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	**95-2961036**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

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

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

Not Applicable

(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 ý No o

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

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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)
Assets		
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
Liabilities and shareholders equity		
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:		

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**
Operating activities		
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
Investing activities		
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)
Financing activities		
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

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.

When we acquire a business, we allocate the excess of the purchase price over the fair value of the net assets acq

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.

When we acquire a business, we allocate the excess of the purchase price over the fair value of the net assets acq

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

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

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

On June 18, 2002, the Company 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, a charge of approximately $3,598,000 was recorded 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, the Company eliminated some employee positions primarily in the area of the clinical trials department. A charge of approximately $468,000 was recorded in the third quarter of 2002. The charge comprised $199,000 of severance payments for employees whose positions were eliminated and a $269,000 write-off of certain assets related to the clinical trials business.

In November 2002, in the Company s continuing efforts to manage costs and align the business with current business levels, a reduction in workforce occurred focused primarily on the laboratory. A restructuring charge of approximately $984,000 was recorded in the fourth quarter of 2002. Approximately $508,000 of the charge related to reductions in force, primarily laboratory operations. In addition, approximately $476,000 of the charge was recorded for the write-off of certain capitalized costs associated with the delayed move to the new Valencia facility, and the related termination of the synthetic lease financing arrangement with the banking group led by BNP Paribas.

Severance obligations for the nine months ended September 30, 2003 are as follows:

	2002 Expense	Paid Through September 30, 2003	Unpaid Balance at September 30, 2003
		(dollar amounts in thousands)	
Severance and related obligations	$ 4,276	$ 3,479	$ 797*

* Unpaid balance is expected to be paid through 2004.

NOTE 8. COMMITMENTS AND CONTINGENCIES

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

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.

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:

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

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.