. As our loss narrows and we return to profitability, the effective tax rate could fluctuate quarterly between 10% to 60%, depending on the exact nature of operating results. In addition, we may not be able to fully realize any additional tax benefits, as the exact nature of future operating results may limit our ability to fully utilize any net operating loss carryforwards. Please see Risk Factors. Our effective tax rate may fluctuate and we may not be able to fully realize a portion of our deferred tax assets.

### *Net Loss*

A net loss of \$2.3 million was recorded for the quarter ended September 30, 2003 compared to a net loss of \$3.3 million for the comparable prior year quarter, an improvement of approximately \$1.0 million. This improvement is fundamentally due to a reduction in cost of services in the third quarter of 2003 due to lower accession volume and a decrease in outsourced testing costs. These cost reductions were partially offset by the \$2.6 million decrease in net revenue primarily due to the loss of Unilab business. In addition, increased costs of \$2.0 million were recognized in the third quarter of 2003 for the

In comparing the third quarter of 2003 to the second quarter of 2003, costs of services remained essentially flat, wh



one-time charges for legal settlements and charges for the Valencia facility, as compared to \$468,000 of one-time restructuring charges recorded in the third quarter of 2002. As a result, the income tax benefits for the third quarter of 2003 are lower than the comparable prior year quarter due to a lower pretax loss being recorded and a reduced effective tax rate. As a percentage of revenue, a net loss of 7.6% was recorded for the quarter ended September 30, 2003 as compared to a net loss of 10.2% for the comparable prior year quarter.

***EBITDA***

EBITDA, or earnings before interest, income taxes, depreciation and amortization, reflected a loss of nearly \$1.8 million for the quarter ended September 30, 2003 as compared to a loss of \$4.1 million for the comparable prior year quarter. As a percentage of net revenue, EBITDA decreased to a loss of 6.0% for the quarter ended September 30, 2003 from a loss of 12.6% for the quarter a year ago. This improvement is fundamentally due to a reduction in cost of services in the third quarter of 2003 due to lower accession volume and a decrease in outsourced testing costs. These cost reductions were partially offset by the \$2.6 million decrease in net revenue primarily due to the loss of Unilab business. In addition, increased costs of \$2.0 million were recognized in the third quarter of 2003 for the one-time charges for legal settlements and charges for the Valencia facility, as compared to \$468,000 of one-time restructuring charges recorded in the third quarter of 2002. For a reconciliation of EBITDA to net loss, see footnote (1) under Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations .

**Nine Months Ended September 30, 2003 Compared with Nine Months Ended September 30, 2002**

*Net Revenue*

Net revenue decreased approximately \$21.1 million, or 19.1% to \$89.2 million for the nine months ended September 30, 2003 from \$110.3 million for the nine months ended September 30, 2002. Revenues for the current nine-month period were impacted primarily by a reduction in accession volume down nearly 18% as compared to the volume in the first nine months of 2002. The year-over-year decline in accession volume resulted primarily from business loss due to our regulatory matters that were resolved in the third quarter of 2002. In addition, with the February 2003 completion of Quest Diagnostics' acquisition of Unilab Corporation, previously our largest customer, we saw a significant decline in accessions from this customer. We also experienced a decline of approximately 1.7% in the aggregate average selling price for the first nine months of 2003 as compared to the first nine months of 2002. This decline in aggregate average selling price was due to our continued client mix-shift to hospitals and the reduction in independent laboratory business. In addition during the first nine months of 2002, approximately \$2.3 million of net revenue was not recognized due to the lack of billing rights for Medicare and Medicaid services.

*Cost of Services*

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, decreased \$17.1 million, or 21.0% to \$64.5 million for the first nine months of 2003 from \$81.6 million for the comparable prior year period. This decrease is a result of lower accession volumes, which declined approximately 18% year-over-year, and resultant reductions in costs for reagents and royalties, laboratory labor, and distribution. In addition, we were able to decrease our outsourced testing costs by approximately \$3.0 million in the first nine months of 2003 as compared to the first nine months of 2002. As a percentage of revenue, cost of services decreased to 72.3% for the nine months ended September 30, 2003 from 74.0% from the comparable prior year period.

*Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased \$6.4 million or 15.9% to \$33.4 million for the first nine months of 2003 from \$39.8 million for the first nine months of 2002. This decrease was primarily due to us controlling our staffing and discretionary expenditures. In addition, approximately \$2.2 million of the decline resulted from improvement in bad debt performance and certain sales costs that declined commensurate with revenues. Our bad debt performance, as measured as a percentage of net revenue, was 3.3% for the first nine months of 2003 as compared to 4.2% for the first nine months of 2002. This decrease in current year expenses is partially offset by nearly \$2.0 million of one-time charges for legal settlement costs and charges for the Valencia facility, while the first nine months of 2002 incurred approximately \$0.5 million of one-time costs. As a percentage of revenue, selling, general and administrative expenses increased to 37.5% for the first nine months of 2003 from 36.1% from the comparable prior year period.

*Stock-Based Compensation Charges*

Stock-based compensation charges increased from approximately (\$9,000) recorded in the first nine months of 2002 to approximately \$52,000 recorded in the first nine months of 2003. The negative expense in the first nine months of 2002 was primarily due to forfeited stock options resulting from the reduction in workforce in June and September of 2002 that had the effect of reducing amortization expense.

*Restructuring Charge*

We had no restructuring charge for the first nine months of 2003. On June 18, 2002, we announced a reduction in workforce of approximately 10% as part of an overall restructuring plan. In connection with the restructuring effort, we recorded a charge of approximately \$3.6 million during the second quarter of 2002. The charge was comprised of severance payments and related obligations for employees whose positions were eliminated.

During September 2002, as a result of further business review and the refinement of our core strategic business, we eliminated some employee positions primarily in the area of our clinical trials department. We recorded a restructuring charge of \$468,000 in the third quarter of 2002. The charge was comprised of \$199,000 of severance payments for employees whose positions were eliminated and a \$269,000 write-off of certain assets related to our clinical trials business.

Approximately \$3.5 million of severance and related obligations have been paid as of September 30, 2003. The remaining severance costs of approximately \$0.8 million will be paid through 2004.

*Charge Related to Regulatory Matters*

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

As a result of the actions taken in April 2002 by the federal Centers for Medicare and Medicaid Services (CMS), we recorded a charge of approximately \$1.9 million for the nine months ended September 30, 2002. Of this charge, approximately \$1.1 million was reserved for Medicare and Medicaid services earned and billed but not collected for the period of February 22, 2002, beginning of the sanction period, to March 31, 2002 with the remaining \$0.8 million for regulatory fines, inspection costs, and related legal expenses. We had no additional charge related to regulatory matters for the first nine months of 2003.

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

Net interest income decreased from approximately \$1.2 million to \$503,000 from the first nine months ended 2002 to the first nine months ended 2003. This reduction directly reflects the cash utilized for capital expenditures for the new Valencia facility construction and an information technology

infrastructure upgrade for our existing facilities coupled with the significant interest rate declines experienced in 2001 and 2002 resulting in lower interest yields on our investments.

*Provision for Income Taxes (Benefits)*

Provision for income taxes (benefits) was approximately a \$2.7 million benefit for the first nine months of 2003 as compared to a \$6.4 million benefit for the comparable prior year period. This decrease is primarily due to the reduction in pretax losses. Our effective tax rate was approximately 32.4% for the first nine months of 2003 as compared to 40.3% for the first nine months of 2002. As our loss narrows and we return to profitability, the effective tax rate could fluctuate significantly depending on the exact nature of operating results. In addition, we may not be able to fully realize any additional tax benefits, as the exact nature of future operating results may limit our ability to fully utilize any net operating loss carryforwards. Please see Risk Factor - Our effective tax rate may fluctuate and we may not be able to fully realize a portion of our deferred tax assets .

*Net Loss*

We recorded a net loss of \$5.6 million for the first nine months of 2003 compared to a net loss of \$9.5 million for the comparable prior year period. This resulted in an improvement of approximately \$3.9 million or 40.8%. While net revenues declined \$21.1 million for the first nine months of 2003 as compared to the first nine months of 2002, our total costs and expenses declined by \$29.3 million. A portion of the overall cost reduction was due to significant one-time components included in the nine months ended September 30, 2002, primarily \$4.1 million of restructuring charges and \$1.9 million of charges related to our regulatory matters. Our income tax benefits declined by \$3.7 million for the first nine months of 2003 as compared to the first nine months of 2002, a result of a lower pretax loss being recorded and a reduced effective tax rate for the current year. As a percentage of net revenue, a net loss of 6.3% was recorded for the nine months ended September 30, 2003 as compared to a net loss of 8.6% for the comparable prior year period.

*EBITDA*

EBITDA was a loss of \$3.8 million for the first nine months of 2003 as compared to a loss of \$11.8 million for the comparable prior year period. As a percentage of net revenue, EBITDA decreased to a loss of 4.3% for the nine months ended September 30, 2003 from a loss of 10.7% for the comparable prior year period. While net revenues declined \$21.1 million for the first nine months of 2003 as compared to the first nine months of 2002, our total costs and expenses declined by \$29.3 million. A portion of the overall cost reduction was due to significant one-time components included in the nine months ended September 30, 2002, primarily \$4.1 million of restructuring charges and \$1.9 million of charges related to our regulatory matters. For a reconciliation of EBITDA to net Loss, see footnote (1) under "Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations".

**Liquidity and Capital Resources**

Our cash and cash equivalents combined with short-term and long-term investments totaled \$41.7 million as of September 30, 2003 as compared to \$40.9 million as of December 31, 2002. This \$0.8 million increase is a result of receiving most of our income tax refunds, as reflected in

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

operating activities, and \$5.0 million in initial borrowings on our line of credit, as reflected in financing activities, during the third quarter of 2003. This increase in cash was offset by investments in capital expenditures of approximately \$10.4 million, primarily for the new Valencia facility and information technology investments that are related to our infrastructure upgrade for our existing facilities and the move of our data center to a third party location. Our short-term and long-term investments as of September 30, 2003 were \$14.2 million and were almost entirely in corporate bonds and government securities.

Operating activities for the first nine months ended September 30, 2003 provided cash of \$5.8 million. The effect of taxes were the primary contributors generating cash of approximately \$4.7 million,

as \$7.8 million was provided by income tax refunds and tax benefits related to the exercise of employee stock options partially offset by approximately \$3.1 million of deferred income taxes. The net increase of the combined accounts payable and accrued liabilities provided cash of approximately \$2.1 million. The net loss of \$5.6 million was offset by depreciation and amortization of \$5.0 million. For the first nine months ended September 30, 2002, \$901,000 of cash was used in operating activities. This net use of cash resulted primarily from the loss from operations, net of \$5.2 million of depreciation and amortization, of \$4.3 million for the first nine months of 2002. This loss is offset by \$8.3 million of cash provided by accounts receivable collections and an increase in accounts payable provided \$2.0 million primarily due to an increase in outsourced testing. In addition, the increase in our tax receivable, as reflected in refundable income taxes, used \$7.4 million of cash for the first nine months of 2002.

Investing activities in the first nine months of 2003 used cash of \$6.3 million as we invested \$10.4 million to complete the Core and Shell phase of our Valencia facility, complete an information technology infrastructure upgrade for our existing facilities, and improve certain core client electronic ordering and resulting applications. This investment was partially offset by \$4.1 million of cash generated through the sale of investments. For the first nine months of 2002, investing activities provided \$13.7 million in cash as we repositioned \$34.8 million of short-term and long-term investments to cash and cash equivalents, partially offset by approximately \$21.1 million in capital expenditures.

Net cash provided by financing activities was \$5.6 million for the first nine months of 2003 as compared to \$5.9 million for the first nine months of 2002. For 2003, net cash provided by financing activities resulted from borrowings from a new line of credit and the exercise of stock options and the sale of common stock to employees through the Employee Stock Purchase Plan. For 2002, net cash provided by financing activities resulted from funds borrowed from BNP Paribas in March 2002 for the Valencia facility construction and from the exercise of stock options and the sale of common stock to employees through the Employee Stock Purchase Plan.

In March 2002, we entered into a 6.5 year lease agreement to finance the construction of our new laboratory and headquarters facility in Valencia, California. BNP Paribas and a syndication of banks arranged our lease, which was initially structured as an off balance sheet financing arrangement, sometimes referred to as a synthetic lease. In the fourth quarter of 2002, we decided to go on balance sheet with the Valencia facility lease transaction and notified the banking group led by BNP Paribas that we were ending the synthetic lease by exercising our purchase option under the agreement.

In March 2002, we also obtained a bank loan agreement that provided for a revolving line of credit up to \$40,000,000. The bank group led by BNP Paribas also provided this loan agreement. We had no borrowings under this bank loan agreement and terminated the loan agreement in fourth quarter of 2002.

On September 24, 2003, we entered into a \$25 million asset-based credit agreement with CIT Business Credit, a unit of CIT Group Inc. The credit facility is secured primarily by accounts receivable, with the availability of funds being commensurate with this asset. The credit agreement provides us with an initial \$15 million line of credit. The principal amount of borrowings is due three years from the closing date, the date the line of credit matures. Only interest is due and payable monthly. As of September 30, 2003, we had \$5 million in outstanding borrowings against the line of credit.

With the resolution of sanctions imposed by CMS and CDHS, our focus has been on rebuilding client confidence and stabilizing our business. To minimize disruptions in service to our customers by a move to a new facility during this rebuilding period, in October 2002, we announced that we would postpone the move to our new facility in Valencia until the second half of 2004. Accordingly, the construction of the new facility was suspended at completion of the Core and Shell of the facility, which was substantially completed in January 2003. During the construction postponement period, we expect to see an increase in operating costs to provide security, insurance, maintenance, and funds taxes, and expect these costs to be between \$100,000 and \$200,000 per quarter. Upon restart of the facility construction, we plan to fund completion with new



financing. We expect to decide whether and when to recommence

the facility's construction by the end of 2003. However, we can provide no assurances that we will be able to obtain financing on favorable terms to fund construction of the new facility, that we will have the ability to complete a move to a new facility without incurring disruptions in service to our customers and loss of client confidence, or that we will need a larger facility for our operations in light of our reduced testing volume and employee headcount. Based on these and other factors, it is possible that we may never recommence construction of the new facility in Valencia, or decide to recommence construction after December 31, 2003. If we do not provide notice of our intent to resume construction prior to that date, the agreement for construction of the facility will be deemed terminated, and we could be subject to substantial termination costs and penalties, which could be in excess of \$2.5 million.

We expect existing cash and cash equivalents, short-term investments and our new financing arrangement will be sufficient to fund our operations, meet our capital requirements to support our growth and allow strategic technology licensing and acquisitions for the next year. Although we believe we have sufficient capital to fund our activities for at least the next twelve months, our future capital requirements may vary materially from those now planned. It is possible that we may need or elect to raise additional funds to fund our activities beyond the next year or to consummate acquisitions of other businesses, assets or technologies. We could raise such funds by selling 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 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.

#### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

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

This Quarterly Report on Form 10-Q, (the Quarterly Report ) includes information incorporated herein by reference and contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as projects, believes, anticipates, will, estimate, plans, expects, intends, and similar words and expressions are intended to identify forward-looking statements. These forward-looking statements are based on the current expectations, assumptions, estimates and projections about Specialty Laboratories, Inc. and the esoteric clinical laboratory industry. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. 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 filings with the Securities and Exchange Commission ( SEC ) 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.

## **Risk Factors**

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

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

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

### *Fraud and Abuse*

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

### *Federal and State Clinical Laboratory Licensing*

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

In June and October, 2001, we underwent unannounced inspections by the California Department of Health Services, or CDHS, representing both the State of California and acting as agent of the federal Centers for Medicare & Medicaid Services, or CMS, under CLIA. As a result, the laboratory was cited by CDHS with 20 deficiencies under California law and CLIA. A separate statement indicating 12 overlapping deficiencies under CLIA was issued by CMS in February 2002 based upon the same inspections. We submitted a response and corrective action plan to

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

CDHS in December 2001 in response to the CDHS statement of deficiencies. A more detailed response and corrective action plan was submitted to CMS in February 2002 in response to the CMS statement of deficiencies. By letter dated February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance.

By letter dated March 28, 2002, CDHS notified us of its intent to impose sanctions of a directed plan of correction, random onsite monitoring, and a civil money penalty based upon deficiencies cited on November 28, 2001 following laboratory inspections conducted during June and October 2001. The

sanctions were based on findings that we were permitting unlicensed personnel to perform and supervise clinical laboratory testing in violation of California law.

By letter dated April 12, 2002, CMS notified us that it concluded our February 2002 response to deficiencies detected in the June and October 2001 inspections conducted by CDHS did not constitute a credible allegation of compliance. As a result, CMS imposed certain sanctions, including notice of revocation of our CLIA certificate, cancellation of our approval to receive Medicare and Medicaid payments for services performed on or after February 22, 2002, imposing a civil money penalty of \$3,000 per day for each day during the sanction period, and imposing a directed plan of correction by which CMS could notify our customers of our non-compliance and the nature and effective date of any sanctions imposed. We filed an appeal to the CMS action on April 17, 2002.

After we filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS, additional unannounced inspections by CDHS, CDHS notified us by letter dated June 28, 2002, and amended on July 18, 2002, that we were in substantial compliance with California clinical laboratory law. CDHS imposed sanctions of a civil money penalty of \$344,000, plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections.

On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's ability to bill Medicare and Medicaid for its testing services was reinstated as of June 19, 2002, and that all actions against our CLIA certificate were rescinded. We withdrew the appeal of the sanctions we filed with CMS on April 17, 2002 and paid a monetary fine of \$351,000.

In May of 2003 CDHS inspectors conducted an unannounced site survey, and CDHS determined that we continue to maintain condition level compliance with state laboratory law. However, 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, state 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 payments and/or loss of licensure, certification or accreditation, and could divert a substantial amount of management's time and resources, and any such action could materially harm our business. In addition, substantial expenditures are required on an ongoing basis to ensure that we comply with existing regulations and to bring us into compliance with newly instituted regulations.

#### ***Food & Drug Administration***

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



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

#### *Anti-Kickback Regulations*

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

#### *Fee-Splitting*

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

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

Because of uncertainty surrounding the sanctions imposed by CMS, 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 from the second quarter of 2002 through the second quarter of 2003. While we experienced an increase in accession volume in the third quarter of 2003, we cannot provide any assurances that our clients will continue sending us specimens for testing, nor can we provide assurances that our accessions will continue increasing and they may decline again.

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



Some of our customers, such as Quest, LabCorp, Mayo and ARUP, also compete with us by providing esoteric testing services. They often refer assays to us that they either cannot or elect not to perform themselves. During 2002, we saw a significant decline in test volumes referred to us from our competitors. For the year ended December 31, 2002, sales to our competitors were less than 4% of our net revenue as compared to more than 6% of our net revenue for the year ended December 31, 2001. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours, and we may experience a further decline in our net revenues from these competitors. For example, in July 1997, SmithKline Beecham Clinical Laboratories, or SmithKline Labs, began to significantly limit the

number of assays it referred to us. We believe that SmithKline Labs terminated its relationship with us because it decided to offer assays similar to ours. In 1996, SmithKline Labs comprised 21.7% of our net revenue, whereas in 2001, after being acquired by Quest, SmithKline Labs (excluding Quest accounts prior to the acquisition) only comprised approximately 2% of our net revenue. We experienced a significant reduction in volume from Quest, LabCorp, Mayo and ARUP in 2002, and if these or other laboratories decide to reduce or discontinue purchases of our assays for competitive reasons, it will reduce the number of our accessions and reduce our net revenue.

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

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

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

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

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

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

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

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

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

affect our business, financial condition, results of operations and prospects.

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

Our quarterly operating results have varied significantly in the past and may vary significantly in the future. If our quarterly net revenue and operating results fall below the expectations of securities analysts and investors, the market price of our common stock could fall substantially. Operating results vary depending on a number of factors, many of which are outside our control, including:

demand for our assays and ancillary services;

loss of a significant customer or group purchasing organization contract;

new assay introductions by competitors;

changes in our pricing policies or those of our competitors;

the hiring and retention of key personnel;

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

changes in healthcare laws and regulations;

costs related to acquisitions of technologies or businesses; and

the effect of litigation.

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

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

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

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

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

**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. Third party payors accounted for approximately 7.3% of our net revenue in 2000, approximately 6.9% of our net revenue in 2001, and approximately 6.6% of our net revenue in 2002. 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.

In April 2002, we received a letter from CMS imposing certain sanctions as a result of laboratory inspections conducted by CDHS in June and October 2001. The penalties included cancellation of Medicare and Medicaid payments for services performed by us on and after February 22, 2002. On April 17, 2002, we filed an appeal to the sanction imposed by CMS. On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's ability to bill Medicare and Medicaid for its testing services has been reinstated as of June 19, 2002, and that all actions against our CLIA certificate had been rescinded. We withdrew the appeal of the sanctions we filed with CMS on April 17, 2002 and we paid a monetary fine of \$351,000.

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

We reported \$5,280,000 of deferred income taxes (current and long-term) in the September 30, 2003 balance sheet, with approximately \$4,916,000 related to federal and state net operating loss carryforwards (NOLs). Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes, requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some portion of the deferred tax asset will not be realized. We believe that there is not sufficient uncertainty regarding the realizability of the NOLs and therefore has not established a valuation allowance. Realization of the NOLs incurred through September 30, 2003 is dependent on Specialty's ability to generate approximately \$13,000,000 of ordinary income in future years. Our inability to generate the necessary ordinary income, or an unfavorable outcome in the realization of the NOLs, could have a material adverse effect on our results of operations in future quarters.

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

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

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

Our future success also depends on our ability to identify, attract, hire, train, retain and motivate

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

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

As we previously reported, we are constructing a 195,000 square foot facility in Valencia, California that will enable us to consolidate all of our laboratory and administrative functions in one location. The location of the new facility is approximately 30 miles from our current location in Santa Monica, California.

Moving our entire laboratory and administrative functions to a new location is a time-consuming and complicated process, and includes physically moving and setting up delicate and complex laboratory equipment over a short period of time, transferring specimens and reagents from one facility to another, changing processes and procedures for delivery of testing specimens, ensuring that we have adequate staffing of laboratory and administrative personnel at the new facility, and continuing to conduct our testing of specimens during the process. If we are unable to execute the move to Valencia effectively and efficiently, it could result in short-term service disruptions that would negatively affect our business and could reduce our revenue. Such service disruptions could also result in customer dissatisfaction, and could materially hurt our business if our customers decided not to purchase our services any longer as a result of the service disruptions. Furthermore, planning for the move of our facility is also expected to divert the attention of key management personnel.

In October 2002 we announced that we would postpone the move to our new Valencia facility until the second half of 2004. While the delay will allow us to focus on rebuilding client confidence and stabilizing our business, and minimize disruptions in service to our customers, we can provide no assurances that key management will not be distracted by planning for the facility move. We can also provide no assurances that we will be able to complete the move to the new Valencia facility efficiently or effectively, or on time, or that we will not experience service disruptions, loss in customers, or decreased revenue as a result of the move. Because the new Valencia facility is located 30 miles away from our current headquarters, some of our key employees may choose not to remain employed with us after the move. In addition, because one of the leases to the buildings we currently occupy in Santa Monica, California expires in the first quarter 2004, we will need to extend or renegotiate our current lease. We can provide no assurance that we will be able to obtain lease extensions on commercially reasonable terms, if at all. The occurrence of any of the foregoing events affecting or resulting from our move could harm our business.

**We may decide to further postpone or cancel our planned move to a new facility in Valencia, which could create financial liabilities.**

We are postponing the move to our new Valencia facility until the second half of 2004, to focus on rebuilding client confidence and stabilizing our business, and minimize disruptions in service to our customers. During the period that the facility construction is postponed, we will incur certain charges for maintenance and security of the site and facility that could be as much as \$200,000 per quarter. We have negotiated certain amendments to the agreement for construction of the new facility with our primary construction partners. The amendments call for the construction of the facility to be resumed no later than December 31, 2003. If we do not provide notice of our intent to resume construction prior to that date, the agreement for construction of the facility will be deemed terminated, and we could be subject to termination costs and penalties to our construction partners and subcontractors, which could be in excess of \$2.5 million.





In addition, failure to resume construction by December 31, 2003 may impair the existing value of the facility, and we may have to incur certain write-downs of the asset value.

We expect to decide whether and when to recommence the facility's construction sometime in the last half of 2003. We can provide no assurances that we will be able to obtain financing on favorable terms to fund construction of the new facility, that we will have the ability to complete a move to a new facility without incurring disruptions in service to our customers and loss of client confidence, or that we will need a larger facility for our operations in light of our reduced testing volume and employee headcount. Based on these and other factors, it is possible that we may never recommence construction of the new facility in Valencia, or decide to recommence construction after December 31, 2003, and we could thus be liable for the termination costs and penalties noted above. If we do not resume construction on or before December 31, 2003, our business may be harmed, our assets may be impaired, and our stock price may fluctuate.

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

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

Our participation in group purchasing organizations constitutes one aspect of our overall strategy to attract new hospital customers. We have contracts with several group purchasing organizations: AmeriNet, MedAssets HSCA (formerly Health Services Corporation of America), Managed Healthcare Associates (MHA), Shared Services Healthcare (now affiliated with MedAssets HSCA), and Consorta. We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at various times from 2003 to 2006. On May 1, 2002, we announced that Novation, a national purchasing group for hospitals, has discontinued its service agreement with us. The termination of the agreement was without cause and was effective on July 29, 2002. The original agreement was initiated on May 1, 2001 and provided Novation members with access to discounted clinical laboratory services from us. While we have experienced some loss of Novation clients, the exact consequences of the agreement's termination are difficult to quantify, particularly since the termination of the contractual relationship with Novation does not prevent its members from using our services, and it may take a significant period of time before any individual Novation member decides to stop utilizing our services.

Through the contract termination date of July 29, 2002, sales of our services to hospitals utilizing the Novation group purchasing organization contract comprised \$21 million, or approximately 15% of net revenue for the year ended December 31, 2002. Sales of our services to hospitals utilizing the pricing structures under the AmeriNet group purchasing organization contract, comprised approximately \$9 million during the year ended December 31, 2002, or approximately 6% of our net revenue. Sales to hospitals within the other three group purchasing organizations comprised approximately 3% of our net revenues for the same period. These group purchasing organizations offer a substantial growth opportunity to gain additional revenue from existing hospital customers.

We cannot be certain that the termination of our agreement with Novation will not affect our ability to retain any of the accounts of participating hospitals. We have entered into direct agreements with many Novation members to provide them with laboratory services, but we cannot predict that we will be successful in entering into any additional such agreements, or that if our agreement with AmeriNet or any other group purchasing organization is terminated or not renewed, we will be able to retain any of the accounts of their participating hospitals. If any

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

hospital customer affiliated with a group purchasing organization no longer uses our services, it will reduce our net revenue. In addition, if we are unable to attract new hospital customers because any group purchasing organization contract is terminated, it may adversely affect our ability to grow our business.

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

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

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

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

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

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

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



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

Our principal shareholder is Specialty Family Limited Partnership, whose sole general managing partner, James B. Peter, M.D., Ph.D., is a member of our board of directors. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 63% of the outstanding shares of our common stock. Accordingly, the Specialty Family Limited Partnership along with Dr. Peter will have significant influence in determining the outcome of any corporate transaction or other matter submitted to the shareholders for approval, including election of directors, mergers, consolidations and the sale of all or substantially all of our assets. Our principal shareholder will also have the power to prevent or cause a change in control. The interests of this shareholder may differ from other shareholders' interests. In addition, this concentration of ownership may delay, prevent, or deter a change in control and could deprive other shareholders of an opportunity to receive a premium for their common stock as part of a sale of our business.

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

Typically, we market new esoteric assays at premium prices for several years before similar assays are developed as either standardized prepared kits for broad application or as internally developed assays by competing laboratories. The opportunity to sell our products at premium prices may be reduced or eliminated if our competitors are able to develop and market competing assays more quickly than they currently do. If we are unable to develop newer assays which meet market demand, our net revenue and profit margins may decrease.

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

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

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

Our ability to accelerate new assay development and improve existing performance will depend, in part, on our ability to license new or improved assay technology platforms on favorable terms. We may not be able to negotiate acceptable licensing arrangements and we cannot be certain that such arrangements will yield commercially successful assays. Further, even if we enter into such arrangements with these third parties, their devotion of resources to these efforts may not be within our control or influence. If we are unable to license these technologies at competitive rates, our research and development costs may increase. In addition, if we are unable to develop new or improved assays through such research and development efforts, our assays may be outdated when compared with our competitors' assays, and our net revenue may decrease.



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

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

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

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

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



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

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

A significant portion of our net revenue is derived from 30 assays. Net revenue from these 30 assays comprised approximately 45% of our total net revenue for the year ended December 31, 2002. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue could decrease.

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

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

material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

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

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

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

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. As a result, we may be found to be, or accused of, infringing on the proprietary rights of others. For example, in response to a patent infringement allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease. We also received letters from Chiron Corporation ( Chiron ) in February 1998, and the National Institute of Health (NIH) in 2000, 2001, and 2002 claiming that some of our assays may violate their patents. In August 2003 we reported that we had entered into a letter agreement with Chiron that called for us to make payments to Chiron for alleged past infringement of Chiron patents by certain Hepatitis C Virus ( HCV ) and Human Immunodeficiency Virus ( HIV ) testing performed by us, and Chiron agreed not to assert its patent rights, or bring any claim against Specialty for any alleged infringement relating to nucleic acid clinical assays for the detection, quantitation, genotyping and/or phenotyping of HCV and HIV occurring at any time prior to October 15, 2003. We cannot provide any assurances that the NIH or other patent holders will not bring suit against us in the future for alleged patent infringement. We intend to defend any such suit that may arise vigorously and to assert all available defenses to allegations of patent infringement that would be available to us. Such suits could be expensive to defend and could divert management's time and resources, regardless of the merit or validity of any such suit. Furthermore, we cannot provide any assurances that we would be successful in defending any such suit, and there can be no assurance that there will be no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and such litigation, or the threat of such litigation, could force us to do one or more of the following:

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

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

redesign or reengineer our assays.

We can provide no assurances that we will be able to secure licenses for such patents on commercially reasonable terms, if at all. Licenses for such patents may require the payment of material

sums of money as license fees and royalties, including fees and royalties for past infringement. Any efforts to reengineer our assays or any inability to sell our assays, or an obligation to pay license fees and royalties could substantially increase our costs, force us to interrupt product sales, delay new assay releases, decrease our competitiveness in the marketplace, reduce our revenues, and materially impair our business. In addition, if a suit were brought against us alleging patent infringement, and we were found to have infringed the patents at issue, we could be forced to pay substantial damages, including possible treble damages for allegations of willful infringement. While we intend to defend any such suit vigorously, and assert all available defenses, we cannot provide any assurances that we would be successful in defending any such suit. If we were to lose such a suit, it could create a material financial liability, negatively affect our operating results, and negatively impact our stock price.

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

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

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

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

If we are unable to consistently process patient samples on a timely basis because of delays or failures in our implementation of these automated systems, or if we encounter problems with our established automated processes, we will be required to develop alternate means to process our 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 all of our clinical laboratory facilities are located in Santa Monica, California, an earthquake-prone area. In the event our existing facilities or equipment are affected by man-made or natural disasters, we may be unable to process our customers' samples in a

timely manner and unable to operate our business in a commercially competitive manner. To address these risks, we have in place formal recovery plans for such interruptions of service. This includes identification of alternate laboratory testing facilities and disaster recovery protocols. We also carry earthquake insurance with a coverage amount of up to \$20 million and we have outsourced part of our data storage and processing equipment to a facility designed to withstand most earthquakes. Despite these precautions, the self-insured retention amount for earthquake insurance is very high, and there is no assurance that we could recover quickly from a serious earthquake or other disaster.

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

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

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

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

**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 September 30, 2003, 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 September 30, 2003, we had cash and cash equivalents of \$27.5 million, which had a weighted average yield of 1.15% per annum. At September 30, 2003, our short-term investment balance of \$10.1 million, consisting of corporate bonds and government securities with maturity dates less than one year, had a weighted average yield per annum of 4.1% and an average of 137 days until maturity. At September 30, 2003, our long-term investment balance of \$4.1 million consisted of government securities with maturity dates beyond one year had a weighted average yield per annum of 3.4% and an average of 13.7 months until maturity.

### **ITEM 4. CONTROLS AND PROCEDURES**

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

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

## PART II. OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

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, and elsewhere in this Quarterly Report, we are involved in various legal proceedings arising in the ordinary course of business.

As previously reported, in May and June 2002, we were named as a defendant, together with certain of our current or former board members and officers, in four substantially identical class-action lawsuits filed in the United States District Court for the Central District of California. In September 2002 an amended and consolidated complaint was filed. The lawsuit purports to state claims on behalf of an alleged class of investors who bought our stock in the open market between December 8, 2000 and April 15, 2002 ( Class Period ). The lawsuit alleges that the market price of our stock was artificially inflated during the Class Period as a result of alleged misrepresentations made in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with our initial public offering of common stock and subsequent public disclosures. The lawsuit alleges, among other things, false and misleading statements about our compliance with certain regulatory requirements imposed by the California Department of Health Services and the federal Centers for Medicare & Medicaid Services. Plaintiffs seek compensatory damages, including interest, costs and expenses, attorneys' fees, and other relief. In October 2002 we filed a motion to dismiss the amended complaint, and in February 2003 the court ruled on the motion, dismissing some claims and not dismissing others. In response to the judge's ruling, plaintiffs filed an amended complaint in March 2003, and we filed another motion to dismiss. In August 2003 the court ruled on the new motion, dismissing some claims and not dismissing others. The court allowed plaintiffs to proceed with their claims against the Company and several current and former officers and directors for alleged violations of both the Securities Act of 1933 and the Securities Exchange Act of 1934. We have provided notice to our directors and officer's insurers, and believe that we have insurance applicable to the defense of the lawsuits. We also believe that the claims against us and our current and former officers and directors are without merit, and intend to defend the lawsuits vigorously.

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

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 which may cause us to pay substantial damages and prohibit us from selling our assays.

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

None.

**ITEM 3.        DEFAULTS UPON SENIOR SECURITIES**

None.

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

None.

**ITEM 5.        OTHER INFORMATION**

None.

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

## (a) Exhibits.

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

Number	Description
3.1**	Articles of Incorporation.
3.2**	Form of By-laws.
4.1**	Specimen Common Stock Certificate.
4.2	See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
10.1**	2000 Stock Incentive Plan.
10.2**	2000 Employee Stock Purchase Plan.
10.3***	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.
10.4A**	Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (sublandlord) and Registrant (subtenant) for the property located at 1620 20th Street, Santa Monica, California.
10.5***	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.
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.
10.7A**	Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant.
10.8++	Expanded PCR Diagnostics Services Agreement dated August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant.
10.9+	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended.
10.10A**	Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant.
10.11A**	Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant.
10.12**	Shared Services Health Care letter of confirmation dated June 5, 2000.
10.13**	License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property.
10.14	Employment Agreement dated May 15, 2002 between Douglas S. Harrington and Registrant.
10.15	Form of Employment Agreement between executive officers of the Registrant and Registrant.
10.16#	James B. Peter, M.D., Ph.D. severance agreement dated June 7, 2002.
10.17#	Paul F. Beyer severance agreement dated June 6, 2002.
10.18**	Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant.
10.19**	Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant.
10.20**	Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant.
10.21**	License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant.
10.22#	Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002.
10.23 I	Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc.



Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

- 10.24\* Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended.
- 10.25\*\*\* Employment Agreement dated January 28, 2003 between Thomas E. England and Registrant.
- 10.26 Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant.
- 10.27 Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant.
- 10.28 Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant.
- 10.29 Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant.
- 10.30 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant.
- 10.31 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant.
- 10.32 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant.
- 10.33 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant.
- 10.34 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant.
- 10.35 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant.
- 10.36 Agreement dated August 15, 2003 between Chiron Corporation and Registrant.
- 10.37 Agreement dated September 24, 2003 between CIT Group/Business Credit, Inc. and Registrant.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002
- 99.2++ California Department of Health Services Letter dated June 28, 2002.
- 99.3++ Center for Medicare and Medicaid Services Letter dated July 17, 2002.
- 99.4++ California Department of Health Services Letter dated July 18, 2002.

---

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

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

\*\*\* This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2002 with the Securities & Exchange Commission on March 21, 2003 and is incorporated by reference herein.

I This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2001 with the Securities & Exchange Commission on March 13, 2002 and is incorporated by reference herein.





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

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

Confidential treatment requested as to certain portions of this agreement.

Indicates a management contract or compensatory arrangement.

# This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2002 with the Securities and Exchange Commission on August 13, 2002 and is incorporated herein for reference.

++ This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2002 with the Securities and Exchange Commission on October 30, 2002 and is incorporated herein for reference.

(b) Reports on Form 8-K:

A Current Report, on Form 8-K under Item 9 was filed on July 30, 2003 with the Commission by the Registrant in connection with a press release dated July 30, 2003 announcing financial results for the second quarter ended June 30, 2003.

A Current Report, on Form 8-K under Item 5 was filed on August 21, 2003 with the Commission by the Registrant announcing the Registrant entered into a letter agreement with Chiron Corporation, of Emeryville, California, and a separate Settlement and License Agreement with the Diagnostics Division of Bayer Healthcare LLC of Tarrytown, New York.

A Current Report, on Form 8-K under Item 5 was filed on September 16, 2003 with the Commission by the Registrant in connection with a press release dated September 16, 2003 announcing the resignation of Terrance H. Gregg from the Board of Directors.

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

A Current Report, on Form 8-K under Item 5 was filed on September 29, 2003 with the Commission by the Registrant in connection with a press release dated September 29, 2003 announcing the Registrant had signed a \$25 million asset-based credit agreement with CIT Business Credit, a unit of CIT Group Inc.

**SIGNATURES**

Edgar Filing: SPECIALTY LABORATORIES INC - Form 10-Q

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

SPECIALTY LABORATORIES, INC.,  
a California corporation

Dated: November 13, 2003 By: /s/ Douglas S. Harrington

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

Dated: November 13, 2003 By: /s/ Frank J. Spina

Name: Frank J. Spina  
Title: *Chief Financial Officer (Principal Financial and Accounting Officer)*

**EXHIBIT INDEX**

<b>Number</b>	<b>Description</b>
3.1**	Articles of Incorporation.
3.2**	Form of By-laws.
4.1**	Specimen Common Stock Certificate.
4.2	See Exhibits 3.1 and 3.2 for provisions of the Articles of Incorporation and By-laws of the Registrant defining the rights of holders of Common Stock of the Registrant.
10.1**	2000 Stock Incentive Plan.
10.2**	2000 Employee Stock Purchase Plan.
10.3***	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.
10.4A**	Sublease dated July 9, 1996, as amended on March 9, 1998 between The Rand Corporation (sublandlord) and Registrant (subtenant) for the property located at 1620 20th Street, Santa Monica, California.
10.5***	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.
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.
10.7A**	Agreement dated August 26, 1996, as amended on October 23, 1998 and as amended on December 31, 1999 between Triple G Corporation and Registrant.
10.8++	Expanded PCR Diagnostics Services Agreement dated August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant.
10.9+	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant as amended.
10.10A**	Laboratory Services Agreement effective as of March 1, 1999 between Joint Purchasing Corporation and Registrant.
10.11A**	Agreement dated June 7, 2000 between Managed Health Care Associates and Registrant.
10.12**	Shared Services Health Care letter of confirmation dated June 5, 2000.
10.13**	License Agreement, undated, between Southern California Edison Company (Licensor) and Registrant (Licensee) regarding Santa Monica Service Center property.
10.14	Employment Agreement dated May 15, 2002 between Douglas S. Harrington and Registrant.
10.15	Form of Employment Agreement between executive officers of the Registrant and Registrant.
10.16#	James B. Peter, M.D., Ph.D. severance agreement dated June 7, 2002.
10.17#	Paul F. Beyer severance agreement dated June 6, 2002.
10.18**	Purchase and License Agreement dated June 19, 2000 between Sequenom, Inc. and Registrant.
10.19**	Letter Agreement dated April 14, 2000 between Third Wave Technologies, Inc. and Registrant.
10.20**	Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant.
10.21**	License Agreement dated March 15, 2000 between Gen-Probe Incorporated and Registrant.
10.22#	Albert Rabinovitch, M.D., Ph.D. severance agreement dated June 10, 2002.
10.23 I	Asset Purchase Agreement among Registrant, Boston Biomedica, Inc. and BBI Clinical Laboratories, Inc.
10.24*	Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant, as amended.
10.25***	Employment Agreement dated January 28, 2003 between Thomas E. England and Registrant.
10.26	Employment Agreement dated September 11, 2003 between Frank J. Spina and Registrant.
10.27	Employment Agreement dated September 11, 2003 between Dan R. Angress and Registrant.
10.28	Employment Agreement dated September 11, 2003 between Mark R. Willig and Registrant.
10.29	Employment Agreement dated September 11, 2003 between Michael C. Dugan, M.D. and Registrant.



- 10.30 Employment Agreement dated September 11, 2003 between Thomas J. Kosco and Registrant.
- 10.31 Employment Agreement dated September 11, 2003 between Robert M. Harman and Registrant.
- 10.32 Employment Agreement dated September 11, 2003 between Nicholas R. Simmons and Registrant.
- 10.33 Employment Agreement dated September 11, 2003 between Cheryl G. Gallarda and Registrant.
- 10.34 Employment Agreement dated September 11, 2003 between Cynthia K. French and Registrant.
- 10.35 Agreement dated August 15, 2003 between Bayer Healthcare, LLC and Registrant.
- 10.36 Agreement dated August 15, 2003 between Chiron Corporation and Registrant.
- 10.37 Agreement dated September 24, 2003 between CIT Group/Business Credit, Inc. and Registrant.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) under the Securities Exchange Act of 1934
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002
- 99.2++ California Department of Health Services Letter dated June 28, 2002.
- 99.3++ Center for Medicare and Medicaid Services Letter dated July 17, 2002.
- 99.4++ California Department of Health Services Letter dated July 18, 2002.

---

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

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

\*\*\* This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2002 with the Securities & Exchange Commission on March 21, 2003 and is incorporated by reference herein.

I This exhibit was previously filed as an exhibit to the Company's Annual Report on Form 10-K for the period ended December 31, 2001 with the Securities & Exchange Commission on March 13, 2002 and is incorporated by reference herein.

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

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

Confidential treatment requested as to certain portions of this agreement.



Indicates a management contract or compensatory arrangement.

# This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending June 30, 2002 with the Securities and Exchange Commission on August 13, 2002 and is incorporated herein for reference.

++ This exhibit was originally filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the period ending September 30, 2002 with the Securities and Exchange Commission on October 30, 2002 and is incorporated herein for reference.