

SPECIALTY LABORATORIES  
Form 10-Q  
May 07, 2002

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

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

For the quarterly period ended March 31, 2002

OR

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

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

Commission file number 001-16217

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**SPECIALTY LABORATORIES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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

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

**2211 Michigan Avenue  
Santa Monica, California 90404**

(Address of principal executive offices, including zip code)

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

**Not Applicable**

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

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

As of April 30, 2002, there were approximately 21,779,536 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 8, 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>March 31, 2002</u>
		(Unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,183	\$ 36,489
Short-term investments	22,491	1,002
Accounts receivable, less allowance for doubtful accounts of \$2,828 as of December 31, 2001 and \$3,581 as of March 31, 2002	33,783	33,068

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	December 31, 2001	March 31, 2002
Deferred income taxes	1,571	2,617
Inventory	2,711	2,641
Prepaid expenses and other assets	1,785	2,617
<b>Total current assets</b>	<b>77,524</b>	<b>78,434</b>
Property and equipment, net	27,095	27,223
Long-term investments	37,389	38,428
Deferred income taxes	1,051	629
Goodwill, net	5,655	5,655
Other assets	5,274	5,080
	<b>\$ 153,988</b>	<b>\$ 155,449</b>
<b>Liabilities and shareholders' equity</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 9,465	\$ 10,589
Accrued liabilities	8,206	6,334
Income taxes payable	1,117	510
<b>Total current liabilities</b>	<b>18,788</b>	<b>17,433</b>
Long-term liabilities	2,544	2,438
Commitments and contingencies		
<b>Shareholders' equity:</b>		
Preferred stock, no par value: Authorized shares 10,000,000 Issued and outstanding shares none		
Common stock, no par value: Authorized shares 100,000,000 shares Issued and outstanding shares 21,473,886 as of December 31, 2001 and 21,632,194 as of March 31, 2002	96,056	97,760
Retained earnings	37,182	38,436
Deferred stock-based compensation	(726)	(524)
Accumulated other comprehensive income	144	(94)
<b>Total shareholders' equity</b>	<b>132,656</b>	<b>135,578</b>
	<b>\$ 153,988</b>	<b>\$ 155,449</b>

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**Specialty Laboratories, Inc.**  
**Consolidated Statements of Operations**  
**(Unaudited)**

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

	Three Months Ended March 31,	
	2001	2002
Net revenue	\$ 43,822	\$ 43,614
Costs and expenses:		

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	Three Months Ended March 31,	
	2001	2002
Costs of services	24,534	26,829
Selling, general and administrative (exclusive of stock-based compensation charges)	14,314	13,760
Stock-based compensation charges	315	141
Charge related to CMS actions		1,241
<b>Total costs and expenses</b>	<b>39,163</b>	<b>41,971</b>
Operating income	4,659	1,643
Interest income	(1,146)	(494)
Interest expense	38	33
<b>Income before income taxes</b>	<b>5,767</b>	<b>2,104</b>
Provision for income taxes	2,365	850
<b>Net income</b>	<b>\$ 3,402</b>	<b>\$ 1,254</b>
Basic earnings per common share	\$ .16	\$ .06
Diluted earnings per common share	\$ .15	\$ .06

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

	Three Months Ended March 31,	
	2001	2002
<b>Operating activities</b>		
Income from operations	\$ 3,402	\$ 1,254
Adjustments to reconcile income from operations to net cash provided by operating activities:		
Depreciation and amortization	1,673	1,700
Tax benefits related to employee stock options		1,457
Deferred income taxes	288	(459)
Stock-based compensation charges	315	141
Loss on disposals of property and equipment	1	
Changes in assets and liabilities, net of effects of acquisition:		
Accounts receivable, net	(3,297)	715
Inventory, prepaid expenses and other assets	213	(640)
Accounts payable	2,625	1,124
Accrued liabilities	(856)	(1,872)
Income taxes payable	76	(607)
Other long-term liabilities	(132)	(106)
<b>Net cash provided by operating activities</b>	<b>4,308</b>	<b>2,707</b>
<b>Investing activities</b>		
Cash paid for acquisition of BBI Clinical Laboratories	(9,500)	

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	<b>Three Months Ended March 31,</b>	
Purchases of property and equipment	(1,600)	(1,756)
(Purchases) sales of investments, net	(36,953)	20,047
Net cash (used in) provided by investing activities	(48,053)	18,291
<b>Financing activities</b>		
Proceeds from exercise of stock options		308
Net cash provided by financing activities		308
Net (decrease) increase in cash and cash equivalents	(43,745)	21,306
Cash and cash equivalents at beginning of period	75,604	15,183
Cash and cash equivalents at end of period	\$ 31,859	\$ 36,489
Supplemental disclosures of cash flow information:		
Acquisition of BBI Clinical Laboratories consisted of the following:		
Acquired assets	\$ 10,148	
Assumed liabilities	(648)	
Total cash paid	\$ 9,500	

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**SPECIALTY LABORATORIES, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**March 31, 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 (the "Company") have been prepared, without audit, in accordance with generally accepted accounting principles for interim financial reporting and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, the financial statements do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. In the opinion of management, such interim financial statements contain all adjustments (consisting of normal recurring items) considered necessary for a fair presentation of our financial position, results for operations and cash flows for the interim periods presented. The results of operations and cash flows for any interim periods are not necessarily indicative of results that may be reported for the full year.

The accompanying financial statements should be read in conjunction with the audited consolidated financial statements, and the notes thereto, included in our Annual Report on Form 10-K for the year ended December 31, 2001, as filed with the Securities and Exchange Commission.

**NOTE 2. ACQUISITION**

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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 three months ended March 31, 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>Three Months Ended March 31, 2001</b>	
Net revenue	\$	44,725
Net income	\$	3,317
Basic earnings per common share	\$	.16
Diluted earnings per common share	\$	.15

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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-month period ended March 31, 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-month period ended March 31, 2001:

	<b>Three Months Ended March 31,</b>	
	<b>2001</b>	<b>2002</b>
Net income		
As reported	\$ 3,402	\$ 1,254
Pro forma	\$ 3,416	
Basic earnings per common share		
As reported	\$ .16	\$ .06
Pro forma	\$ .16	
Diluted earnings per common share		
As reported	\$ .15	\$ .06
Pro forma	\$ .15	

#### *Goodwill*

Goodwill related to the acquisition of BBICL is as follows:

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

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*Intangible Assets (included in other assets)*

Intangible assets are as follows:

	<b>December 31, 2001</b>	<b>March 31, 2002</b>
Customer list related to the acquisition of BBICL	\$ 1,932	\$ 1,932
Other intangible assets	425	425
Less accumulated amortization	(172)	(245)
<b>Total intangible assets, net</b>	<b>\$ 2,185</b>	<b>\$ 2,112</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 CMS ACTIONS**

By letter dated April 12, 2002, the federal Centers for Medicare and 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 has concluded that our February 2002 response to deficiencies detected in the inspections did not constitute a credible allegation of compliance. As a result, CMS has taken action consisting of revoking 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, as we believe that we are in compliance with all applicable regulations. The revocation of our CLIA certificate will be stayed for the full duration of our administrative appeal, and the revocation will not become effective if we are successful in our appeal. The cancellation of Medicare and Medicaid payments is effective for services performed by us on and after February 22, 2002. While the Medicare and Medicaid billing issue is under review by CMS, we believe that this sanction should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but will instead apply only to testing for which we bill the Medicare and Medicaid programs directly. We plan to continue to perform testing on behalf of Medicare and Medicaid patients during our appeal of the CMS action. If successful in our appeal, we believe we may be eligible to receive reimbursement retroactively to the February 22, 2002 effective date. The civil money penalty of \$3,000 per day applies to each day of non-compliance on or after February 22, 2002. This penalty will not be collected if we are successful on appeal. We recorded a charge in first quarter 2002 of approximately \$1.2 million to reserve for Medicare and Medicaid services earned and billed but not collected and a civil money penalty, all pertaining to the period February 22, 2002 to March 31, 2002.

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**NOTE 5. PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:

<b>December 31, 2001</b>	<b>March 31, 2002</b>
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Information technology equipment and systems	\$ 25,729	\$ 26,129
Professional equipment	11,134	11,660
Leasehold improvements	8,768	8,789
Land	8,658	8,658
Office furniture and equipment	4,199	4,223
Construction in progress	423	1,208
	58,911	60,667
Less accumulated depreciation and amortization	(31,816)	(33,444)
<b>Total property and equipment, net</b>	<b>\$ 27,095</b>	<b>\$ 27,223</b>

**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. Our lease was arranged by BNP Paribas and 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 facility will be leased from BNP Paribas Leasing Corporation, a substantive leasing company with assets in excess of \$1.5 billion.

Payments under the lease are based on a maximum of \$60 million of construction cost of the property funded by the third-party and are adjusted as the London Interbank Offering Rate ("LIBOR") fluctuates. Under the terms of the lease agreement, the lease commences on March 28, 2002 and terminates in 6.5 years. Rent payments will commence upon our moving to the new facility which is expected to occur in the second half of 2003. Upon termination or expiration of the lease, we have the option to purchase the property for the amount financed. If we elect not to purchase the property, we may arrange the sale of the facility to one or more third parties and have guaranteed to the lessor a residual value equal to approximately 82% of the amount financed. We believe that any potential liability relating to the residual value guarantee will not have a material adverse effect on our financial condition or results of operations. Upon completion of construction, we are required to provide cash equal to 20% of the outstanding loan balance as collateral to the lessor. The cash collateral is restricted from withdrawal and will be classified as restricted cash and investments in the balance sheet. Certain financial covenants are to be maintained during the entire lease term. In the event of a default under the lease, the lease could be terminated and we would be obligated to pay the residual value guarantee.

The Financial Accounting Standards Board is evaluating existing accounting guidance involving off-balance sheet financing arrangements and is expected to issue a new interpretation in 2002. We are

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uncertain as to what effect, if any, the interpretation will have on the accounting for the lease of our facility.

In March 2002, we obtained a bank loan agreement which provides for a revolving line of credit up to \$40 million subject to a borrowing base limitation of 85% of eligible accounts receivable. Borrowings are cross collateralized by substantially all of our assets and contain certain restrictive covenants, including maintenance of certain levels of financial ratios. Borrowings under this agreement bear interest at LIBOR plus a defined rate and are payable in March 2005. This new line of credit replaces our existing credit facility of \$30 million. We had no borrowings under this agreement at March 31, 2002.

Due to recent company events surrounding the actions imposed by the federal Centers for Medicare and Medicaid Services (CMS), we are currently reevaluating the lease and bank loan agreements with our banking partners to determine if any modifications need to be made to the terms and conditions of each agreement.

**NOTE 7. EARNINGS PER SHARE**

Basic earnings per share is computed by dividing income 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 per share for the respective periods are set forth in the table below:



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	Three Months Ended March 31,	
	2001	2002
Net income	\$ 3,402	\$ 1,254
Basic earnings per common share	\$ .16	\$ .06
Diluted earnings per common share	\$ .15	\$ .06
Basic weighted average shares	20,938	21,524
Dilutive effect of outstanding stock options	1,185	968
Diluted weighted average shares	22,123	22,492

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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 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 actions imposed by the California Department of Health Services (CDHS) and the federal Centers for Medicare and Medicaid Services (CMS), our test menu was comprised of more than 3,200 esoteric assays. In light of recent CDHS sanctions, we only have California-licensed Clinical Laboratory Scientists performing assays, and have reorganized our test menu to focus our efforts on core assays with the greatest importance to our clients. Accordingly, we have 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.

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.

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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 paid \$9.5 million in cash which was accounted for as a purchase in the first quarter of 2001. BBI

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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 plan to build 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 2002 with our move to the new facility expected to occur in the second half of 2003.

On February 13, 2002, Beckman Coulter, Inc. and Specialty announced a cross-licensing agreement to collaborate on the development of novel multi-analyte assays based on Beckman Coulter's new Progressive MicroArray platform. Multi-analyte assays combine multiple testing analyses in a single testing process.

On February 26, 2002, Zyomyx, Inc. and Specialty announced an agreement to collaborate on the application of the Zyomyx Protein Profiling Biochip technology for clinical diagnostics. As part of the collaboration, the two companies will pursue the identification of new disease marker patterns by re-analyzing archived clinical specimen using the protein chip technology. The two companies have an agreed structure whereby they share in the revenues generated by any potential assay or diagnostic kit resulting from the collaboration.

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, 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 will be leased from BNP Paribas Leasing Corporation, a substantive leasing company with assets in excess of \$1.5 billion.

By letter dated March 28, 2002, the California Department of Health Services (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 the federal Centers for Medicare and Medicaid Services (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.

### **Recent Developments**

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 8.0% of our net revenue for the year ended December 31, 2001. Quest has not indicated to us any plans to alter the terms of the Unilab agreement nor have they indicated any action regarding our existing contract with Unilab which expires October 2002. We believe that Quest will perform the majority of testing currently sent to us after the contract expires.

By letter dated April 12, 2002, the federal Centers for Medicare and Medicaid Services (CMS) notified us of its conclusions regarding laboratory inspections in June and October 2001 conducted by

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the California Department of Health Services (CDHS). CMS has concluded that our February 2002 response to deficiencies detected in the inspections did not constitute a credible allegation of compliance. As a result, CMS has taken action consisting of revoking our Clinical Laboratory Improvement Act (CLIA) certificate, canceling our approval to receive Medicare and Medicaid payments for services performed,

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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, as we believe that we are in compliance with all applicable regulations. The revocation of our CLIA certificate will be stayed for the full duration of our administrative appeal, and the revocation will not become effective if we are successful in our appeal. The cancellation of Medicare and Medicaid payments is effective for services performed by us on and after February 22, 2002. While the Medicare and Medicaid billing issue is under review by CMS, we believe that this sanction should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but will instead apply only to testing for which we bill the Medicare and Medicaid programs directly. We plan to continue to perform testing on behalf of Medicare and Medicaid patients during our appeal of the CMS action. If successful in our appeal, we believe we may be eligible to receive reimbursement retroactively to the February 22, 2002 effective date. The civil money penalty of \$3,000 per day applies to each day of non-compliance on or after February 22, 2002. This penalty will not be collected if we are successful on appeal.

On April 22, 2002, James B. Peter, M.D., Ph.D., resigned from the positions of chairman and chief executive officer. Thomas R. Testman has been elected by our board of directors to serve as chairman. Douglas S. Harrington, M.D. has been appointed interim chief executive officer by our board of directors. Both Dr. Harrington and Mr. Testman are long-time members of our board of directors. Our board of directors has narrowed its search for a permanent chief executive officer and is currently reviewing qualified candidates.

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 is without cause and is 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.

### **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.

#### *Expense Recognition*

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

#### *Stock-Based Compensation Charges*

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

We have recorded deferred stock-based compensation related to unvested stock options granted to employees and directors. Based on the number of outstanding options granted as of March 31, 2002, we expect to amortize approximately \$524,000 of deferred stock-based compensation in future periods. We expect to amortize this deferred stock-based compensation approximately as follows: \$316,000 during the remainder of 2002, \$181,000 during 2003, and \$27,000 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 during the first quarter 2002. We concluded that there was no impairment of goodwill for the three-month period ended March 31, 2002 since our fair value exceeded the book equity value.

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## **Results of Operations**

The following table sets forth the percentage of net revenue represented by certain items in our consolidated statements of operations and our working capital as calculated from our consolidated balance sheet for the three months ended March 31, 2001 and 2002.

	Three Months Ended March 31,	
	2001	2002
Net revenue	100.0%	100.0%
Cost of services	56.0	61.5
Selling, general and administrative (exclusive of stock-based Compensation charges)	32.7	31.5
Charge related to CMS actions		2.8
Operating income	10.6	3.8
Income from operations before taxes	13.2	4.8
Net income	7.8	2.9

### **Quarter Ended March 31, 2002 Compared with Quarter Ended March 31, 2001**

#### *Net Revenue*

Net revenue decreased approximately \$0.2 million, or 0.5%, to \$43.6 million for the quarter ended March 31, 2002 from \$43.8 million for the quarter ended March 31, 2001. The change in revenue is a result of a year-over-year increase in accessions of approximately 10% in our existing business offset by an approximately 10% decline in average selling price. The recent accelerated consolidation in the laboratory services industry, including the acquisitions of Clinical Diagnostic Services, Inc. and American Medical Laboratories, Inc., has resulted in a loss of testing referred by regional laboratory clients, and this has caused a decrease in average selling price. In addition, there was a slowdown in the launch of new hospital accounts, primarily in the Northeast. Continued consolidations and acquisitions of independent laboratories, as well as the completion of the announced acquisition of Unilab by Quest, will negatively impact accession growth rates and cause continued decreases in the aggregate average selling price. During first quarter 2002, approximately \$2.5 million of net revenue was recorded for Medicare and

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Medicaid services, with approximately \$1.1 million recorded from February 22, 2002, the effective date of the CMS actions of April 12, 2002, through March 31, 2002. Delays in resolving the CMS and CDHS matters will cause further reductions in revenues for Medicare and Medicaid services.

### *Cost of Services*

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased \$2.3 million, or 9.4%, to \$26.8 million for the first quarter 2002 from \$24.5 million for the comparable prior year quarter. This increase is attributed to the increase in assay volume and to approximately \$800,000 of costs incurred in the first quarter 2002 to meet the state of California requirements for licensed personnel. As a percentage of revenue, cost of services increased to 61.5% for the quarter ended March 31, 2002 from 56.0% from the comparable prior year quarter. On a going forward basis, we expect to incur higher cost of services as a percent of revenue due to increased outsourcing of tests and increased personnel and recruitment costs. As we hire additional licensed personnel, we expect to reduce the amount of outsourced tests, however this is dependent on our ability to recruit from a limited resource pool, and our ability to retain existing licensed personnel.

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### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses decreased \$554,000, or 3.9%, to \$13.8 million for the first quarter 2002 from \$14.3 million for the first quarter 2001. This cost reduction is a result of overall tightening of administrative and other general support expenditures during the first quarter 2002. This cost reduction is a continuation of cost reductions experienced over the second half of 2001. In addition, first quarter of 2002 included approximately \$500,000 of one-time costs for the recruiting of the CEO and Vice President of Sales, costs associated with the state of California review and certain one-time receivable write-offs associated with the closure of an independent laboratory. However, first quarter of 2001 included approximately \$400,000 of one-time costs for the acquisition of BBI Clinical Laboratories. As a percentage of revenue, selling, general and administrative expenses decreased to 31.5% for the quarter ended March 31, 2002 from 32.7% from the comparable prior year quarter.

### *Stock-Based Compensation Charges*

Stock-based compensation charges decreased from approximately \$315,000 to \$141,000 from the first quarter 2001 to the first quarter 2002. This increase was related to the amortization of deferred stock compensation.

### *Charge Related to CMS Actions*

In April 2002, we received a letter from the federal Centers for Medicare and Medicaid Services (CMS) imposing certain sanctions as a result of laboratory inspections conducted by the California Department of Health Services (CDHS). The penalties include 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. We have recorded a charge relating to these actions of approximately \$1.2 million for the first quarter 2002. On April 17, 2002, we filed an appeal to the sanctions imposed by CMS.

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

Net interest income decreased from approximately \$1.1 million to \$461,000 from the first quarter 2001 to the first quarter 2002. The decrease is due to the significant interest rate declines that occurred during 2001 which resulted in lower interest yields on our investments.

### *Provision for Income Taxes*

Provision for income taxes was \$850,000 for the first quarter 2002 as compared to \$2.4 million for the comparable prior year quarter. Our effective tax rate was 40.4% for the first quarter 2002 as compared to 41% for the first quarter 2001. The first quarter 2002 effective tax rate is consistent with the tax rate experienced for the fiscal year 2001.

### *Net Income*

Net income decreased by \$2.1 million, or 63.1%, to \$1.3 million for first quarter 2002 from \$3.4 million for the comparable prior year quarter. The decrease is primarily due to increased operating costs from higher accession volumes, cost incurred to meet the state of California

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requirements for license review, expenses related to the recruiting of a CEO and Vice President of Sales, certain one-time receivable write-offs, expenses incurred as a result of CMS actions, a reduction of interest income due to lower interest rates, and a decrease in the average selling price. As a percentage of revenue, net income decreased to 2.9% for the quarter ended March 31, 2002 from 7.8% from the comparable prior year quarter.

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### *EBITDA*

EBITDA decreased by \$3.0 million, or 47.2%, to \$3.3 million for the first quarter 2002 from \$6.3 million for the comparable prior year quarter. As a percentage of net revenue, EBITDA decreased to 7.7% for the quarter ended March 31, 2002 from 14.4% for the quarter a year ago. The decrease is primarily due to increased operating costs due to higher accession volumes, cost incurred to meet the state of California requirements for license review, expenses related to the recruiting of a CEO and Vice President of Sales, certain one-time receivable write-offs, expenses incurred as a result of CMS actions and a decrease in average selling price.

### **Liquidity and Capital Resources**

Net cash provided by operating activities was \$2.7 million in the first quarter 2002 as compared to \$4.3 million for the prior year quarter. The \$1.6 million decrease is primarily due to a decline in operating performance as income from operations decreased by \$2.1 million.

Investing activities in the first quarter of 2002 provided net cash of \$18.3 million as we repositioned \$20.0 million of short-term investments to cash and cash equivalents, partially offset by approximately \$1.8 million in capital expenditures. This compares to a cash use of \$48.1 million for the first quarter of 2001, as we repositioned \$37.0 million of cash to short-term and long-term investments, spent \$1.6 million in capital expenditures, and paid \$9.5 million in cash for the acquisition of BBI Clinical Laboratories.

Net cash provided in financing activities was \$0.3 million for first quarter 2002 as compared to zero in first quarter 2001. Cash provided in the first quarter 2002 was from exercise of stock options.

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. Our lease was arranged by BNP Paribas and 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 facility will be leased from BNP Paribas Leasing Corporation, a substantive leasing company with assets in excess of \$1.5 billion.

Payments under the lease are based on a maximum of \$60 million of construction cost of the property funded by the third-party and are adjusted as the London Interbank Offering Rate ("LIBOR") fluctuates. Under the terms of the lease agreement, the lease commences on March 28, 2002 and terminates in 6.5 years. Rent payments will commence upon our moving to the new facility which is expected to occur in the second half of 2003. Upon termination or expiration of the lease, we have the option to purchase the property for the amount financed. If we elect not to purchase the property, we may arrange the sale of the facility to one or more third parties and have guaranteed to the lessor a residual value equal to approximately 82% of the amount financed. We believe that any potential liability relating to the residual value guarantee will not have a material adverse effect on our financial condition or results of operations. Upon completion of construction, we are required to provide cash equal to 20% of the outstanding loan balance as collateral to the lessor. The cash collateral is restricted from withdrawal and will be classified as restricted cash and investments in the balance sheet. Certain financial covenants are to be maintained during the entire lease term. In the event of a default under the lease, the lease could be terminated and we would be obligated to pay the residual value guarantee.

The Financial Accounting Standards Board is evaluating existing accounting guidance involving off-balance sheet financing arrangements and is expected to issue a new interpretation in 2002. We are uncertain as to what effect, if any, the interpretation will have on the accounting for the lease of our facility.

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In March 2002, we obtained a bank loan agreement which provides for a revolving line of credit up to \$40 million subject to a borrowing base limitation of 85% of eligible accounts receivable. Borrowings are cross collateralized by substantially all of our assets and contain certain restrictive covenants, including maintenance of certain levels of financial ratios. Borrowings under this agreement bear interest at LIBOR plus a defined rate and are payable in March 2005. This new line of credit replaces our existing credit facility of \$30 million. We had no borrowings

under this agreement at March 31, 2002.

Due to recent company events surrounding the actions imposed by the federal Centers for Medicare and Medicaid Services (CMS), we are currently reevaluating the lease and bank loan agreements with our banking partners to determine if any modifications need to be made to the terms and conditions of each agreement.

We expect that existing cash and cash equivalents, short-term investments, and our new credit facility along with funds generated from operations will be sufficient to fund our operations, meet our capital requirements to support our growth, and allow strategic technology licensing and acquisitions for the next year.

## **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.

#### *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-88). For certification under CLIA-88, 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-88, 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-88. As a result, the

laboratory was cited by CDHS with 20 deficiencies under California law and CLIA-88. A separate statement indicating 12 overlapping deficiencies under CLIA-88 was issued by CMS in February 2002 based upon the same inspections. CDHS and CMS have indicated that if we fail to correct a total of six of the deficiencies, relating primarily to personnel licensing and the enforcement of regulatory requirements, we could face monetary and other penalties, up to and including revocation of our CLIA-88 license. 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 February 28, 2002, CDHS determined that the December 2001 submission did not constitute a credible allegation of compliance. In a letter dated March 28, 2002, CDHS notified us of their intent to impose certain sanctions against us. Such sanctions include the required licensing of certain laboratory employees, random and unannounced onsite inspections, and monetary penalties. The monetary penalties are not expected to have a material affect on us. We filed supplemental documentation supporting our compliance with the applicable requirements with CDHS and the federal Centers for Medicare and Medicaid Services (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.

By letter dated April 12, 2002, the federal Centers for Medicare and 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 has concluded that our February 2002 response to deficiencies detected in the inspections did not constitute a credible allegation of compliance. As a result, CMS has taken action consisting of revoking 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. The revocation of our CLIA certificate will be stayed for the full duration of our administrative appeal, and the revocation will not become effective if we are successful in our appeal. The cancellation of Medicare and Medicaid payments is effective for services performed by us on and after February 22, 2002. While the Medicare and Medicaid billing issue is under review by CMS, we believe that this sanction should not affect testing for Medicare and Medicaid patients for whom we bill our hospital and other clients, but will instead apply only to testing for which we bill the Medicare and Medicaid programs directly. We plan to continue to perform testing on behalf of Medicare and Medicaid patients during our appeal of the CMS action. If successful in our appeal, we believe we may be eligible to receive reimbursement retroactively to the February 22, 2002 effective date. The civil money penalty of \$3,000 per day applies to each day of non-compliance on or after February 22, 2002. This penalty will not be collected if we are successful on appeal. We recorded a charge in first quarter 2002 of approximately \$1.2 million to reserve for Medicare and Medicaid services earned and billed but not collected and a civil money penalty, all pertaining to the period February 22, 2002 to March 31, 2002. However, there can be no assurance that we will win our appeal. If we do not win our appeal, we will lose our CLIA certificate and be unable to receive Medicare and Medicaid payments, which will materially affect our ability to operate our current business, if at all. In addition, any delay in granting our appeal will divert management time and resources.

Furthermore, 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. 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.

**Recent activities 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 are reevaluating our material agreements to determine if any modifications need to be made to the terms and conditions of each agreement. There can be no assurance that the actions by CMS and CDHS will not affect our material agreements.

**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;

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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

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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.

**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. Although we have entered into an agreement with Unilab in which it has agreed to refer to us, until the agreement expires 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, there is no assurance that it will uphold this obligation. In addition, if Unilab does not renew this agreement in October 2002, it will then no longer be under any obligation to provide us with minimum assay referrals. If, for any reason, Unilab's purchase of our services were to be materially reduced or if Unilab failed to renew its contract with us in October 2002, it would decrease our net revenue.

On April 2, 2002, Quest Diagnostics Inc. announced that they had entered into an agreement to acquire Unilab. Quest has not indicated to us any plans to alter the terms of the Unilab agreement nor have they indicated any action regarding our existing contract with Unilab which expires October 2002.

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We believe that Quest will perform the majority of testing currently sent to us after the contract expires.

**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.

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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 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. We may become involved in this type of litigation in the future. Litigation of this type is often expensive and diverts management's attention and resources.

### **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 five group purchasing organizations: AmeriNet, Health Services Corporation of America, Managed Healthcare Associates, Novation

(formerly known as VHA) 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 is without cause and is 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.

We cannot be certain that upon the termination of our agreement with Novation or 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.

### **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 the federal Centers for Medicare and Medicaid Services (CMS) imposing certain sanctions as a result of laboratory inspections conducted by the California Department of Health Services (CDHS). The penalties include cancellation of Medicare and Medicaid payments for services performed by us 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. We have recorded a charge relating to these actions of approximately \$1.2 million for the first quarter 2002. On April 17, 2002, we filed an appeal to the sanction imposed by CMS.

**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.

**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 HIPPA, 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 HIPPA that would protect the privacy of individually identifiable health information that is transmitted or received electronically. Prior to that, 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 HIPPA. We have implemented encryption technology to protect patient medical information, however, use of encryption technology does not guarantee the privacy and security of confidential information. We believe that we are in material compliance with all currently applicable state and federal laws and regulations governing the confidentiality, dissemination and use of medical record information. However, differing interpretations of existing laws and regulations, or the adoption of new laws and regulations, could reduce or eliminate our ability to obtain or use patient information which, in turn, could limit our ability to use our information technology products for electronically transmitting patient data.

**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 66% 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 a third party web hosting company, Exodus Communications, in El Segundo, California, and we cannot control the maintenance and operation of the Exodus 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 a third party web hosting company, Exodus Communications, in El Segundo, California. Exodus Communications filed for Chapter 11 bankruptcy protection in September of 2001, and certain assets of Exodus have apparently 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 another provider. We expect to complete the move to another provider sometime in the first half of 2002.

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 another provider could result in interruption and or delays in our operations. While we are building a

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parallel system at the new service provider, 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.**

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

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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 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

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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

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

At March 31, 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 March 31, 2002, we had cash and cash equivalents of \$36.5 million, which had a weighted average yield of 2.21% per annum. At March 31, 2002, our short-term investment balance of \$1 million, consisting of corporate bond with maturity dates over 90 days and less than one year, had a weighted average yield per annum of 3.94% and an average of 26 days until maturity. At March 31, 2002, our long-term investment balance of \$38.4 million consisted of corporate bonds and government securities with maturity dates beyond one year, had a weighted average yield per annum of 4.02%.

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**PART II. OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

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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.

A former officer filed an action in federal district court against us and two of our officers alleging violations of federal and state securities laws and other causes of action in connection with the sale of our common stock by the former officer and our application of our insider trading policy. Our motion to compel arbitration was previously granted, and the matter has been submitted to binding arbitration before a former federal judge. The arbitrator granted in part our motion to dismiss, and concurrently granted leave to amend the claim. The plaintiff recently filed an amended claim, and dropped one of the individual defendants from his claims. We believe 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 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.

### **ITEM 5. OTHER INFORMATION**

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. Our lease was arranged by BNP Paribas and 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 facility will be leased from BNP Paribas Leasing Corporation, a substantive leasing company with assets in excess of \$1.5 billion.

Payments under the lease are based on a maximum of \$60 million of construction cost of the property funded by the third-party and are adjusted as the London Interbank Offering Rate ("LIBOR") fluctuates. Under the terms of the lease agreement, the lease commences on March 28, 2002 and terminates in 6.5 years. Rent payments will commence upon our moving to the new facility which is expected for the second half of 2003. Upon termination or expiration of the lease we have the option to purchase the property for the amount financed. If we elect not to purchase the property, we may arrange the sale of the facility to one or more third parties and have guaranteed to the lessor a residual value equal to approximately 82% of the amount financed. We believe that any potential liability relating to the residual value guarantee will not have a material adverse effect on our financial condition or results of operations. Upon completion of construction, we are required to provide cash equal to 20% of the outstanding loan balance as collateral to the lessor. The cash collateral is restricted

from withdrawal and will be classified as restricted cash and investments in the balance sheet. Certain financial covenants are to be maintained during the entire lease term. In the event of a default under the lease, the lease could be terminated and we would be obligated to pay the residual value guarantee.

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The Financial Accounting Standards Board is evaluating existing accounting guidance involving off-balance sheet financing arrangements and is expected to issue a new interpretation in 2002. We are uncertain as to what effect, if any, the interpretation will have on the accounting for the lease of our facility.

In March 2002, we obtained a bank loan agreement which provides for a revolving line of credit up to \$40 million subject to a borrowing base limitation of 85% of eligible accounts receivable. Borrowings are cross collateralized by substantially all of our assets and contain certain restrictive covenants, including maintenance of certain levels of financial ratios. Borrowings under this agreement bear interest at LIBOR plus a defined rate and are payable in March 2005. This new line of credit replaces our existing credit facility of \$30 million. A copy of the main agreements to the credit facilities are filed herewith as Exhibits 10.1 - 10.8. A copy of the press release issued by us on April 2, 2002 concerning the foregoing matter is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

On April 22, 2002, Specialty Laboratories announced that James B. Peter, M.D., Ph.D., resigned from the positions of chairman and chief executive officer. A copy of the press release issued by us on April 22, 2002 concerning the foregoing matter is filed herewith as Exhibit 99.2 and is incorporated herein by reference.

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 is without cause and is 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. A copy of the press release issued by us on May 1, 2002 concerning the foregoing matter is filed herewith as Exhibit 99.3 and is incorporated herein by reference.

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

(a)

Reports on Form 8-K:

A Current Report, Form 8-K, was filed on April 18, 2002 with the Commission, by the Registrant, in connection with a press release dated April 15, 2002 announcing action taken by the federal Centers for Medicare and Medicaid Services as the result of alleged non-compliance by the Registrant with requirements of the federal Clinical Laboratory Improvement Act of 1988.

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(b)

Exhibits.

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

Number	Description
10.1	Credit Agreement, among the Registrant, BNP Paribas, as Agent and certain financial institutions, as lenders, dated March 26, 2002.
10.2	Lease Agreement between BNP Paribas Leasing Corporation and the Registrant, dated March 26, 2002.
10.3	Ground Lease between BNP Paribas Leasing Corporation and the Registrant, dated March 26, 2002.
10.4	Purchase Agreement between BNP Paribas Leasing Corporation and the Registrant, dated March 26, 2002.
10.5	Construction Management Agreement between BNP Paribas Leasing Corporation and the Registrant, dated March 26, 2002.
10.6	Pledge Agreement among BNP Paribas Leasing Corporation, BNP Paribas, as Agent, the Registrant and the participants described therein, dated March 26, 2002.
10.7	Security Agreement by the Registrant in favor of BNP Paribas, individually and as agent, dated March 26, 2002.
10.8	Form of Promissory Note by the Registrant dated March 26, 2002.

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<b>Number</b>	<b>Description</b>
99.1	Press Release dated April 2, 2002.
99.2	Press Release dated April 22, 2002.
99.3	Press Release dated May 1, 2002.

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

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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: May 6, 2001

By: /s/ DOUGLAS S. HARRINGTON

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

Dated: May 6, 2001

By: /s/ FRANK J. SPINA

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

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**EXHIBIT INDEX**

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