SPECIALTY LABORATORIES
Form 10-Q
August 10, 2001

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2001

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

SPECIALTY LABORATORIES, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

As of August 6, 2001, there were approximately 21,322,159 shares of Common Stock outstanding, no par value.

FORM 10-Q QUARTERLY REPORT

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This Quarterly Report on Form 10-Q, (the "Quarterly Report") including information incorporated herein by reference, contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements relate to expectations concerning matters that are not historical facts. Words such as "projects," "believes," "anticipates," "will," "estimate," "plans," "expects," "intends," and similar words and expressions are intended to identify forward-looking statements. Although we believe that such forward-looking statements are reasonable, we cannot assure you that such expectations will prove to be correct. Important language regarding factors which could cause actual results to differ materially from such expectations are disclosed in this Quarterly Report and in filings with the Securities and Exchange Commission ("SEC") made from time to time by Specialty Laboratories, including our Registration Statement on Form S-1 declared effective on December 7, 2000, our Annual Report on Form 10-K filed on March 30, 2001 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 Sheet

	December 31, 2000	June 30, 2001
		(Unaudited)
Assets		

	December 31, 2000	June 30, 2001
Current assets:		
Cash and cash equivalents	$ 75,603,555	$ 12,717,678
Short-term investments		39,668,253
Accounts receivable, less allowance for doubtful accounts of $4,030,665 as of December 31, 2000 and $4,800,790 as of June 30, 2001	32,775,147	37,038,472
Deferred income taxes	4,238,857	2,774,077
Inventory	1,623,115	2,695,874
Prepaid expenses and other assets	1,496,125	1,789,205
Total current assets	115,736,799	96,683,559
Property and equipment, net	19,891,132	19,292,491
Long-term investments		23,300,643
Deferred income taxes	2,863,427	2,863,427
Goodwill, net		5,366,050
Other assets	3,513,707	4,694,841
	$ 142,005,065	$ 152,201,011
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$ 11,921,443	$ 13,688,620
Accrued liabilities	10,387,764	11,459,811
Income taxes payable	4,638,422	1,453,803
Total current liabilities	26,947,629	26,602,234
Long-term liabilities	3,259,950	2,739,338
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, no par value; 10,000,000 shares authorized, none issued		
Common stock, no par value; 100,000,000 shares authorized, 20,937,507 shares issued and outstanding as of December 31, 2000 and 21,299,025 shares issued and outstanding as of June 30, 2001	89,824,176	93,262,659
Retained earnings	24,102,877	30,751,353
Deferred stock-based compensation	(2,129,567)	(1,170,130)
Unrealized gain on investments		15,557
Total shareholders' equity	111,797,486	122,859,439
	$ 142,005,065	$ 152,201,011

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

	Three Months Ended June 30,	Six Months Ended June 30,

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	2001	2000	2001
Net revenue	$ 38,556,948	$ 45,157,566	$ 74,164,044	$ 88,979,188
Costs and expenses:				
Costs of services	21,699,723	25,518,326	42,215,395	50,052,366
Selling, general and administrative (exclusive of stock-based compensation charges)	12,280,474	14,615,335	23,885,148	28,929,246
Stock-based compensation charges	111,096	364,054	144,362	679,129
Total costs and expenses	34,091,293	40,497,715	66,244,905	79,660,741
Operating income	4,465,655	4,659,851	7,919,139	9,318,447
Interest income		(882,724)	(13,017)	(2,028,568)
Interest expense	389,062	40,459	760,160	78,189
Income before income taxes	4,076,593	5,502,116	7,171,996	11,268,826
Provision for income taxes	1,671,000	2,256,000	2,940,000	4,620,350
Net income	$ 2,405,593	$ 3,246,116	$ 4,231,996	$ 6,648,476
Basic earnings per common share	$ .15	$ .15	$ .26	$ .32
Diluted earnings per common share	$ .14	$ .15	$ .24	$ .30

Specialty Laboratories, Inc.
Consolidated Statements of Cash Flows
(Unaudited)

	Six Months Ended June 30,	
	2000	2001
Operating activities		
Income from operations	$ 4,231,997	$ 6,648,476
Adjustments to reconcile income from operations to net cash provided by operating activities:		
Depreciation and amortization	2,894,879	3,429,407
Tax benefits related to employee stock options		2,400,000
Deferred income taxes	(144,000)	1,464,780
Stock-based compensation charges	144,362	679,129
Loss on disposals of property and equipment	20,624	5,084
Changes in assets and liabilities, net of effects of acquisition:		
Accounts receivable, net	(2,517,401)	(2,226,330)
Inventory, prepaid expenses and other assets	1,471,743	(58,406)
Accounts payable	(1,574,545)	1,119,293
Accrued liabilities	881,665	1,071,636
Income taxes payable	818,907	(3,184,619)
Other long-term liabilities	562,024	(520,611)

	Six Months Ended June 30,	
Net cash provided by operating activities	6,790,255	10,827,839
Investing activities		
Cash paid for acquisition of BBI Clinical Laboratories		(9,500,000)
Purchases of property and equipment	(2,925,350)	(2,579,168)
Purchase of short-term investments		(39,668,253)
Purchase of long-term investments, net of unrealized gains		(23,285,085)
Net cash used in investing activities	(2,925,350)	(75,032,506)
Financing activities		
Sale of common stock to employees		1,318,790
Net change in revolving bank line of credit	(9,209,589)	
Borrowings under bank term loans	6,057,607	
Repayment of bank term loans	(1,496,892)	
Repayment of loan by shareholder	850,000	
Net cash provided by (used in) financing activities	(3,798,874)	1,318,790
Net increase (decrease) in cash and cash equivalents	66,031	(62,885,877)
Cash and cash equivalents at beginning of period	717,297	75,603,555
Cash and cash equivalents at end of period	$ 783,328	$ 12,717,678
Supplemental disclosures of cash flow information:		
Acquisition of BBI Clinical Laboratories consisted of the following:		
Acquired assets		$ 10,148,298
Assumed liabilities		(648,298)
Total cash paid		$ 9,500,000

SPECIALTY LABORATORIES, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2001

(Unaudited)

NOTE 1. BASIS OF PRESENTATION

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 the Company's 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.

On December 13, 2000, we completed our initial public offering of our common stock, no par value. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement Form S-1 (the "Registration Statement")

(Reg. No. 333-45588) that was declared effective by the Securities and Exchange Commission on December 7, 2000. The offering commenced on December 8, 2000 where all 5,000,000 shares of common stock registered under the Registration Statement were sold at a price of $16.00 per share. The Underwriters also exercised an overallotment option of 750,000 shares on December 11, 2000. All 750,000 shares were sold at a price of $16.00 per share. The aggregate price of the offering amount registered, including the overallotment was $92.0 million. In connection with the offering, we incurred underwriting discounts and commissions and other related offering expenses in the amount of approximately $8.7 million. We received net proceeds from the offering of approximately $83.3 million.

The accompanying financial statements should be read in conjunction with the audited consolidated financial statements, and the notes thereto, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2000, as filed with the Securities and Exchange Commission.

NOTE 2. ACQUISITIONS

On February 20, 2001, the Company acquired certain assets and liabilities of BBI Clinical Laboratories, Inc., 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. Of the $9.5 million purchase price, approximately $5.45 million was allocated to goodwill and $1.97 million was allocated to the customer list. The amortization life for goodwill and the customer list is 20 years and 10 years, respectively. The acquisition has been accounted for under the purchase method of accounting.

The following unaudited pro forma information presents the consolidated results of the Company's operations and the results of operations of the acquisition for the three and six months ended June 30, 2001 as if the acquisition had been consummated on January 1, 2001. Consolidated operating results for the three and six months ended June 30, 2000 are also presented on a pro forma basis as if the acquisition had been consummated on January 1, 2000. 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 the Company.

The unaudited pro forma information for the three and six months ended June 30, 2000 and 2001 presented below is for illustrative information purposes only and is not indicative of results that may have been achieved or results that may be achieved in the future.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	2001	2000	2001
Net revenue	$ 40,828,948	$ 45,157,566	$ 78,776,044	$ 89,882,381
Net income	$ 2,366,593	$ 3,246,116	$ 4,117,996	$ 6,562,888
Basic earnings per common share	$ .15	$ .15	$ .26	$ .31
Diluted earnings per common share	$ .13	$ .15	$ .23	$ .30

NOTE 3. COMPOSITION OF CERTAIN BALANCE SHEET CAPTIONS

Property and Equipment

Property and equipment consists of the following:

	December 31, 2000	June 30, 2001
Information technology equipment and systems	$ 23,102,531	$ 24,441,229
Professional equipment	9,463,936	10,322,750
Office furniture and equipment	4,095,544	4,174,618
Leasehold improvements	7,962,575	8,195,288
Construction in progress	614,835	772,842
	45,239,421	47,906,727
Less accumulated depreciation and amortization	(25,348,289)	(28,614,236)
Total property and equipment, net	$ 19,891,132	$ 19,292,491

	December 31, 2000	June 30, 2001

Goodwill

Goodwill related to the acquisition of BBI Clinical Laboratories is as follows:

	December 31, 2000	June 30, 2001
Goodwill	$	$ 5,457,000
Less accumulated amortization		(90,950)
Total goodwill, net	$	$ 5,366,050

Accrued and Long-Term Liabilities

Accrued liabilities consist of the following:

	December 31, 2000	June 30, 2001
Employee compensation related	$ 7,052,042	$ 8,965,524
Royalties	3,335,722	2,494,287
Total accrued liabilities	$ 10,387,764	$ 11,459,811

The Company has various royalty agreements for technology licensed from third parties which require that royalty fees be paid based upon a percentage of net revenue derived from assays using the licensed technology. Royalty payments are generally made on a semiannual basis.

Long-term liabilities consist of the following:

	December 31, 2000	June 30, 2001
Deferred compensation	$ 1,908,057	$ 1,920,752
Annuity payments due to former employee	453,164	401,391
Non-current portion of accrued rent for unused facility	232,359	107,462
Non-current installment of software acquisition costs	600,000	300,000
Other	66,370	9,733
Total long-term liabilities	$ 3,259,950	$ 2,739,338

NOTE 4. 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	2001	2000	2001
Net income	$ 2,405,593	$ 3,246,116	$ 4,231,996	$ 6,648,476
Basic earnings per common share	$ .15	$ .15	$ .26	$ .32
Diluted earnings per common share	$ .14	$ .15	$ .24	$ .30
Basic weighted average shares outstanding	16,066,681	21,037,705	16,066,681	20,987,605
Effects of dilutive stock options	1,623,940	1,171,557	1,553,239	1,171,788
Diluted weighted average shares outstanding	17,690,621	22,209,262	17,619,920	22,159,393

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 believe we offer one of the industry's most comprehensive menus, comprised of more than 3,500 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.

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 assay 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 obtaining or renewing large customer or group purchasing organization contracts, our average price per assay may slightly decrease, as these contracts typically incorporate volume discounts.

On December 13, 2000, we completed our initial public offering of our common stock, no par value. The shares of common stock sold in the offering were registered under the Securities Act of 1933, as amended, on a Registration Statement Form S-1 (the "Registration Statement") (Reg. No. 333-45588) that was declared effective by the Securities and Exchange Commission on December 7, 2000. The offering commenced on December 8, 2000 where all 5,000,000 shares of common stock registered under the Registration Statement were sold at a price of $16.00 per share. The Underwriters also exercised an overallotment option of 750,000 shares on December 11, 2000. All 750,000 shares were sold at a price of $16.00 per share. The aggregate price of the offering amount registered, including the overallotment was $92.0 million. In connection with the offering, we incurred underwriting discounts and commissions and other related offering expenses in the amount of approximately $8.7 million. We received net proceeds from the offering of approximately $83.3 million.

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 Clinical Laboratories, a private company founded in 1989, is a leading esoteric clinical reference laboratory specializing in infectious disease testing, such as Lyme Disease and viral hepatitis. BBI Clinical Laboratories' primary customers include hospitals, physician specialists, pharmaceutical and diagnostic companies and other clinical and research laboratories. During the second quarter of 2001, we began transitioning customers from BBI Clinical Laboratories operations in New Britain, Connecticut to our facility in Santa Monica, California. As of July 20**,** we have ceased substantially all clinical operations at the New Britain, Connecticut facility. It is anticipated some administrative personnel will remain through the end of October 2001 to complete and close the New Britain facility operations.

On May 24, 2001, we announced the signing of a three-year agreement with AmeriNet, renewing our affiliation with this membership-based group purchasing organization in health care. We will serve as a preferred provider of clinical laboratory services to AmeriNet's more than 14,000 member facilities, including 1,800 member hospitals. The renewal took effect on June 1, 2001 and includes option rights to renew and extend the contract beyond the three-year period.

On June 21, 2001, Specialty Laboratories announced an agreement with Axis-Shield plc of Dundee, Scotland for exclusive U.S. rights to a new gene-based test for predisposition to osteoporosis, a disease which affects more than 10 million Americans. The test, utilizing the patent of Gemini Genomics plc on the type 1 collagen gene (Co11A1), detects changes in this gene associated with predisposition to osteoporosis and increased risk of bone fracture.

Recent Developments

On July 24, 2001, Specialty Laboratories and Epoch Biosciences, Inc. announced the commercial availability of diagnostic tests for human leukemias that incorporate Epoch's proprietary Minor Groove Binder (MGB) technology that greatly improves the performance of the polymerase chain reaction (PCR).

Results of Operations

The following table sets forth the percentage of net revenue represented by certain items in our consolidated statements of operations for the three months and six months ended June 30, 2000 and 2001. Also presented is our working capital as calculated from our consolidated balance sheet for the six months ended June 30, 2000 and 2001.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2000	2001	2000	2001
Net revenue	100.0%	100.0%	100.0%	100.0%
Cost of services	56.3	56.5	56.9	56.3
Selling, general and administrative (exclusive of stock-based compensation charges)	31.9	32.4	32.2	32.5
Operating income	11.6	10.3	10.7	10.5
Income from operations before taxes	10.6	12.2	9.7	12.7
Net income	6.2	7.2	5.7	7.5

	Six Months Ended June 30,	
	2000	2001
Working capital	$ 7,831,310	$ 70,081,325

Quarter Ended June 30, 2001 Compared with Quarter Ended June 30, 2000

Net Revenue

Net revenue increased $6.6 million, or 17.1%, to $45.2 million for the quarter ended June 30, 2001 from $38.6 million for the quarter ended June 30, 2000. Revenue grew as a direct result of increased accession volumes, which increased over 20%, offset somewhat by a decline in average selling prices. This accession growth came primarily from our existing business, increasing by nearly 18% in the second quarter of 2001 as compared to the year ago quarter. The accession volumes resulting from the acquisition of BBI Clinical Laboratories on February 20, 2001 accounted for approximately three additional percentage points of growth. Average selling prices in the second quarter of 2001 were down approximately 3% as compared to the second quarter of 2000, and also reflect a decline of approximately 1% as compared to the first quarter of 2001. This slight reduction in average selling prices is reflective of our growing customer base and pricing reductions in contract renewals.

Cost of Services

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased $3.8 million, or 17.6%, to $25.5 million for the second quarter 2001 from $21.7 million for the comparable prior year quarter. This increase is directly attributed to the increase in assay volume and the costs associated with the addition of the clinical operations of BBI Clinical Laboratories acquired in the first quarter of 2001. As a percentage of net revenue, cost of services increased slightly to 56.5% for the quarter ended June 30, 2001 from 56.3% from the comparable prior year quarter. This slight increase is primarily the result of maintaining redundant operations as we transition the clinical operations of BBI Clinical Laboratories to our Santa Monica facilities.

Selling, General and Administrative Expenses

Selling, general and administrative expenses (S,G&A) increased $2.3 million, or 19.0%, to $14.6 million for the second quarter 2001 from $12.3 million for the second quarter 2000. Selling, marketing and related expenses accounted for nearly $1.0 million of the growth in S,G&A resulting from increased revenues and servicing a larger customer base. The acquisition of BBI Clinical Laboratories added approximately $400,000 to S,G&A, which includes $117,000 recorded for amortization of intangible assets in the second quarter of 2001. The continued rollout of our customer related offerings of DataPassport and DataPassportMD and the beta testing of our Outreach Express product contributed approximately $200,000 of incremental S,G&A. The majority of the remaining increase is attributable to increasing our corporate infrastructure to support our business growth and to meeting the requirements of being a public company. As a percentage of net revenue, selling, general and administrative expenses increased to 32.4% for the second quarter of 2001 as compared to 31.9% for the quarter a year ago.

Stock-Based Compensation Charges

Stock-based compensation charges increased from approximately $111,000 recorded in the second quarter of 2000 to $364,000 recorded in the second quarter 2001. This increase was related to the amortization of deferred stock compensation.

Interest Income

Interest income of approximately $883,000 was recorded for the second quarter 2001. This income is the result of investments being made with the proceeds from our initial public offering held in December 2000 as funds have been invested in money market, short-term and long-term investments.

Interest Expense

Interest expense decreased to approximately $40,000 for the second quarter 2001 from $389,000 for the second quarter 2000. This decrease is due to the reduction of our bank borrowings and the payoff of our outstanding revolving and term loans in December 2000 with a portion of the funds received from our initial public offering.

Provision for Income Taxes

Provision for income taxes was $2.3 million for the second quarter 2001 as compared to $1.7 million for the comparable prior year quarter. Our effective tax rate remained at 41% for the second quarter 2001 representing no change from the prior year.

Net Income

Net income increased by approximately $840,000, or 34.9%, to $3.2 million for second quarter 2001 from $2.4 million for the comparable prior year quarter. The increase is due primarily to an increase in operating income resulting from higher assay volume, efficiencies provided by ongoing automation of assays, and interest income recognized on the investment of funds from our initial public offering. As a percentage of net

revenue, net income increased to 7.2% for the quarter ended June 30, 2001 as compared to 6.2% for the comparable quarter of 2000.

EBITDA and Adjusted EBITDA

EBITDA increased by $500,000, or 8.1%, to $6.4 million for the second quarter 2001 from $5.9 million for the comparable prior year quarter. As a percentage of net revenue, EBITDA decreased to 14.2% for the quarter ended June 30, 2001 from 15.4% for second quarter 2000. Adjusting EBITDA for the non-cash expense related to stock-based compensation charges, adjusted EBITDA increased by approximately $800,000, or 12.2%, to $6.8 million for the second quarter 2001 from $6.0 million for the comparable prior year quarter. As a percentage of net revenue, adjusted EBITDA decreased to 15.0% for the quarter ended June 30, 2001 from 15.7% for the second quarter 2000. These results reflect the costs associated with the addition of the clinical operations of BBI Clinical Laboratories acquired in first quarter of 2001 partially offset by the improved efficiencies provided by the ongoing automation of our laboratory operations and the economies of scale realized by processing significantly higher assay volume.

Six Months Ended June 30, 2001 Compared with Six Months Ended June 30, 2000

Net Revenue

Net revenue increased $14.8 million, or 20.0%, to $89.0 million for the six months ended June 30, 2001 from $74.2 million for the six months ended June 30, 2000 as revenues from our hospital clients grew by nearly 34% in the first half of 2001. Revenue grew as a direct result of increased accession volumes, which increased by nearly 22%, offset partially by a decline in average selling prices. This accession growth came primarily from our existing business, increasing by more than 19% in the first six months of 2001 as compared to the year ago period. The accession volumes resulting from the acquisition of BBI Clinical Laboratories on February 20, 2001 accounted for the additional three percentage points of growth. Average selling prices for the first six months of 2001 declined slightly more than 1% as compared to the first half of 2000. This slight reduction in average selling prices is reflective of our growing customer base and pricing reductions in contract renewals.

Cost of Services

Cost of services, which includes costs for laboratory operations, distribution services, and research and development, increased $7.8 million, or 18.6%, to $50.0 million for the first six months of 2001 from $42.2 million for the comparable prior year period. This increase is directly attributed to the increase in assay volume and the costs associated with the acquisition of the clinical operations of BBI Clinical Laboratories in first quarter 2001. During this period, we maintained redundant operations as we began transitioning the clinical operations of BBI Clinical Laboratories to our Santa Monica facilities. As a percentage of revenue, cost of services decreased to 56.3% for the six months ended June 30, 2001 from 56.9% from the comparable prior year period. This improvement is reflective of the improved efficiencies provided by the ongoing automation of our laboratory operations and the economies of scale realized by processing significantly higher assay volume, offset partially by the additional costs associated with the BBI Clinical Laboratories acquisition.

Selling, General and Administrative Expenses

Selling, general and administrative expenses (S,G&A) increased $5.0 million, or 21.1%, to $28.9 million for the first six months of 2001 from $23.9 million for the first six months of 2000. Selling, marketing and related expenses accounted for approximately $1.4 million of this growth in S,G&A resulting from increased revenues and servicing a larger customer base. Approximately $1.2 million of the increase was due to us increasing our corporate infrastructure to support our business growth and to meet the requirements of being a public company. The acquisition of BBI Clinical Laboratories added more than $1.0 million to S,G&A, which includes $400,000 of certain one-time charges associated with the acquisition and $157,000 recorded for amortization of intangible assets during the first six months of 2001. Expansion of our customer related offerings of DataPassportMD and the beta testing of our Outreach Express contributed approximately $500,000 of incremental S,G&A. As a percentage of revenue, selling, general and administrative expenses increased to 32.5% for the first six months of 2001 as compared to 32.2% for the same period last year.

Stock-Based Compensation Charges

Stock-based compensation charges increased from approximately $144,000 recorded in the first six months of 2000 to $679,000 recorded in the first six months of 2001. This increase was related to the amortization of deferred stock compensation.

Interest Income

Interest income of approximately $2.0 million was recorded for the first six months of 2001 as compared to $13,000 for the same period in 2000. This income is the result of investments being made with the proceeds from our initial public offering held in December 2000 as funds have been invested in money market, short-term and long-term investments.

Interest Expense

Interest expense decreased to approximately $78,000 for the first six months of 2001 from $760,000 for the first six months of 2000. This decrease is due to the reduction of our bank borrowings and the payoff of our outstanding revolving and term loans in December 2000 with a portion of the funds received from our initial public offering.

Provision for Income Taxes

Provision for income taxes was $4.6 million for the first six months of 2001 as compared to $2.9 million for the comparable prior year period. Our effective tax rate remained at 41% for the first six months of 2001 representing no change from the prior year.

Net Income

Net income increased by $2.4 million, or 57.1%, to $6.6 million for first six months of 2001 from $4.2 million for the comparable prior year period. The increase is due primarily to an increase in operating income resulting from higher assay volume, efficiencies provided by ongoing automation of assays, and interest income recognized on the investment of funds from our initial public offering. As a percentage of net revenue, net income increased to 7.5% for the six months ended June 30, 2001 as compared to 5.7% for the comparable prior year period.

EBITDA and Adjusted EBITDA

EBITDA increased by $1.9 million, or 18.3%, to $12.7 million for the first six months of 2001 from $10.8 million for the comparable prior year period. As a percentage of net revenue, EBITDA decreased to 14.3% for the six months ended June 30, 2001 from 14.5% for the comparable prior year period. These results reflect our maintaining redundant operations as we transition the clinical operations of BBI Clinical Laboratories to our Santa Monica facilities. Adjusting EBITDA for the non-cash expense related to stock-based compensation charges, adjusted EBITDA increased by $2.5 million, or 23.0%, to $13.4 million for the first six months of 2001 from $10.9 million for the comparable prior year period. As a percentage of net revenue, adjusted EBITDA increased to 15.1% for the six months ended June 30, 2001 from 14.7% for the comparable prior year period.

Liquidity and Capital Resources

The Company's working capital reached $70.1 million at June 30, 2001 an increase of $62.3 million from $7.8 million at June 30, 2000. This increase is primarily due to the funds received from our initial public offering in December 2000 that yielded approximately $83.3 million. A large portion of these funds is reflected in our working capital as part of cash and cash equivalents and short-term investments. In addition, $23.3 million of these proceeds have been invested in long-term investments.

Net cash provided by operating activities was $10.8 million in the first six months 2001 as compared to $6.8 million for the prior year period. The $4.0 million improvement was primarily due to our improved operating performance as income from operations increased by $2.4 million and tax benefits, reflected in deferred income taxes, related to employee stock option exercises increased by $2.4 million.

Net cash used in investing activities reached $75.0 million for six months ended June 30, 2001 up $72.1 million from $2.9 million for the six months ended June 30, 2000. During the first six months of 2001, we repositioned a portion of our cash and equivalents to short-term and long-term investments. These investments, accounting for $63 million, are in high-grade instruments and commercial paper and will provide a better net after tax yield on our funds. Major uses of cash were $9.5 million to acquire BBI Clinical Laboratories and $2.6 million spent for capital expenditures to expand our information technology platform and laboratory automation and equipment.

Net cash provided by financing activities was $1.3 million for the first six months 2001 as compared to cash used in financing activities of $3.8 million in first six months 2000. The only activity to report during the first six months of 2001 was the purchase of common stock by employees through our Employee Stock Purchase Plan and employees exercising stock options. Since we did not borrow any funds from the bank and our outstanding revolving and term loans were paid off in fourth quarter 2000 with funds from our initial public offering, there was no cash used in financing activities for the first six months of 2001.

We are currently evaluating the long-term costs of supporting the Company's growth out of our current facilities in Santa Monica, California. With the majority of our leases expiring in mid 2003, we are evaluating the possibility of relocating to a more cost-effective location that will allow consolidation

of our laboratory operations with all support functions. While we do not expect to relocate prior to 2003, costs associated with this evaluation will be incurred and, depending on the final decision to relocate, costs and potentially significant capital expenditures could be incurred as soon as the second half of 2001.

We expect that existing cash and cash equivalents, short-term investments, and our current 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.

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.

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

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

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

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

institutions such as Mayo Medical Laboratories, or Mayo, and Associated Regional University Pathologists, or Associated, 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.

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.

For example, our net revenue from one assay for HIV Quantitation was:

in 1998, $19.7 million, or 17.3% of total 1998 net revenue;

in 1999, $17.3 million, or 13.3% of total 1999 net revenue; and

in 2000, $16.3 million, or 10.7% of total 2000 net revenue.

This decreasing trend has been primarily due to competition from subsequently introduced assays. If we are unable to develop newer assays which meet market demand, our net revenue and profit margins may decrease.

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 Associated, also compete with us by providing esoteric testing services. They often refer to us assays that they either cannot or elect not to perform themselves. For the year ended December 31, 2000, sales to our competitors were $10.4 million or 6.8% 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 2000, after being acquired by Quest, SmithKline Labs (excluding Quest accounts prior to the acquisition) only comprised 1.5% 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 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.

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 year ended December 31, 2000 and the year ended December 31, 1999, services to Unilab Corporation accounts comprised 9.6% and 7.4% 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 may decrease our net revenue.

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 20 assays. Net revenue from these 20 assays comprised approximately 54.5% of our total net revenue for the year ended December 31, 2000 and approximately 53.4% for the year ended December 31, 1999. In addition, for each of past three years, over 10% of our net revenue has been derived from one assay for HIV Quantitation. As a result, a significant portion of our net revenue is concentrated among these assays, and in particular, our HIV Quantitation assay. If competing assays are introduced by competitors or demand for these assays otherwise decreases, our net revenue would 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.

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, results of operations and financial condition 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 insurance policies designed to cover losses arising from such interruptions. Our policies include coverage for commercial general liability with a limit of $10 million. However, these insurance policies may not adequately compensate us for 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 four 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. Based on management's experience in the industry and discussions with our customers, we believe that our competitors have not yet implemented similar information technology tools. We further 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.

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.

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. From time to time, we often receive letters from universities, institutions, and others alleging such infringement. Although we believe that these claims generally lack any merit, at times, 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 and the National Institute of Health in February 1998 and April 2000, respectively, claiming that some of our assays may violate their patents. The assays which may be affected by these claims comprised approximately $22.9 million of our net revenue for the year ended December 31, 2000. While management believes 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 recently acquired BBI Clinical Laboratories, Inc. Please see "Management's Discussion and Analysis of Financial Condition and Results of Operations Overview." 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. If we

consummate any significant acquisitions using stock or other securities as consideration, your equity in us could be significantly diluted. If we make any significant acquisitions using cash consideration, we may be required to use a substantial portion of our available cash. Acquisition financing may not be available on favorable terms, if at all. In addition, we may be required to amortize significant amounts of goodwill and other intangible assets in connection with future acquisitions, which would harm our operating results.

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, Joint Purchasing Organization, Managed Healthcare Associates, Novation (formerly known as VHA) and Shared Services Healthcare. We are typically granted non-exclusive provider status under these contracts. Our contract with our group purchasing organizations will expire at times from 2001 to 2004.

For the year ended December 31, 2000, sales of our services to hospitals which utilized the pricing structures under the Novation and AmeriNet group purchasing organization contracts comprised approximately $34.3 million or 22.4%, and approximately $7.6 million or 5.0% of our net revenues, respectively. Sales to hospitals within the other three group purchasing organizations comprised less than 1% 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. While we believe that over 1,800 of our 2,200 hospital customers are affiliated with these five group purchasing organizations, only approximately 400 of these customers qualify for discounts under these contracts.

We cannot be certain that if our agreement with Novation, AmeriNet or any other group purchasing organization is terminated or not renewed, that 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.

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. 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.

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. While 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 are common in the clinical laboratory industry, we are only in the process of implementing such a program.

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. For certification under the Clinical Laboratory Improvement Amendments, laboratories such as us must meet various requirements, including requirements relating to quality assurance, quality control and personnel standards. 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, and therefore are subject to their requirements and evaluation. Our failure to comply with Clinical Laboratory Improvement Amendments, state or other applicable requirements could result in various penalties, including 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. 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. 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.

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 requires the U.S. Secretary of Health and Human Services to develop regulations to protect the security and privacy of individually identifiable health information that is electronically transmitted or received. In November 1999, the U.S. Secretary of Health and Human Services published proposed regulations under the Health Insurance Portability and Accountability Act of 1996 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 the Health Insurance Portability and Accountability

Act of 1996. 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.

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 United States 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 7.4% of our net revenue in 1999 and 7.3% of our net revenue for the year ended December 31, 2000. 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.

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 complete disaster recovery protocols. We also carry earthquake insurance with coverage amount of up to $10 million and have outsourced part of our data storage and processing equipment to a facility designed to withstand most earthquakes. Despite these precautions, 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. California is in the midst of an energy crisis that could disrupt our operations and increase our expenses. In the event power reserves for the State of California fall to critically low levels, California may implement rolling power blackouts throughout the State. The State of California has already experienced such occasional power blackouts. We

currently have backup power generators for our laboratories in the event of a blackout. Our current insurance, however, does not provide coverage for any damages we may suffer as a result of any interruption in our power supply. If blackouts interrupt our third party power supply, we may be temporarily unable to continue operations. Any such interruption in our ability to continue operations

would delay our processing of laboratory samples, disrupt communications with our customers and suppliers and delay product shipment. Power interruptions could also damage our reputation and could result in lost revenue. Any loss of power could have a material adverse effect on our business, operating results and financial condition. Furthermore, shortages in wholesale electricity supplies have caused power prices to increase. If wholesale prices continue to increase, our operating expenses will likely increase which will have a negative effect on our operating results.

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;
- changes in healthcare laws and regulations; and
- costs related to acquisitions of technologies or businesses.

We plan to expand our sales and marketing, research and development and general and administrative efforts, which will lead to an increase in expenses. If our net revenue does not increase along with these expenses, our business, operating results and financial condition 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.

Since our initial public offering in December 2000, our stock price has fluctuated between $16.75 and $47.00. 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.

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 is our Chairman and Chief Executive Officer, Dr. James B. Peter. Specialty Family Limited Partnership, together with Dr. Peter, currently beneficially own approximately 70% 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.

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:

imitations on who may call special meetings of shareholders;

advance notice requirements for nominations for election to the board of directors or 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

Our exposure to market rate risk for change in interest rates relates primarily to our investment portfolio. In addition, our holdings are also exposed to the risks of changes in the credit quality of the issuer. At June 30, 2001, our holdings, which had an original maturity date of less than 90 days, were classified as cash and cash equivalents on our consolidated balance sheet. At June 30, 2001, we had cash and cash equivalents of $12.7 million, which had a weighted average yield of 4.50% per annum and an average of 13.0 days until maturity. At June 30, 2001, our short-term investment balance of $39.7 million, consisting of commercial paper and corporate bonds with maturity dates over 90 days and less than one year, had a weighted average yield per annum of 6.06% and an average of 86.79 days until maturity. At June 30, 2001, our long-term investment balance of $23.3 million consisted of corporate bonds with maturity dates beyond one year.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Reference is made to our Annual Report on Form 10-K filed March 30, 2001 under the heading "Legal Proceedings" for a discussion of litigation involving us and our former international operations.

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

and prohibit us from selling our assays."

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

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

The Company's Annual Meeting of Shareholders was held on May 11, 2001. The matters voted on at the annual meeting and the tabulation of votes on such matters are as follows:

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

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

	Number Voting	For	Against or Withheld
James B. Peter, M.D., Ph.D.	19,816,919	19,810,716	6,203
Paul F. Beyer	19,816,919	18,906,612	910,307
Deborah A. Estes	19,816,919	19,810,716	6,203
Richard E. Belluzzo	19,816,919	18,906,042	910,877
Douglas S. Harrington, M.D.	19,816,919	19,810,716	6,203
Thomas R. Testman	19,816,919	19,810,716	6,203
William J. Nydam	19,816,919	19,810,716	6,203
John C. Kane	19,816,919	19,810,716	6,203
Nancy-Ann DeParle	19,816,919	19,810,716	6,203

b) To ratify the appointment of Ernst & Young LLP as independent accountants of the Company for the fiscal year ending December 31, 2001.

The shareholders ratified the reappointment of Ernst & Young LLP as the Company's independent public accountants, by the following vote:

Number Voting	For	Against or Withheld
19,816,919	19,810,769	6,150

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Reports on Form 8-K:

A Current Report, Form 8-K, dated April 9, 2001, was filed with the Commission, by the Registrant, in connection with a press release dated April 9, 2001 electing Nancy-Ann DeParle to its Board of Directors.

A Current Report, Form 8-K, dated May 24, 2001, was filed with the Commission, by the Registrant, in connection with a press release dated May 24, 2001 announcing the signing of a three-year agreement with AmeriNet.

A Current Report, Form 8-K, dated June 21, 2001, was filed with the Commission, by the Registrant, in connection with a press release dated June 21, 2001 announcing an agreement with Axis-Shield plc of Dundee, Scotland for exclusive U.S. rights to a new gene-based test for predisposition to osteoporosis.

A Current Report, Form 8-K, dated July 24, 2001, was filed with the Commission, by the Registrant, in connection with a press release dated July 24, 2001 announcing the commercial availability of diagnostic tests for human leukemias that incorporate Epoch Biosciences' proprietary Minor Groove Binder (MGB) technology.

A Current Report, Form 8-K, dated July 31, 2001, was filed with the Commission, by the Registrant, advising that Paul F. Beyer, President, Chief Operating Officer and Director of the Company has established a written plan to sell shares of the Company's common stock in accordance with Rule 10b5-1 of the Securities Exchange Act of 1934, as amended.

(b) Exhibits.

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

Number	Description
10.1	Marketing Arrangement dated April 5, 2001 between Axis-Shield Diagnostics Limited and Registrant.
10.17*	Group Purchasing Agreement effective as of July 15, 1998 between AmeriNet, Inc. and Registrant, as amended.
10.30A**	Collaborative Research, Development and License Agreement dated May 9, 2000 between Epoch Biosciences, Inc. (formerly known as Epoch Pharmaceuticals, Inc.) and Registrant

*
This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 33-45588) under the same exhibit number.

**
This exhibit was previously filed as an exhibit to the Company's Registration Statement on Form S-1 declared effective on December 7, 2000 (File No. 33-45588) under the same exhibit number, and is incorporated by reference herein.

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

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

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: August 6, 2001 By: /s/ JAMES B. PETER

Name: James B. Peter
Title: *Chief Executive Officer and Chairman of the Board of Directors*

Dated: August 6, 2001 By: /s/ FRANK J. SPINA

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

EXHIBIT INDEX

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QuickLinks

FORM 10-Q
SPECIALTY LABORATORIES, INC.
FORM 10-Q QUARTERLY REPORT
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