

SPECIALTY LABORATORIES  
Form 10-Q  
October 30, 2002

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended September 30, 2002

OR

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

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

Commission file number 001-16217

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**SPECIALTY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

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

**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)

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

As of October 28, 2002, there were approximately 21,947,223 shares of Common Stock outstanding, no par value.

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## SPECIALTY LABORATORIES, INC.

## FORM 10-Q QUARTERLY REPORT

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*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. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. Important language regarding factors which could cause actual results to differ materially from such expectations are disclosed in this Quarterly Report and in filings with the Securities and Exchange Commission ("SEC") made from time to time by Specialty Laboratories, including our Registration Statement on Form S-1 declared effective on December 7, 2000, our most recent Annual Report on Form 10-K filed on March 13, 2002, and other periodic filings on Form 10-Q and Form 8-K. All forward-looking statements attributable to Specialty Laboratories are expressly qualified in their entirety by such language. We do not undertake any obligation to update any forward-looking statements.*

## PART I. FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS

**Specialty Laboratories, Inc.**  
**Consolidated Balance Sheets**  
*(Dollar amounts in thousands)*

	<u>December 31, 2001</u>	<u>September 30, 2002</u>
		(Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,183	\$ 33,858
Short-term investments	22,491	

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	December 31, 2001	September 30, 2002
Accounts receivable, less allowance for doubtful accounts of \$2,828 as of December 31, 2001 and \$4,120 as of September 30, 2002	33,783	25,445
Income tax receivable		6,236
Deferred income taxes	1,571	2,412
Inventory	2,711	1,919
Prepaid expenses and other assets	1,785	3,120
<b>Total current assets</b>	<b>77,524</b>	<b>72,990</b>
Property and equipment, net	27,095	43,173
Long-term investments	37,389	25,261
Deferred income taxes	1,051	2,574
Goodwill, net	5,655	5,655
Other assets	5,274	4,414
	<b>\$ 153,988</b>	<b>\$ 154,067</b>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 9,465	\$ 11,501
Accrued liabilities	8,206	8,518
Income tax payable	1,117	
Bank loan		4,609
<b>Total current liabilities</b>	<b>18,788</b>	<b>24,628</b>
Long-term liabilities	2,544	2,331
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 21,473,886 as of December 31, 2001 and 21,915,148 as of September 30, 2002		
	96,056	99,320
Retained earnings	37,182	27,713
Deferred stock-based compensation	(726)	(176)
Accumulated other comprehensive income	144	251
<b>Total shareholders' equity</b>	<b>132,656</b>	<b>127,108</b>
	<b>\$ 153,988</b>	<b>\$ 154,067</b>

See accompanying notes.

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2002	2001	2002
Net revenue	\$ 42,842	\$ 32,505	\$ 131,821	\$ 110,265
Costs and expenses:				
Costs of services	25,049	26,331	75,102	81,647
Selling, general and administrative (exclusive of stock-based compensation charges)	13,559	11,568	42,488	39,777
Stock-based compensation charges	228	49	907	(9)
Restructuring charge		468		4,066
Charge related to regulatory matters				1,853
Total costs and expenses	38,836	38,416	118,497	127,334
Operating income (loss)	4,006	(5,911)	13,324	(17,069)
Interest income	(838)	(391)	(2,866)	(1,390)
Interest expense	31	46	109	185
Income (loss) before income taxes (benefits)	4,813	(5,566)	16,081	(15,864)
Provision for income taxes (benefits)	1,901	(2,243)	6,521	(6,395)
Net income (loss)	\$ 2,912	\$ (3,323)	\$ 9,560	\$ (9,469)
Basic earnings (loss) per common share	\$ .14	\$ (0.15)	\$ .45	\$ (0.44)
Diluted earnings (loss) per common share	\$ .13	\$ (0.15)	\$ .43	\$ (0.44)

See accompanying notes.

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**Specialty Laboratories, Inc.**  
**Consolidated Statements of Cash Flows**  
**(Unaudited)**  
*(Dollar amounts in thousands)*

	Nine Months Ended September 30,	
	2001	2002
<b>Operating activities</b>		
Net income (loss)	\$ 9,560	\$ (9,469)
Adjustments to reconcile income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	5,221	5,232
Tax benefits related to employee stock options	3,607	2,565
Deferred income taxes	2,441	(2,439)
Stock-based compensation charges	907	(9)
Loss on disposal of property and equipment	8	
Changes in assets and liabilities, net of effects of acquisition:		
Accounts receivable, net	(974)	8,338
Income tax receivable		(6,236)

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	<b>Nine Months Ended September 30,</b>	
	<b>_____</b>	
Inventory, prepaid expenses and other assets	(213)	99
Accounts payable	893	2,036
Accrued liabilities	(2,452)	312
Income tax payable	(3,344)	(1,117)
Long-term liabilities	(759)	(213)
	<b>_____</b>	<b>_____</b>
Net cash provided by (used in) operating activities	14,896	(901)
<b>Investing activities</b>		
Cash paid for acquisition of BBI Clinical Laboratories	(9,500)	
Purchases of property and equipment	(3,796)	(21,092)
(Purchases) sales of short-term investments	(29,815)	22,486
(Purchases) sales of long-term investments	(29,371)	12,315
	<b>_____</b>	<b>_____</b>
Net cash (used in) provided by investing activities	(72,482)	13,709
<b>Financing activities</b>		
Borrowings under bank loan		4,609
Proceeds from exercise of stock options	1,491	635
Sale of common stock to employees		623
	<b>_____</b>	<b>_____</b>
Net cash provided by financing activities	1,491	5,867
	<b>_____</b>	<b>_____</b>
Net (decrease) increase in cash and cash equivalents	(56,096)	18,675
Cash and cash equivalents at beginning of period	75,604	15,183
	<b>_____</b>	<b>_____</b>
Cash and cash equivalents at end of period	\$ 19,508	\$ 33,858
	<b>_____</b>	<b>_____</b>
Supplemental disclosures of cash flow information:		
Acquisition of BBI Clinical Laboratories consisted of the following:		
Acquired assets	\$ 10,148	
Assumed liabilities	(648)	
	<b>_____</b>	
Total cash paid	\$ 9,500	
	<b>_____</b>	

See accompanying notes.

**SPECIALTY LABORATORIES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**September 30, 2002**

**(Unaudited)**

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

**NOTE 1. BASIS OF PRESENTATION***Financial Statement Preparation*

The accompanying financial statements of Specialty Laboratories Inc. (the "Company" or "Specialty") 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 accounting principles generally accepted in the United States 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, 2001, as filed with the Securities and Exchange Commission.

**NOTE 2. ACQUISITION**

On February 20, 2001, we acquired certain assets and liabilities of BBI Clinical Laboratories, Inc. (BBICL), a Massachusetts corporation, for \$9.5 million in cash. The purchase price was allocated to the assets acquired and liabilities assumed based on the estimated fair values as of the purchase closing date. The acquisition agreement provided for a reduction of the purchase price if certain performance measurements (i.e., asset delivery, client retention and accounts receivable collections) were not achieved. A subsequent evaluation of these performance measurements resulted in the return of \$358,000 by BBICL to us in December 2001. Of the \$9.1 million net purchase price, approximately \$5.9 million was allocated to goodwill and \$1.9 million was allocated to the customer list. The acquisition has been accounted for under the purchase method of accounting.

The following unaudited pro forma information presents the consolidated results of our operations for the nine months ended September 30, 2001 as if the BBICL acquisition had been consummated on January 1, 2001. Such unaudited pro forma information is based on historical financial information with respect to the acquisition and does not include operational or other changes that might have been effected by us.

	<b>Nine Months Ended September 30, 2001</b>	
Net revenue	\$	132,725
Net income	\$	9,475
Basic earnings per common share	\$	.45
Diluted earnings per common share	\$	.43

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**NOTE 3. 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. Prior to 2002, we amortized goodwill and intangible assets evenly over periods ranging from 10 to 20 years.

In July 2001, the Financial Accounting Standards Board issued Statements of Financial Accounting Standards (SFAS) No. 141, "Business Combinations", and No. 142, "Goodwill and Other Intangible Assets", effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill is no longer amortized, but is subject to annual impairment tests. The tests for measuring goodwill impairment under SFAS No. 142 are more stringent than previous tests required by SFAS No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to be Disposed of". Under SFAS No. 121, we applied an undiscounted cash flow model to assess the fair value of our Company, which did not result in the recognition of goodwill impairment.

Under the guidance of SFAS No. 142, we concluded that there was no impairment of goodwill for the three and nine-month periods ended September 30, 2002 since our fair value exceeded the book equity value. The following table reflects consolidated results adjusted as though the adoption of the SFAS No. 142 non-amortization of goodwill provision occurred as of the beginning of the three and nine-month periods ended September 30, 2001 and 2002:

	<b>Three Months Ended September 30,</b>	<b>Nine Months Ended September 30,</b>
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	2001	2002	2001	2002
<b>Net income (loss)</b>				
As reported	\$ 2,912	\$ (3,323)	\$ 9,560	\$ (9,469)
Pro forma	\$ 2,953		\$ 9,655	
<b>Basic earnings (loss) per common share</b>				
As reported	\$ .14	\$ (.15)	\$ .45	\$ (.44)
Pro forma	\$ .14		\$ .46	
<b>Diluted earnings (loss) per common share</b>				
As reported	\$ .13	\$ (.15)	\$ .43	\$ (.44)
Pro forma	\$ .13		\$ .43	

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*Goodwill*

Goodwill related to the acquisition of BBICL is as follows:

	December 31, 2001	September 30, 2002
Goodwill	\$ 5,882	\$ 5,882
Less accumulated amortization (prior to adopting SFAS No. 142)	(227)	(227)
<b>Total goodwill, net</b>	<b>\$ 5,655</b>	<b>\$ 5,655</b>

*Intangible Assets (included in other assets)*

Intangible assets are as follows:

	December 31, 2001	September 30, 2002
Customer list related to the acquisition of BBICL	\$ 1,932	\$ 1,932
Other intangible assets	425	425
Less accumulated amortization	(172)	(389)
<b>Total intangible assets, net</b>	<b>\$ 2,185</b>	<b>\$ 1,968</b>

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 five years.

**NOTE 4. CHARGE RELATED TO REGULATORY MATTERS**

By letter dated April 12, 2002, the federal Centers for Medicare & Medicaid Services (CMS) notified us of its conclusions regarding laboratory inspections in June and October 2001 conducted by the California Department of Health Services (CDHS). CMS concluded that our February 2002 response to deficiencies detected in the inspections 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, canceling our approval to receive Medicare and Medicaid payments for services performed, imposing a civil money penalty of \$3,000 per day for each day of non-compliance, and imposing a directed plan of correction by which CMS may 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, and the appeal stayed the revocation of our CLIA certificate during our administrative appeal. The cancellation of Medicare and Medicaid payments was effective for services performed by us on and after February 22, 2002. On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level

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requirements of CLIA and, that Specialty's ability to bill Medicare and Medicaid for its testing services has been reinstated, effective

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June 19, 2002, and that all actions against our CLIA certificate have been rescinded. In order to facilitate an immediate resolution with CMS, we elected to withdraw the appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day of non-compliance during the sanction period. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services performed from February 22, 2002 through June 19, 2002 should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly. We recorded a charge in first quarter 2002 of approximately \$1.2 million 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 second quarter 2002, we did not recognize any net revenue related to Medicare and Medicaid services and recorded a charge of approximately \$0.6 million for additional civil money penalties, costs for inspections, and incremental legal costs related to the CDHS and CMS regulatory actions. With the resolution of sanctions imposed by CMS, we resumed the recognition of net revenue related to Medicare and Medicaid services performed subsequent to June 19, 2002 amounting to approximately \$2.2 million in the third quarter 2002.

### NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	<b>December 31, 2001</b>	<b>September 30, 2002</b>
	<u>                    </u>	<u>                    </u>
Information technology equipment and systems	\$ 25,729	\$ 28,899
Professional equipment	11,134	12,830
Leasehold improvements	8,768	8,843
Land	8,658	8,657
Office furniture and equipment	4,199	4,223
	<u>                    </u>	<u>                    </u>
	58,488	63,452
Less accumulated depreciation and amortization	(31,816)	(36,778)
Construction in progress	423	16,499
	<u>                    </u>	<u>                    </u>
<b>Total property and equipment, net</b>	<b>\$ 27,095</b>	<b>\$ 43,173</b>
	<u>                    </u>	<u>                    </u>

### NOTE 6. COMMITMENTS AND CONTINGENCIES

In March 2002, Specialty 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 the existing location was scheduled shortly thereafter.

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Construction costs incurred through September 30, 2002 were \$13.4 million, of which we financed \$8.8 million with investments and cash generated from operations and \$4.6 million was funded through borrowings from BNP Paribas.

As previously reported, we have been reevaluating the lease and bank loan agreements with our banking partners to amend the terms and conditions of each agreement, including the overall size of the agreements. We have decided to go on balance sheet with the Valencia facility lease transaction, and have provided notice to the banking group led by BNP Paribas that we intend to exercise our purchase option under the agreement, paying off the debt so we can obtain title to the ground lease and facility improvements, thus ending the synthetic lease. Accordingly, we have reflected this in our September 30, 2002 financial statements, with the building now recorded in property and equipment on our balance



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sheet, and the \$4.6 million owed to BNP Paribas reflected as a bank loan in current liabilities. We anticipate paying off the \$4.6 million bank loan in November 2002 and may record one-time charges in fourth quarter of 2002 for expenses associated with the lease termination.

In March 2002, we also obtained a bank loan agreement that provides for a revolving line of credit up to \$40 million. The banking group led by BNP Paribas also provided this loan agreement. We had no borrowings under this bank loan agreement. We are currently reevaluating our existing credit line with our existing banking partners, and we plan to reduce the amount of the credit line, and may terminate this existing agreement.

With the resolution of sanctions imposed by CMS, our focus is on rebuilding client confidence and stabilizing our business. To minimize any disruptions in service to our customers based on planning and executing 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 first half of 2004. Accordingly, the construction of the new facility will be paused. We have notified our construction contractors of our intent to delay the project's completion date, and our plan is to halt the project upon completion of the building's shell. We estimate spending approximately \$18 million in additional capital expenditures to complete the building's shell, targeted for January 2003. We will pursue a more traditional, on-balance sheet financing arrangement with our current banking partners to fund some of these efforts. In addition, we will have further discussions with our construction management partners in fourth quarter, to finalize our budget for the completion of the building's shell as well as identify the additional costs to secure and maintain our facility during this postponement period. Upon restart of the facility construction, we will look to more traditional construction and mortgage financing to complete the project. While the postponement will increase costs, we do not believe the cost of the postponement will materially affect our financial position, results of operations, or cash flows.

### NOTE 7. RESTRUCTURING CHARGE

On June 18, 2002, we announced a reduction in workforce totaling 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.

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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 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. We will continue to examine and refine our business model throughout the remainder of the year.

Severance activities for the nine months ended September 30, 2002 were as follows:

	<u>Expense</u>	<u>Paid Through September 30, 2002</u>	<u>Unpaid Balance at September 30, 2002</u>
Severance and related obligations	\$3,781	\$1,243	\$2,538*

\*

Expected to be disbursed through 2004.

### NOTE 8. EARNINGS PER SHARE

Basic earnings (loss) per share is computed by dividing income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the respective periods. Diluted earnings 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.

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

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	Three Months Ended September 30,		Nine Months Ended September 30,	
	2001	2002	2001	2002
Net income (loss)	\$ 2,912	\$ (3,323)	\$ 9,560	\$ (9,469)
Basic earnings (loss) per common share	\$ .14	\$ (.15)	\$ .45	\$ (.44)
Diluted earnings (loss) per common share	\$ .13	\$ (.15)	\$ .43	\$ (.44)
Basic weighted average shares	21,334	21,903	21,103	21,755
Dilutive effect of outstanding stock options (1)	980		1,101	
Diluted weighted average shares	22,314	21,903	22,204	21,755

(1)

Dilutive potential common shares are excluded from the diluted loss per common share calculation for the three and nine-month periods ended September 30, 2002 because they are antidilutive.

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**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. Our actual results could differ materially from those anticipated by forward-looking statements.*

*For purposes of the following discussion, EBITDA consists of income (loss) from operations before interest, income taxes, depreciation and amortization. EBITDA should not be considered a measure of financial performance under GAAP. Items excluded from EBITDA are significant components in understanding and assessing overall 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 indicators of financial performance or liquidity.*

**Overview**

Specialty Laboratories is a leading research-based clinical laboratory predominantly focused on developing and performing esoteric clinical laboratory tests, which we refer to as assays. We offer a broad, comprehensive menu of esoteric assays, many of which have been developed through our internal research and development efforts. Esoteric assays are complex, comprehensive or unique tests used to diagnose, evaluate and monitor patients. These assays are often performed on sophisticated instruments by highly skilled personnel and are therefore offered by a limited number of clinical laboratories.

Prior to the sanctions imposed by the California Department of Health Services (CDHS) and the federal Centers for Medicare and Medicaid Services (CMS) in March and April 2002, our test menu was comprised of more than 3,200 esoteric assays. However, in order to ensure compliance with the CDHS personnel licensing requirements, we changed to using only California-licensed clinical laboratory scientists to perform clinical testing, and reorganized our test menu to focus our efforts on core assays with the greatest importance to our clients. Accordingly, we discontinued many low volume assays. Certain of these assays can be replaced by other Specialty assays or outsourced to other 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.

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We believe that our typical esoteric assay is priced at approximately twice that of a routine test. Our assays also have higher costs than routine tests due to the necessity of specialized laboratory instruments and highly skilled laboratory personnel. If we are successful in the expansion of our hospital customer base, and we obtain or renew large customer or group purchasing organization contracts, our average price per assay will decrease as hospital esoteric referral testing is at lower average pricing and as large contracts typically incorporate volume discounts.

On February 20, 2001, we completed the acquisition of substantially all of the assets of BBI Clinical Laboratories, Inc., a wholly-owned subsidiary of Boston Biomedica, Inc., a public company. We

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paid \$9.5 million in cash which was accounted for as a purchase in the first quarter of 2001. The acquisition agreement provided for a reduction of the purchase price if certain performance measurements were not achieved. A subsequent evaluation of these performance measurements resulted in a return of \$358,000 by BBI Clinical Laboratories to us in December 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.

In December 2001, we purchased a 13.8 acre site in Valencia, California. We are in the process of building a 195,000 square foot facility which will enable us to consolidate all of our laboratory and administrative functions in one location. Construction began during the second quarter of 2002 and was to be completed in the second half of 2003. In October 2002, we announced that we would postpone the move to our new facility in Valencia until the first half of 2004. Accordingly, the construction of the new facility will be paused. 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. We have notified our construction contractors of our intent to delay the project's completion date, and our plan is to halt the project upon completion of the building's shell. We estimate spending approximately \$18 million in additional capital expenditures to complete the building's shell, targeted for January 2003. We will pursue a more traditional, on-balance sheet financing arrangement with our current banking partners to fund some of these efforts. Upon restart of the facility construction, we will look to more traditional construction and mortgage financing to complete the project.

In March 2002, we completed a \$100 million financing transaction. This credit facility has 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 line of credit with the same lenders that provide the lease financing, with proceeds available for general corporate purposes. Prior to this transaction, we had an existing line of credit of \$30 million, which was provided by Union Bank of California. Our new credit facility, arranged by BNP Paribas, includes Union Bank, US Bank, First Union National Bank, as co-syndication agents, and Allied Irish Banks, Manufacturers Bank, and Bank Leumi, USA, as participants. Our new laboratory and headquarters facility was to be leased from BNP Paribas Leasing Corporation, a substantive leasing company with assets in excess of \$1.5 billion. As previously reported, we have been reevaluating the lease and bank loan agreements with our banking partners to amend the terms and conditions of each agreement, including the overall size of the agreements. We have decided to go on balance sheet with this transaction, and have provided notice to the banking group led by BNP Paribas that we intend to exercise our purchase option under the agreement, paying off the debt so we can obtain title to the ground lease and facility improvements, thus ending the synthetic lease. Accordingly, we have reflected this in our September 30, 2002 financial statements, with the building now recorded in property and equipment on our balance sheet, and the \$4.6 million owed to BNP Paribas reflected as a bank loan in current liabilities. We anticipate paying off the \$4.6 million bank loan in November 2002 and may record one-time charges in fourth quarter of 2002 for expenses associated with the lease termination.

By letter dated March 28, 2002, CDHS notified us of its intent to impose alternative sanctions of a directed plan of correction, random onsite monitoring, and a civil money penalty based upon deficiencies cited during 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. We filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS on April 26, 2002. In addition, on April 26, 2002, we requested that CDHS rescind its proposed sanctions outlined in the March 28, 2002

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letter based on our supplemental submission. 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 also imposed sanctions of a civil money penalty of \$1,000 per day for 344 days (i.e., \$344,000), plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections. We did not appeal these imposed sanctions.

On April 2, 2002, Quest Diagnostics Inc. announced that they had entered into an agreement to acquire Unilab Corporation. Unilab, our largest customer, comprised approximately 8% of our net revenue for the year ended December 31, 2001. Once the acquisition is complete, we believe that Quest will perform the majority of testing previously sent to us by Unilab. As a result, Unilab did not renew our agreement, which expired in October of 2002. We entered into an interim agreement with Unilab in October 2002 which will allow for a more orderly reduction of test volumes, which we estimate will occur during the fourth quarter of 2002, and we have already seen a reduction in test volumes sent to us in October 2002. While we believe that there will be a logical wind down of testing sent to us in the fourth quarter, we do expect it to have a significant negative impact on our accession volumes in the fourth quarter of 2002, and we will see further negative impact in the first quarter of 2003.

By letter dated April 12, 2002, CMS notified us of its conclusions regarding laboratory inspections in June and October 2001 conducted by CDHS. CMS concluded that our February 2002 response to deficiencies detected in the inspections 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, canceling our approval to receive Medicare and Medicaid payments for services performed, imposing a civil money penalty of \$3,000 per day for each day of non-compliance, and imposing a directed plan of correction by which CMS may 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, and the appeal stayed the revocation of our CLIA certificate during our administrative appeal. The cancellation of Medicare and Medicaid payments was effective for services performed by us on and after February 22, 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 has been reinstated as of June 19, 2002, and that all actions against our CLIA certificate have been rescinded. In order to facilitate an immediate resolution with CMS, we elected to withdraw the appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day of non-compliance during the sanction period. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services performed from February 22, 2002 through June 19, 2002 should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly.

On April 22, 2002, James B. Peter, M.D., Ph.D., resigned from the positions of chairman and chief executive officer. On May 21, 2002, we announced that Douglas S. Harrington, M.D. was named chief executive officer. Dr. Harrington has more than 18 years of laboratory services and diagnostic devices industry experience. He served as chief executive officer with ChromaVision Medical Systems from 1996 to 2001, held various executive positions at Nichols Institute including president and laboratory director, is board certified in anatomic, clinical pathology and hematology, and is fully licensed as a Clinical Laboratory Director. Dr. Harrington has served on our board of directors since 1996. As announced on April 22, 2002, Thomas R. Testman was elected by our board of directors to serve as

chairman. Mr. Testman, a retired managing partner with Ernst & Young since 1992, has served on our board of directors since 1996.

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. Although we do not anticipate a material business impact from the discontinuation, the exact consequences are difficult to predict, particularly since the termination of the contractual relationship with Novation does not prevent its members from using our services.

On June 18, 2002, we announced a reduction in workforce totaling 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 \$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.

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On June 24, 2002, we announced the appointment of Terrance H. Gregg to our board of directors. Mr. Gregg, former president of Medtronic MiniMed, brings over 20 years of healthcare experience to the board. He assumes the board seat vacated by Paul F. Beyer who resigned as our president and chief operating officer as announced on June 7, 2002.

On July 23, 2002, we announced the appointment of Mark R. Willig to the position of Vice President, Sales. Mr. Willig has nearly 20 years of experience in the diagnostics and clinical reference laboratory industries, and more recently served as Vice President of Sales at Myriad Genetics from 1997 until joining Specialty.

### **Recent Developments**

On October 24, 2002 we received notice from the College of American Pathologists that, following the completion of their recent inspections conducted in October 2002, our laboratory has been re-certified.

On October 24, 2002, we announced the resignation of John C. Kane from our board of directors. Mr. Kane had been a member of the board of directors since March 2001. As of October 24, 2002, the Company's board of directors consisted of a total of eight members, including five independent directors.

On October 25, 2002, we announced that we would postpone the move to our new laboratory and administrative facility in Valencia, California, until the first half of 2004. Accordingly, construction activity will be paused upon completion of the building's shell, projected for January 2003. We estimate spending approximately \$18 million in additional capital expenditures to complete the building shell by January 2003. The company will pursue a more traditional, on-balance sheet financing arrangement with its current banking partners to fund some of these efforts. Upon restart of the project, we plan to obtain construction and mortgage financing to complete the facility.

In addition, in October 2002 we have notified the banking group led by BNP Paribas that we intend to exercise our purchase option under our lease agreement, sometimes referred to as a "synthetic lease", and to obtain title to the ground lease and facility improvements, thus ending the synthetic lease. BNP has financed approximately \$4.6 million of the \$13.4 million expended to date on

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the construction project. We anticipate paying off the \$4.6 million bank loan in November 2002 and may record one-time charges in fourth quarter of 2002 for expenses associated with the lease termination.

### **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 of America. 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. During second quarter of 2002, we did not recognize any net revenue related to Medicare and Medicaid services; this is a result of CMS canceling our approval to receive Medicare and Medicaid payments for services performed during the sanction period of February 22, 2002 through June 19, 2002. With the resolution of sanctions imposed by CMS, in the third quarter of 2002, we resumed the recognition of net revenue related to Medicare and Medicaid services performed subsequent to June 19, 2002.

#### *Expense Recognition*

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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

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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, 2002, we expect to amortize approximately \$176,000 of deferred stock-based compensation in future periods. We expect to amortize this deferred stock-based compensation approximately as follows: \$55,000 during fourth quarter of 2002, \$106,000 during 2003, and \$15,000 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.

In January 1, 2002, we adopted the Statements of Financial Accounting Standards (SFAS) No. 141, "Business Combinations" and SFAS No. 142, "Goodwill and Other Intangible Assets". Under the new rules, 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 applied an undiscounted cash flow model to assess the fair value of our Company, which did not result in the recognition of goodwill impairment. We concluded that there was no impairment of goodwill for the three and nine-month periods ended September 30, 2002 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 for the three and nine-months ended September 30, 2001 and 2002.

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2001</b>	<b>2002</b>	<b>2001</b>	<b>2002</b>
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of services	58.5	81.0	57.0	74.0
Selling, general and administrative (exclusive of stock-based compensation charges)	31.6	35.6	32.2	36.1
Restructuring charge		1.4		3.7
Charge related to regulatory matters				1.7
Operating income (loss)	9.3	(18.2)	10.1	(15.5)
Income (loss) before income taxes (benefits)	11.2	(17.1)	12.2	(14.4)

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	Three Months Ended September 30,		Nine Months Ended September 30,	
Net income (loss)	6.8	(10.2)	7.3	(8.6)

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### Quarter Ended September 30, 2002 Compared with Quarter Ended September 30, 2001

#### *Net Revenue*

Net revenue decreased approximately \$10.3 million, or 24.1%, to \$32.5 million for the quarter ended September 30, 2002 from \$42.8 million for the quarter ended September 30, 2001. The decline in revenues in the third quarter of 2002 as compared to the year ago quarter resulted primarily from a reduction in testing volumes coupled with a decline in the aggregate average selling price. Testing volumes, as measured by patient accessions, declined by approximately 13% over the third quarter of 2001 resulting in total accessions exceeding 685,000 for the third quarter of 2002. This also reflects a sequential decline from the second quarter of 2002 of more than 7%. This volume decline is a direct result of the loss of business relating to the regulatory issues the company experienced in the second quarter of this year. We experienced a year-over-year reduction of approximately 13% in the aggregate average selling price due to our continued client mix-shift to more hospital based business and the reduction in independent laboratory business. With the resolution of sanctions imposed by CMS, in the third quarter of 2002, we resumed the recognition of net revenue related to Medicare and Medicaid services performed subsequent to June 19, 2002, which resulted in an increase of nearly 3% in the aggregate average selling price from second quarter of 2002. Our fourth quarter is traditionally a slower quarter, with fewer effective workdays, due to the number of holidays in the quarter. This seasonality, which approximates a decline of 20,000 accessions in the quarter, will impact fourth quarter accession volumes. In addition, we will begin to see the wind-out of the Unilab business in October. The loss of Unilab will be significant to the fourth quarter of 2002 and the first quarter of 2003. Accordingly, we expect total accession volumes to fall below 620,000 for the fourth quarter of 2002, assuming no further large client losses. We do not expect these reductions will be offset by recoveries of lost business nor from new business in the fourth quarter.

#### *Cost of Services*

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased approximately \$1.3 million, or 5.1% to \$26.3 million for the third quarter 2002 from \$25.0 million for the comparable prior year quarter, and represents a sequential decline of approximately \$2.2 million from the second quarter of 2002. The increase from the prior year quarter was primarily a result of operational changes implemented in the second quarter of 2002 to ensure compliance with personnel licensing and other regulatory requirements. In April 2002, we suspended more than one thousand tests to ensure full and immediate compliance with personnel licensing requirements for our laboratory. Since April, the orders we continued to receive for the suspended tests were forwarded to other laboratories for processing. This operational change resulted in an increase of outsourced testing, adding over \$2.6 million in cost to the third quarter 2002 as compared to the prior year third quarter. Additionally, the use of only California licensed personnel for analytical procedures adds approximately \$350,000 per quarter of incremental ongoing costs. This increase in cost is partially offset by approximately \$1.6 million in lower reagent and distribution costs due to the lower accession volume for third quarter of 2002. With the successful hiring, training, and certification of additional California licensed personnel during the quarter, as of September 30, 2002, we completed the reinstatement of tests that account for more than 50% of the outsourced volume. As of October 24, 2002, we have reinstated tests that account for approximately 70% of the test volumes we had been outsourcing and we expect to reduce outsourced testing costs in the fourth quarter by approximately \$1.5 million from the third quarter levels. As a percentage of revenue, cost of services increased to 81.0% for the quarter ended September 30, 2002 from 58.5% from the comparable prior year quarter.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses (S,G&A) decreased approximately \$2.0 million, or 14.7%, to \$11.6 million for the third quarter 2002 from \$13.6 million for the third quarter 2001, and

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represents a sequential decline of approximately \$2.9 million from the second quarter of 2002. This decrease was primarily due to lower salary and benefit costs over \$1.1 million resulting from our reduction in workforce in June 2002 and an additional \$500,000 resulted from certain sales and marketing costs that declined commensurate with our revenues. In addition, approximately \$300,000 of costs was incurred in the third quarter of 2001 for the operation of BBI Clinical Laboratories facility in Connecticut, in which we ceased operations last year. As a percentage of revenue, selling, general and administrative expenses increased to 35.6% for the quarter ended September 30, 2002 from 31.6% from the

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comparable prior year quarter.

### *Stock-Based Compensation Charges*

Stock-based compensation charges decreased from approximately \$228,000 for the third quarter 2001 to \$49,000 for the third quarter 2002. This decline is a result of normal amortization coupled with forfeited stock options resulting from the second quarter 2002 reduction in workforce that had the effect of reducing future amortization.

### *Restructuring Charge*

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 \$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.

During third quarter of 2002, approximately \$0.6 million of severance payments were disbursed related to both the June and September 2002 reductions in workforce. The remaining severance costs of approximately \$2.5 million will be disbursed from 2002 through 2004.

### *Charge Related to Regulatory Matters*

In April 2002, we received a letter from CMS imposing certain sanctions as a result of laboratory inspections conducted by the California Department of Health Services (CDHS) in June and October 2001. The sanctions included cancellation of Medicare and Medicaid payments for services performed by the Company on and after February 22, 2002 and a civil money penalty of \$3,000 per day for each day of non-compliance on or after February 22, 2002. On July 17, 2002 we were informed by CMS that it had deemed Specialty to be in compliance with all condition level requirements of CLIA as of June 19, 2002 and that Specialty's ability to bill Medicare and Medicaid for its testing services has been reinstated as of June 19, 2002. In addition, the July 17 letter from CMS notified us of a civil money penalty of \$3,000 per day for each day of non-compliance from February 22, 2002 through June 19, 2002. In order to facilitate an immediate resolution with CMS, we elected to withdraw our appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day of non-compliance during the sanction period. In second quarter 2002, we recorded a charge of approximately \$612,000 for the regulatory fines, inspection costs and incremental legal expenses related to the CDHS and CMS regulatory actions. In third quarter 2002, we did not record any additional charges related to regulatory matters, and we do not anticipate any further charges as a result of this matter.

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

Net interest income decreased from approximately \$807,000 to \$345,000 from the third quarter 2001 to the third quarter 2002, respectively. The decrease was primarily due to the significant interest

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rate declines that occurred during 2001, resulting in lower interest yields on our investments, coupled with cash utilized for capital expenditures and the new facility.

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

Provision for income taxes (benefits) reflect a tax benefit of approximately \$2.2 million for the third quarter 2002 as compared to a \$1.9 million tax expense for the comparable prior year quarter. Our effective tax rate (benefit) was 40.3% for the third quarter 2002 as compared to 39.5% for the third quarter 2001.

### *Net Income (Loss)*

A net loss of \$3.3 million was recorded for the third quarter of 2002 compared to net income of \$2.9 million for the comparable prior year quarter. This resulted in a decrease of approximately \$6.2 million. These results reflect the impact of lower accession volumes, lower aggregate average selling price, increased outsourced testing costs, and additional one-time charges for severance costs and the write-off of certain assets



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related to our clinical trials business. As a percentage of net revenue, a net loss of 10.2% was recorded for the quarter ended September 30, 2002 as compared to net income of 6.8% from the comparable prior year quarter.

### *EBITDA*

EBITDA reflected a loss of approximately \$4.1 million for the third quarter 2002 as compared to earnings of \$5.8 million for the comparable prior year quarter, reflecting a decrease of approximately \$9.9 million. As a percentage of net revenue, EBITDA decreased to a loss of 12.6% for the quarter ended September 30, 2002 from earnings of 13.5% for the quarter a year ago. The decrease is primarily due to the impact of lower accession volumes, lower aggregate average selling price, increased outsourced testing costs, and additional one-time charges for severance costs and the write-off of certain assets related to our clinical trials business.

### **Nine Months Ended September 30, 2002 Compared with Nine Months Ended September 30, 2001**

#### *Net Revenue*

Net revenue decreased approximately \$21.5 million, or 16.4%, to \$110.3 million for the nine months ended September 30, 2002 from \$131.8 million for the nine months ended September 30, 2001. Revenues for the current nine-month period were impacted primarily by the decline in aggregate average selling price and the loss of Medicare and Medicaid revenue, in addition to a decline in testing volumes. Testing volumes for the first nine months of 2002 declined by approximately 3% when compared to the prior year period. We experienced a decline of more than 13% in the aggregate average selling price for the first nine months of 2002 as compared to the first nine months of 2001. This decline in aggregate average selling price was due to our continued client mix-shift to more hospital based business and the reduction in independent laboratory business. We continued to perform testing for patient-beneficiaries of Medicare and Medicaid for the period of February 22, 2002 through June 19, 2002, despite the fact that, under CMS sanctions, we were not permitted to bill for such services while the sanctions were in effect. During the nine months ended September 30, 2002, approximately \$2.5 million of net revenue was recorded for Medicare and Medicaid services in the first quarter of 2002, with approximately \$1.1 million recorded from February 22, 2002, the effective date of the CMS actions, through March 31, 2002. The \$1.1 million of net revenues were fully reserved during the first quarter of 2002 as described below in the section "Charge Related to Regulatory Matters". For the period of April 1, 2002 through June 30, 2002, approximately \$2.3 million of net revenue was not recognized due to the lack of billing rights for Medicare and Medicaid services. For the period of July 1, 2002 through September 30, 2002, with the resolution of sanctions imposed by CMS, we

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recognized net revenue of approximately \$2.2 million for testing performed for patient-beneficiaries of Medicare and Medicaid.

#### *Cost of Services*

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$6.5 million, or 8.7%, to \$81.6 million for the first nine months of 2002 from \$75.1 million for the comparable prior year period. The increase was primarily a result of operational changes implemented during the nine months ended September 30, 2002 to ensure compliance with personnel licensing and other regulatory requirements. In April 2002, we suspended more than one thousand tests to ensure full and immediate compliance with personnel licensing requirements for our laboratory. Since April, the orders we continued to receive for the suspended tests were forwarded to other laboratories for processing. This operational change resulted in an increase of outsourced testing, adding approximately \$4.7 million in cost to the period ended September 30, 2002 as compared to the prior year period. Additional costs of approximately \$1.1 million were incurred to meet state of California requirements for licensed personnel and approximately \$350,000 of one-time costs were incurred associated with the subleasing of our Memphis facility for the period July 1, 2002 through September 14, 2007. This increase is partially offset by approximately \$500,000 in lower reagent and distribution costs due to lower accession volumes. With the successful hiring, training, and certification of additional California licensed personnel during the third quarter of 2002, as of September 30, 2002, we completed the reinstatement of tests that account for more than 50% of the outsourced volume. As of October 24, 2002, we have reinstated tests that account for approximately 70% of the test volumes we had been outsourcing and we expect to reduce outsourced testing costs in fourth quarter by \$1.5 million from the third quarter levels. Additionally, the use of only California licensed personnel for analytical procedures adds approximately \$350,000 per quarter of incremental ongoing costs. As a percentage of revenue, cost of services increased to 74.0% for the nine months ended September 30, 2002 from 57.0% from the comparable prior year period.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses (SG&A) decreased \$2.7 million, or 6.4%, to \$39.8 million for the first nine months of 2002 from \$42.5 million for the first nine months of 2001. This decrease is due primarily to the approximately \$1.4 million of costs incurred during

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the first nine months of 2001 for the acquisition and operation of BBI Clinical Laboratories facility in Connecticut, in which we ceased operations last year. Of the remaining decrease, salary and benefit costs are lower by approximately \$1.1 million as a result of our reduction in workforce in June 2002 and approximately \$700,000 resulted from certain sales and marketing costs that declined commensurate with our lower revenue volume. As a percentage of revenue, selling, general and administrative expenses increased to 36.1% for the first nine months of 2002 as compared to 32.2% for the same period last year.

### *Stock-Based Compensation Charges*

Stock-based compensation charges decreased from approximately \$907,000 recorded in the first nine months of 2001 to approximately \$(9,000) recorded in the first nine months of 2002. This decrease was primarily due to forfeited stock options resulting from the second quarter 2002 reduction in workforce that had the effect of reducing future amortization.

### *Restructuring Charge*

On June 18, 2002, we announced a reduction in workforce totaling 10% as part of an overall restructuring plan. 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.

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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 \$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 \$1.2 million of severance and related obligations have been paid as of September 30, 2002. The remaining severance costs of approximately \$2.5 million will be disbursed from 2002 through 2004.

### *Charge Related to Regulatory Matters*

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 sanctions included cancellation of Medicare and Medicaid payments for services performed by the Company on and after February 22, 2002 and a civil money penalty of \$3,000 per day for each day of non-compliance on or after February 22, 2002. On July 17, 2002 we were informed by CMS that it had deemed Specialty to be in compliance with all condition level requirements of CLIA as of June 19, 2002 and that Specialty's ability to bill Medicare and Medicaid for its testing services has been reinstated as of June 19, 2002. In addition, the July 17 letter from CMS notified us of a civil money penalty of \$3,000 per day for each day of non-compliance from February 22, 2002 through June 19, 2002. In order to facilitate an immediate resolution with CMS, we elected to withdraw our appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day of non-compliance during the sanction period. We have recorded a charge relating to these actions of approximately \$1.9 million for the nine months ended 2002. This \$1.9 million charge is comprised of \$1.1 million to reserve for Medicare and Medicaid services earned and billed for the period of February 22, 2002 to March 31, 2002 with the remaining balance for regulatory fines, inspection costs, and incremental legal expenses related to the CDHS and CMS regulatory actions. In third quarter 2002, we did not record any additional charges related to regulatory matters, and we do not anticipate any further charges as a result of this matter.

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

Net interest income decreased from approximately \$2.8 million to \$1.2 million from the nine months ended 2001 to the nine months ended 2002. The decrease is primarily due to the significant interest rate declines that occurred during 2001, resulting in lower interest yields on our investments coupled with cash utilized for capital expenditures and the new facility.

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

Provision for income taxes (benefits) was approximately a \$6.4 million benefit for the first nine months of 2002 as compared to \$6.5 million in expense for the comparable prior year period. Our effective tax rate (benefit) was approximately 40.3% for the first nine months of 2002 as compared to 40.6% for the first nine months of 2001.

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### *Net Income (Loss)*

A net loss of \$9.5 million was recorded for the first nine months of 2002 compared to net income of \$9.6 million for the comparable prior year period. This resulted in a decrease of approximately \$19.1 million. The decrease is primarily due to significant one-time charges including severance costs and the write-off of certain assets related to our clinical trials business, the loss of Medicare and

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Medicaid profits, and regulatory measures including fines, inspection costs, and incremental legal expenses related to the CDHS and CMS regulatory actions, totaling approximately \$7.3 million for the nine months ended September 30, 2002. In addition, these results reflect the impact of increased outsourced testing costs totaling approximately \$4.7 million for the first nine months of 2002. This decrease is also related to our year-over-year reduction of more than 13% in the aggregate average selling price. As a percentage of net revenue, a net loss of 8.6% was recorded for the nine months ended September 30, 2002 as compared to net income of 7.3% for the comparable prior year period.

### *EBITDA*

EBITDA reflected a loss of \$11.8 million for the first nine months of 2002 as compared to earnings of \$18.5 million for the comparable prior year period. As a percentage of net revenue, EBITDA decreased to a loss of 10.7% for the nine months ended June 30, 2002 from earnings of 14.1% for the comparable prior year period. The decrease is primarily due to significant one-time charges including severance costs and the write-off of certain assets related to our clinical trials business, lost Medicare and Medicaid profits, and regulatory measures including fines, inspection costs, and incremental legal expenses related to the CDHS and CMS regulatory actions, totaling approximately \$7.3 million for the nine months ended September 30, 2002. In addition, these results reflect the impact of increased outsourced testing costs totaling approximately \$4.7 million for the first nine months of 2002. This decrease is also related to our year-over-year reduction of more than 13% in the aggregate average selling price.

### **Liquidity and Capital Resources**

Net cash used in operating activities was \$901,000 in the first nine months 2002 as compared to net cash provided by operating activities of \$14.9 million for the prior year period. This change 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 due primarily to increased outsourced testing, which provided \$2.0 million. In addition, cash was used as a result of an increase in our tax benefits, as reflected in an income tax receivable of \$6.2 million, related to the operating loss.

Investing activities in the nine months ended September 30, 2002 provided net cash of \$13.7 million as we repositioned approximately \$34.8 million of short-term and long-term investments to cash and cash equivalents, offset by approximately \$21.1 million in capital expenditures. This represents a \$17.3 million increase in capital expenditures from the first nine months of 2001. This increase is primarily due to the \$13.4 million of new facility construction costs, of which we financed \$8.8 million of these construction costs with investments and cash generated from operations, and \$4.6 million of which was funded from borrowings from BNP Paribas, and are reflected in financing activities as borrowings under bank loan. Of the remaining capital expenditures, \$2.9 million was expended for the upgrade of our information technology infrastructure and the move of our data center to a third party location which will be completed during the first half of 2003. This compares to a cash use of \$72.5 million for the first nine months of 2001, as we repositioned approximately \$59.2 million of cash to short-term and long-term investments and paid \$9.5 million in cash for the acquisition of BBI Clinical Laboratories.

Net cash provided by financing activities was \$5.9 million for the first nine months ended September 30, 2002 as compared to \$1.5 million for the first nine months 2001. Cash provided in the first nine months of 2002 was primarily from funds borrowed from BNP Paribas for our new facility construction and from the exercise of stock options and the sale of common stock to employees through the Employee Stock Purchase Plan.

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As previously reported, we have been reevaluating the lease and bank loan agreements with our banking partners to amend the terms and conditions of each agreement, including the overall size of the agreements. We have decided to go on balance sheet with the Valencia facility lease transaction, and have provided notice to the banking group led by BNP Paribas that we intend to exercise our purchase option under the agreement, paying off the debt so we can obtain title to the ground lease and facility improvements, thus ending the synthetic lease. Accordingly,

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we have reflected this in our September 30, 2002 financial statements, with the building now recorded in property and equipment on our balance sheet, and the \$4.6 million owed to BNP Paribas reflected as a bank loan in current liabilities. We anticipate paying off the \$4.6 million bank loan in November 2002 and may record one-time charges for expenses associated with the lease termination.

In March 2002, we also obtained a bank loan agreement that provides for a revolving line of credit up to \$40 million. The banking group led by BNP Paribas also provided this loan agreement. We had no borrowings under this bank loan agreement. We are currently reevaluating our existing credit line with our existing banking partners, and we plan to reduce the amount of the credit line and may terminate this existing agreement.

With the resolution of sanctions imposed by CMS, our focus is on rebuilding client confidence and stabilizing our business. To minimize any disruptions in service to our customers based on planning and executing 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 first half of 2004. Accordingly, the construction of the new facility will be paused. We have notified our construction contractors of our intent to delay the project's completion date, and our plan is to halt the project upon completion of the building's shell. We estimate spending approximately \$18 million in additional capital expenditures to complete the building's shell, targeted for January 2003. We will pursue a more traditional, on-balance sheet financing arrangement with our current banking partners to fund some of these efforts. In addition, we will have further discussions with our construction management partners in fourth quarter, to finalize our budget for completion of the building's shell as well as identify the additional costs to secure and maintain our facility during this postponement period. Upon restart of the facility construction, we will look to more traditional construction and mortgage financing to complete the project. While the postponement will increase costs, we do not believe the cost of the postponement will materially affect our financial position, results of operations, or cash flows.

Our cash and cash equivalents combined with short-term and long-term investments totaled approximately \$59.1 million at September 30, 2002 as compared to \$78.9 million at September 30, 2001. Our investments, accounting for \$25.3 million, are primarily in commercial paper, corporate bonds, and government securities. We expect that existing cash and cash equivalents, short and long-term investments will be sufficient to fund our operations, meet our capital requirements to support our growth, and allow strategic technology licensing for the next year.

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### **Risk Factors**

*Any investment in shares of our common stock involves a high degree of risk. You should consider carefully the following information about these risks, together with all of the other information contained in this Quarterly Report and our Form 10-K before you decide to buy our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially adversely affected. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial also may impair our business. Any adverse effect on our business, financial condition or results of operations could result in a decline in the trading price of our common stock and the loss of all or part of your investment.*

### **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.

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### *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 and Medicaid Services, or CMS, under CLIA. As a result, the laboratory

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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 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 March 28, 2002, CDHS notified us of its intent to impose alternative sanctions of a directed plan of correction, random onsite monitoring, and a civil money penalty based upon deficiencies cited during 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 of its conclusions regarding laboratory inspections in June and October 2001 conducted by CDHS. CMS concluded that our February 2002 response to deficiencies detected in the inspections did not constitute a credible allegation of compliance. As a result, CMS imposed certain sanctions, including notice of revocation of our CLIA certificate, canceling our approval to receive Medicare and Medicaid payments for services performed, imposing a civil money penalty of \$3,000 per day for each day of non-compliance, and imposing a directed plan of correction by which CMS may 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, and the appeal stayed the revocation of our CLIA certificate during our administrative appeal. The cancellation of Medicare and Medicaid payments was effective for services performed by us on and after February 22, 2002.

We filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and CMS on April 26, 2002. In addition, on April 26, 2002, we requested that CDHS rescind its proposed sanctions outlined in the March 28, 2002 letter based on our supplemental submission. 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 also imposed sanctions of a civil money penalty of \$1,000 per day for 344 days (i.e., \$344,000), plus \$20,430 for the cost of conducting their investigations, and imposed onsite monitoring for three years, including unannounced inspections. We did not appeal these imposed sanctions.

On July 17, 2002, CMS notified us that it had deemed Specialty in compliance with all condition level requirements of CLIA as of June 19, 2002, that Specialty's right to bill Medicare and Medicaid for its testing services has been reinstated as of June 19, 2002, and that all actions against our CLIA certificate have been rescinded. In order to facilitate an immediate resolution with CMS, we elected to withdraw the appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We also did not challenge CMS' imposition of a monetary fine of \$351,000, representing \$3,000 per day of non-compliance during the sanction period. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services performed from February 22, 2002 through June 19, 2002 should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly.

We will be subject to additional future inspections. No assurances can be given that our facilities will pass all future inspections conducted to ensure compliance with federal or any other applicable licensure or certification laws. Any inability to comply with federal, state or other

applicable regulations could result in substantial monetary penalties, suspension of Medicare payments and/or loss of licensure, certification or accreditation, and could divert a substantial amount of management's time

and resources. In addition, substantial expenditures are required on an ongoing basis to ensure that we comply with existing regulations and to bring us into compliance with newly instituted regulations.

#### *Food & Drug Administration*

Neither the FDA nor any other governmental agency currently fully regulates the new assays we internally develop. Although the FDA previously asserted that its jurisdiction extends to tests generated in a clinical laboratory, it has allowed these tests to be run and the results commercialized without FDA premarket approval. However, we cannot predict the extent of future FDA regulation and there can be no assurance that the FDA will not consider testing conducted at a clinical laboratory to require premarketing clearance. Hence, we might be subject in the future to greater regulation, or different regulations, that could have a material effect on our finances and operations.

#### *Anti-Kickback Regulations*

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

#### *Fee-Splitting*

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

#### **Our accessions have declined and may continue to decline.**

Because of uncertainty surrounding the sanctions imposed by CMS, questions about our client's 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 to more than 685,000 for the third quarter of 2002. We expect our total accessions to fall below 620,000 for the fourth quarter of 2002. While we expect accession volumes will stop declining, and will begin to grow again following the previously announced resolution of our regulatory issues with CMS, due to the potential of continued uncertainty for our clients and the loss of much of our Unilab business, we cannot provide any assurances that our clients will resume sending us specimens for testing, nor can we provide assurances that our accessions will stop declining or begin to increase again.

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

For the years ended December 31, 2001 and 2000, services to Unilab Corporation accounts comprised less than 8.0% and 9.6% of our net revenue, respectively. We previously entered into an

agreement with Unilab in which it agreed to refer to us, until the agreement expired in October 2002, at least 90% of the esoteric laboratory services it outsources each year or, in the event of a change of control of Unilab or the purchase by Unilab of a licensed clinical laboratory with a

test menu materially broader than that of Unilab, at least \$800,000 of esoteric laboratory services per month.

On April 2, 2002, Quest Diagnostics Inc. announced that they had entered into an agreement to acquire Unilab. Once the acquisition of Unilab is complete, we believe that Quest will perform the majority of testing previously sent to us by Unilab. As a result, Unilab did not renew our agreement, which expired in October 2002. In October 2002 we entered into a new agreement with Unilab which should provide for a more orderly reduction of testing volumes. However, the new agreement does not obligate Unilab to provide us with minimum assay referrals, and is cancelable by either party upon thirty days prior notice. We have already seen a reduction in test volumes sent to us by Unilab in October 2002, and we expect further reductions following the completion of Unilab's acquisition by Quest. If the new agreement with Unilab is terminated, or if Unilab starts performing certain testing at its own facilities, Unilab may further reduce or stop sending specimens to us for testing. We expect Unilab's purchase of our services to be materially reduced during the fourth quarter of 2002, and we expect such reductions to also negatively affect the first quarter of 2003. However, we cannot predict what the timing or extent of volume loss from Unilab will be, and such reductions or loss of testing volume may significantly impact other future quarters. Any reduction in the purchase of our service by Unilab will decrease our net revenue.

**Recent sanctions by the federal Centers for Medicare and Medicaid Services (CMS) and the California Department of Health Services (CDHS) may adversely affect our material agreements.**

In light of the recent actions imposed by CMS and CDHS, we may be in default of certain material agreements, including the credit and various lease agreements. If we are in default of any of our material agreements, our business will be harmed. For example, if we are in default or breach of our credit or lease agreements, the lenders may require us to repay any amounts due under the credit facility and we will have to assume the costs of construction of our new facility in Valencia, California from our cash, cash equivalents or investments. We have been reevaluating the lease and bank loan agreements with our banking partners to amend the terms and conditions of each agreement, including the overall size of the agreements. We have decided to go on balance sheet with this Valencia facility lease transaction, and have provided notice to the banking group led by BNP Paribas that we intend to exercise our purchase option under the agreement, paying off the debt so we can obtain title to the ground lease and facility improvements. We are currently reevaluating our existing credit line with our existing banking partners, and we plan to reduce the amount of the credit line and may terminate this existing agreement. Upon the restart of our new facility construction, we will seek traditional construction and mortgage financing to complete the project. There can be no assurance we will be able to secure these new financing agreements.

**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. For the year ended December 31, 2001, sales to our competitors were approximately \$10 million or approximately 6% of our net revenue. These parties may decide not to refer assays to us because they wish to develop and market assays similar to ours. For example, in July 1997, SmithKline Beecham Clinical Laboratories, or SmithKline Labs, began to significantly limit the number of assays it referred to us. We believe that SmithKline Labs terminated its relationship with us because it decided to offer assays similar to ours. In 1996, SmithKline Labs comprised 21.7% of our net revenue, whereas in 2001, after being acquired by Quest, SmithKline Labs (excluding Quest

accounts prior to the acquisition) only comprised approximately 2% of our net revenue. If other independent laboratories decide to reduce or discontinue purchases of our assays for competitive reasons, it will reduce our net revenue.

**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, and acquired Clinical Diagnostics Services, Inc., a provider of routine and esoteric testing. Quest also recently announced that it is in the process of acquiring Unilab Corporation, a leading clinical testing laboratory. Acquisitions among existing and future competitors may emerge and they may 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; and

costs related to acquisitions of technologies or businesses.

We plan to expand our sales and marketing, research and development and general and administrative efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, 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 and approximately 6.9% of our net revenue in 2001. 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 include 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 have been rescinded. In order to facilitate an immediate resolution with CMS, we elected to withdraw the appeal of the sanctions we filed with CMS on April 17, 2002, and we will not seek reimbursement for services performed for beneficiaries of Medicare and Medicaid during the sanction period of February 22, 2002 through June 19, 2002. We did not challenge CMS' imposition of a monetary fine of \$351,000. We believe that the cancellation of our approval to receive Medicare and Medicaid payments for services

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performed from February 22, 2002 through June 19, 2002 should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but instead applies only to testing for which we bill the Medicare and Medicaid programs directly. However, we can provide no assurances that the CMS will not seek to prevent our clients from being reimbursed for services we performed during the period from February 22, 2002 through June 19, 2002.

**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 many of our executive officers, including Dr. Harrington. However, most members of our current senior management group have been recruited and hired over the past 2 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 first 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 Company 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 some of the leases to buildings we currently occupy in Santa Monica, California expire in 2003, we will need to extend or renegotiate our current leases. 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.

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

The price at which our common stock will trade is likely to be volatile. The stock market has from time to time experienced significant price and volume fluctuations that have affected the market prices of securities, particularly securities of clinical laboratory, biotechnology and other healthcare service companies. As a result, the market price of our common stock may materially decline, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. As previously announced, such securities claims were filed against us in May and June of 2002. Litigation of this type is often expensive and diverts management's attention and resources, and we can provide no assurances that we will be successful in defending these actions.

For a more detailed description of the purported class-action securities claims recently filed against us, please see "Legal Proceedings".

**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, Health Services Corporation of America, Managed Healthcare Associates, and Shared Services Healthcare. We are typically granted non-exclusive provider status under these contracts. Our contracts with our group purchasing organizations will expire at times from 2003 to 2004. 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. The exact consequences of the discontinuation of the agreement with Novation are difficult to predict, particularly since the termination of the contractual relationship with Novation does not prevent its members from using our services.

For the year ended December 31, 2001, sales of our services to hospitals, which utilized the pricing structures under the Novation and AmeriNet group purchasing organization contracts, comprised approximately \$40 million or approximately 24% of our net revenues, and approximately \$8 million or approximately 5% of our net revenues, respectively. Sales to hospitals within the other three group purchasing organizations comprised less than 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.

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

**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, requires the Secretary of Health and Human Services (HHS) to develop regulations to protect the security and privacy of individually identifiable health information that is electronically transmitted or received. In November 1999, the Secretary of HHS published proposed regulations under the HIPAA that would protect the privacy of individually identifiable health information that is transmitted or received electronically, and in August 2002 the Secretary of HHS published the final privacy regulations. Previously, the Secretary of HHS published proposed regulations relating to security of individually identifiable health information. When and if the security regulation becomes final, and if the privacy regulation is not modified by HHS or invalidated by Congress under the Congressional Review Act, then they will require that holders or users of electronically transmitted patient health information implement measures to maintain the security and privacy of such information. Ultimately, this and other legislation may even affect the dissemination of medical information that is not individually identifiable. Physicians and other persons providing patient information to us are also required to comply with these laws and regulations. If a patient's privacy is violated, or if we are found to have violated any state or federal statute or regulation with regard to the confidentiality, dissemination or use of patient medical information, we could be liable for damages, or for civil or criminal fines or penalties.

The commercialization of our Internet products including Outreach Express , 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

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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. We can provide no assurances that we will be fully compliant with HIPAA or other related laws and regulations when such laws and regulations become effective.

**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 director of the Company. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 65% 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 competition's 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 net revenue.**

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Our success depends, in part, on the continued and uninterrupted performance of our information technology systems, including our DataPassport® suite of products. Sustained or repeated system failures that interrupt our ability to process assay orders, deliver assay results or perform assays in a timely manner would reduce significantly the attractiveness of our products to our customers. Our business, 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 network security measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because they are located at third party web hosting companies, Exodus Communications, in El Segundo, California, and Qwest Communications in Burbank, California, and we cannot control the maintenance and operation of the Exodus and Qwest data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems.

We have several different insurance policies designed to cover losses arising from such interruptions. However, these insurance policies may not adequately compensate us for any losses that may occur due to any failures in our systems.

**Change of our web hosting company from Exodus Communications to another provider of services could result in a disruption of our operations, and our business, results of operations and financial condition could be materially and adversely affected by any damage or failure that interrupts or delays our operations.**

Some of our network servers are located at third party web hosting companies, Exodus Communications, in El Segundo, California and Qwest Communications in Burbank, California. Exodus Communications filed for Chapter 11 bankruptcy protection in September of 2001, and certain assets of Exodus have been acquired by Cable & Wireless plc. While the server hosting operations have so far continued uninterrupted, and not yet affected any of our operations, we are in the process of changing our network server hosting service to Qwest. We expect to complete the move to Qwest sometime in the first half of 2003.

We cannot guarantee that our operations will be unaffected by Exodus' bankruptcy, or the asset purchase by Cable & Wireless. Furthermore, the actions of transferring our network service hosting to Qwest could result in interruption and or delays in our operations. While we are building a parallel

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system at Qwest, and are taking other precautions to prevent any such interruption or delay in our operations, we cannot guarantee that the act of moving to a different service provider will not result in such interruptions or delays in our operations. Moreover, despite changing web-hosting providers, some of our servers will remain potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems, in part because they will remain at a third party web hosting company, and we cannot control the maintenance and operation of the data centers. Despite the precautions we have taken, unanticipated problems affecting our systems could cause interruptions in our information technology systems. 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 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® and DataPassportMD , to facilitate electronic assay ordering and results reporting as a value added service for our customers. We believe that these solutions are one factor considered by our customers when selecting a reference laboratory. In the future, our competitors may offer similar or better information technology solutions to our existing and potential customer base. If this occurs, we 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.**

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A significant portion of our net revenue is derived from 30 assays. Net revenue from these 30 assays comprised approximately 45% of our total net revenue for the year ended December 31, 2001. In addition, only one assay, HIV Quantitation, accounted for approximately 10% of our net revenue in one of the past three years. In 2001, no assay accounted for 10% or more of our net revenue. 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 medical malpractice. Damages assessed in connection with, and the costs of defending, any legal action could be substantial. We currently maintain insurance with coverage up to \$20 million, either singly or in the aggregate, which we believe to be adequate to cover our exposure in our current professional liability claims and employee-related matters which were incurred in the ordinary course of business. Although we believe that these claims may not have a material effect on us, because we expect them to be covered by this insurance, we may be faced with litigation claims which exceed our insurance coverage or are not covered under our insurance policy. In addition, litigation could have a material adverse effect on our business if it impacts our existing and potential customer relationships, creates adverse public relations, diverts management resources from the operation of the business or hampers our ability to perform assays or otherwise conduct our business.

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

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

**Our assays may infringe on the intellectual property rights of others, which may cause us to engage in costly litigation which may cause us to pay substantial damages and prohibit us from selling our assays.**

Other companies or institutions engaged in assay development, including our competitors, may obtain patents or other proprietary rights that would prevent, limit or interfere with our ability to develop, perform or sell our assays. As a result, we may be found to be, or accused of, infringing on the proprietary rights of others. For example, in response to a patent infringement allegation from Athena Diagnostics in 1997, we ceased performing an assay used to diagnose late onset Alzheimer's disease. We have received letters from Chiron Corporation in February 1998, and from the National Institute of Health in April 2000 and June 2001, claiming that some of our assays may violate their patents. The assays which may be affected by these claims comprised approximately \$18 million of our net revenue for the year ended December 31, 2001. While we believe that none of these claims will have a material adverse effect on our business, there can be no assurance that there will be no adverse consequences to us. As a result of these claims and any other infringement related claims, we could incur substantial costs in defending any litigation, and intellectual property litigation could force us to do one or more of the following:

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

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

redesign or reengineer our assays.

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

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

We have made in the past and we may continue to make acquisitions of complementary businesses, products or technologies. In this regard, we 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, your equity in us could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of other intangible assets in connection with future acquisitions, which would harm our operating results.

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

In order to meet growth in demand for our esoteric assays, we will have to process many more patient samples than we are currently processing. We have implemented a high-speed specimen sorting system known as the Total Accessioning Re-Organization System, or TARO . In addition, we plan to develop and implement other automated systems to enhance our testing procedures, including the implementation of a specimen splitting system, designated as HANA . 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 clinical and processing facility may be affected by catastrophes such as earthquakes or sustained interruptions in electrical service. Earthquakes are of particular significance to us because all of our clinical laboratory facilities are located in Santa Monica, California, an earthquake-prone area. In the event our existing clinical laboratory facility or equipment is affected by man-made or natural disasters, we would be unable to process our customers' samples in a timely manner and unable to operate our business in a commercially competitive manner. To address these risks, we have in place formal recovery plans for all interruptions of service. This includes identification of alternate laboratory testing facilities and disaster recovery protocols. We also carry earthquake insurance with a coverage amount of up to \$10 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 current energy crisis could disrupt our operations and increase our expenses.**

All of our laboratory operations are located in Santa Monica, California and we plan 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, 2002, 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, 2002, we had cash and cash equivalents of \$33.9 million, which had a weighted average yield of 1.86% per annum. At September 30, 2002, our long-term investment balance of \$25.3 million consisted of corporate bonds and government securities with maturity dates beyond one year, had a weighted average yield per annum of 3.84%.

**ITEM 4. CONTROLS AND PROCEDURES**

Within 90 days prior to the date of this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Rules 13a-14 and 15d-14 of the Securities Exchange Act of



1934. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures are effective.

There were no significant changes in the Company's internal controls or in other factors that could significantly affect these internal controls subsequent to the date of their evaluation.

## **PART II. OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

In addition to the California state and federal actions described in "Management's Discussion and Analysis of Financial Condition and Results of Operation-Recent Developments" and "Risk Factors-Our operations and facilities are subject to stringent laws and regulations and if we are unable to comply, our business may be significantly harmed", we are involved in various legal proceedings arising in the ordinary course of business.

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. On September 27, 2002 an amended and consolidated complaint was filed and is serving as the operative complaint in this litigation. 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 and Medicaid Services. Plaintiffs seek compensatory damages, including interest, costs and expenses, attorneys' fees, and other relief. On October 28, 2002 we filed a motion to dismiss the amended complaint, and we expect the court to rule on the motion sometime in the first quarter of 2003. We have provided notice to our directors and officer's insurers, and believe that we have insurance applicable to 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.

As previously reported, a former officer of the Company previously filed an action in federal district court against the Company and two of its officers alleging violations of federal and state securities laws and other causes of action in connection with the sale of the Company's common stock by the former officer and the Company's application of its insider trading policy. The Company's motion to compel arbitration was granted, and one of the individual defendants has subsequently been dropped from plaintiff's claims. The matter has been submitted to binding arbitration before a former federal judge, who recently granted the plaintiff a continuance. We expect the matter to be heard by the arbitrator sometime in the first half of 2003. Management believes the claims to be without merit and will vigorously defend this action.

Reference is made to our Annual Report on Form 10-K filed March 13, 2002 and Form 10-Q filed May 7, 2002 under the heading "Legal Proceedings" for a discussion of litigation involving us and our former international operations and the receipt of letters alleging infringement of patent or other intellectual property rights.

### **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.

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**ITEM 5. OTHER INFORMATION**

On October 24, 2002, the Company announced the resignation of John C. Kane from the Company's board of directors. A copy of the press release issued by the Company on October 24, 2002 concerning the foregoing matter is filed herewith as Exhibit 99.4 and is incorporated herein by reference.

On October 25, 2002 the Company announced that it is postponing its planned move to new laboratory and administrative facilities, currently under construction in Valencia, California. The move, originally scheduled for the second half of 2003, is targeted for the first half of 2004. Accordingly, construction activity will be paused upon completion of the building's shell, projected for January 2003. Resumption of the construction project, including interior improvements and build-out of the laboratory, is expected in the second half of 2003. The financing of the construction project has been provided by a banking group led by BNP Paribas (BNP) under a 6.5-year lease arrangement, sometimes referred to as a "synthetic lease". BNP has financed approximately \$4.6 million of the nearly \$13.4 million expended to date. The Company has notified BNP of its intent to exercise the purchase option under the agreements and to obtain title to the ground lease and facility improvements, thus ending the synthetic lease. The Company anticipates paying off in November the \$4.6 million debt that exists under the agreements, and anticipates spending approximately \$18 million in additional funds to complete the building shell by January 2003. The Company will pursue a more traditional, on-balance sheet financing arrangement with its current banking partners to fund some of these efforts. Upon restart of the project, the company plans to obtain construction and mortgage financing for completion of the Valencia facility. A copy of the press release issued by the Company on October 25, 2002 concerning the foregoing matter is filed herewith as Exhibit 99.5 and is incorporated herein by reference.

**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.

<b>Number</b>	<b>Description</b>
10.1	Expanded PCR Diagnostic Services Agreement, effective August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant.
10.2 *	Laboratory Services Agreement, dated October 15, 1999, by and between Unilab Corporation and Registrant.
99.1**	Centers for Medicare and Medicaid Services Letter dated July 17, 2002.
99.2***	California Department of Health Services Letter dated July 18, 2002.
99.3***	Press Release dated July 23, 2002
99.4	Press Release dated October 24, 2002
99.5	Press Release dated October 25, 2002

Confidential treatment has been requested as to certain portions of this agreement.

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This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed September 12, 2000, as amended.

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This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form 8-K declared effective on July 19, 2002 (File No. 001-16217)

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This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form 10-Q declared effective on August 13, 2002 (File No. 001-16217)

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(b) Reports on Form 8-K:

A Current Report, Form 8-K, was filed on July 3, 2002 with the SEC, by the Registrant, in connection with a press release dated July 3, 2002 announcing that the California Department of Health Services had found the Registrant to be in substantial compliance with California clinical laboratory law.

A Current Report, Form 8-K, was filed on July 19, 2002 with the SEC, by the Registrant, in connection with a press release dated July 17, 2002 announcing the federal Centers for Medicare and Medicaid Services had found the Registrant to be in compliance with all condition level requirements of the federal Clinical Laboratory Improvements Act as of June 19, 2002.

A Current Report, Form 8-K, was filed on August 13, 2002 with the SEC, by the Registrant, in connection with the filing of the Registrant's quarterly report on Form 10-Q for the second quarter of fiscal year 2002, setting forth the text of the certifications required of the Registrant's Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. § 1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002.

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### SIGNATURES

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

SPECIALTY LABORATORIES, INC.,  
a California corporation

Dated: October 30, 2002

By: /s/ DOUGLAS S. HARRINGTON

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

Dated: October 30, 2002

By: /s/ FRANK J. SPINA

\_\_\_\_\_  
Name: Frank J. Spina  
Title:

*Chief Financial Officer (Principal  
Financial and Accounting Officer)*

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### CERTIFICATION

I, Douglas S. Harrington, Chief Executive Officer of Specialty Laboratories, Inc. (the "Company"), certify, pursuant to §302 of the Sarbanes-Oxley Act of 2002, that:

1. I have reviewed this quarterly report on Form 10-Q for the Company;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this quarterly report;
4. The Company's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended) for the Company and have:
  - (i) designed such disclosure controls and procedures to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - (ii) evaluated the effectiveness of the Company's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report ("Evaluation Date"); and
  - (iii) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The Company's other certifying officers and I have disclosed, based on our most recent evaluation, to the Company's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - (i) all significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data and have identified for the Company's auditors any material weaknesses in internal controls; and
  - (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls; and

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6.

The Company's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ DOUGLAS S. HARRINGTON

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Douglas S. Harrington  
*Chief Executive Officer*  
*(Principal Executive Officer)*  
October 30, 2002

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### CERTIFICATION

I, Frank J. Spina, Chief Financial Officer of Specialty Laboratories, Inc. (the "Company"), certify, pursuant to §302 of the Sarbanes-Oxley Act of 2002, that:

1.

I have reviewed this quarterly report on Form 10-Q for the Company;

2.

Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3.

Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this quarterly report;

4.

The Company's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as such term is defined in Rules 13a-14 and 15d-14 of the Securities Exchange Act of 1934, as amended) for the Company and have:

(i)

designed such disclosure controls and procedures to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

(ii)

evaluated the effectiveness of the Company's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report ("Evaluation Date"); and

(iii)

presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5.

The Company's other certifying officers and I have disclosed, based on our most recent evaluation, to the Company's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):

(i)

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all significant deficiencies in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data and have identified for the Company's auditors any material weaknesses in internal controls; and

(ii)

any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls; and

6.

The Company's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ FRANK J. SPINA

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Frank J. Spina  
*Chief Financial Officer*  
*(Principal Financial Officer)*  
October 30, 2002

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### EXHIBIT INDEX

<b>Number</b>	<b>Description</b>
10.1	Expanded PCR Diagnostic Services Agreement, effective August 20, 2001 by and between Roche Molecular Systems, Inc. and Registrant.
10.2 *	Laboratory Services Agreement, dated October 15, 1999, by and between Unilab Corporation and Registrant.
99.1**	Centers for Medicare and Medicaid Services Letter dated July 17, 2002.
99.2***	California Department of Health Services Letter dated July 18, 2002.
99.3***	Press Release dated July 23, 2002
99.4	Press Release dated October 24, 2002
99.5	Press Release dated October 25, 2002

Confidential treatment has been requested as to certain portions of this agreement.

\*

This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 filed September 12, 2000, as amended.

\*\*

This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form 8-K declared effective on July 19, 2002 (File No. 001-16217)

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This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form 10-Q declared effective on August 13, 2002 (File No. 001-16217)

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Specialty Laboratories, Inc. Consolidated Statements of Cash Flows (Unaudited) (Dollar amounts in thousands)

SPECIALTY LABORATORIES, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS September 30, 2002 (Unaudited) (Dollar amounts in thousands except per share data)

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

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#### SIGNATURES

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#### CERTIFICATION