

ENZO BIOCHEM INC  
Form 10-Q  
June 08, 2016  
UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Mark one

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

For the quarterly period ended April 30, 2016

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 001-09974

**ENZO BIOCHEM, INC.**

(Exact name of registrant as specified in its charter)

New York  
(State or Other Jurisdiction  
of Incorporation or Organization)

13-2866202  
(IRS. Employer  
Identification No.)

527 Madison Ave, New York, New York  
(Address of Principal Executive office)

10022  
(Zip Code)

212-583-0100

(Registrant's telephone number, including area code)

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 has required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 45 of Regulation S-T (§232.405 of that chapter) during the preceding 12 months (or such shorter period that the registrant was required to submit and post such files).

Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.)

Yes  No

As of June 2, 2016, the Registrant had approximately 46,265,000 shares of common stock outstanding.

ENZO BIOCHEM, INC.  
FORM 10-Q  
April 30, 2016

INDEX

PART I - FINANCIAL INFORMATION

<u>Item 1. Condensed Financial Statements</u>	3
<u>Consolidated Balance Sheets – April 30, 2016 (unaudited) and July 31, 2015 (audited)</u>	3
<u>Consolidated Statements of Operations for the three and nine months ended April 30, 2016 and 2015 (unaudited)</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended April 30, 2016 and 2015 (unaudited)</u>	5
<u>Consolidated Statement of Stockholders' Equity for the nine months ended April 30, 2016 (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the nine months ended April 30, 2016 and 2015 (unaudited)</u>	7
<u>Notes to the Consolidated Financial Statements</u>	8
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	20
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	32
<u>Item 4. Controls and Procedures</u>	32
<u>Part II – OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	33
<u>Item 1A. Risk Factors</u>	33
<u>Item 6. Exhibits</u>	33
<u>Signatures</u>	33

**Part 1** Financial Information  
**Item 1** Financial Statements

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(in thousands, except share data)

	April 30, 2016 (unaudited)	July 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 32,360	\$ 18,109
Accounts receivable, net of allowances	14,000	12,109
Other receivables	—	6,650
Inventories	6,978	7,396
Prepaid expenses and other	1,819	2,222
Total current assets	55,157	46,486
Property, plant and equipment, net	8,638	7,948
Goodwill	7,452	7,452
Intangible assets, net	4,884	6,155
Other assets	357	353
Total assets	\$ 76,488	\$ 68,394
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Loan payable	\$ 2,000	\$ 3,013
Accounts payable – trade	9,152	8,762
Accrued liabilities	8,056	11,297
Other current liabilities	2,464	886
Total current liabilities	21,672	23,958
Deferred taxes	28	37
Other liabilities	1,820	1,793
Total liabilities	\$ 23,520	\$ 25,788
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock, \$.01 par value; authorized 25,000,000 shares; no shares issued or outstanding	—	—
Common Stock, \$.01 par value; authorized 75,000,000 shares; shares issued and outstanding: 46,254,870 at April 30, 2016 and 46,062,065 at July 31, 2015	463	461
Additional paid-in capital	326,109	324,966
Accumulated deficit	(275,531 )	(284,682)
Accumulated other comprehensive income	1,927	1,861

Total stockholders' equity	52,968	42,606
Total liabilities and stockholders' equity	\$ 76,488	\$ 68,394

The accompanying notes are an integral part of these consolidated financial statements.

3

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(UNAUDITED)**  
**(in thousands, except per share data)**

	Three Months Ended April 30,		Nine Months Ended April 30,	
	2016	2015	2016	2015
<b>Revenues:</b>				
Clinical laboratory services	\$18,162	\$15,657	\$52,775	\$46,204
Product revenues	8,001	7,906	22,266	23,631
Royalty and license fee income	270	423	1,129	2,067
Total revenues	26,433	23,986	76,170	71,902
<b>Operating expenses:</b>				
Cost of clinical laboratory services	11,142	9,724	32,009	29,100
Cost of product revenues	3,846	3,779	10,663	11,292
Research and development	882	809	2,610	2,434
Selling, general, and administrative	10,869	10,146	32,374	30,101
Provision for uncollectible accounts receivable	576	589	1,739	1,731
Legal fee expense	1,632	1,955	5,644	7,225
Legal settlements, net	—	(170 )	(18,450)	(170 )
Total operating expenses	28,947	26,832	66,589	81,713
Operating Income (loss)	(2,514 )	(2,846 )	9,581	(9,811 )
<b>Other income (expense):</b>				
Interest	(40 )	(58 )	(122 )	(176 )
Other	22	26	87	28
Foreign exchange gain (loss)	419	(125 )	(99 )	(856 )
Income (loss) before income taxes	(2,113 )	(3,003 )	9,447	(10,815)
(Provision) benefit for income taxes	(2 )	96	(296 )	88
Net income (loss)	\$(2,115 )	\$(2,907 )	\$9,151	\$(10,727)
<b>Net income (loss) per common share:</b>				
Basic	\$(0.05 )	\$(0.06 )	\$0.20	\$(0.24 )
Diluted	\$(0.05 )	\$(0.06 )	\$0.20	\$(0.24 )
<b>Weighted average common shares outstanding:</b>				
Basic	46,201	45,797	46,115	45,120
Diluted	46,201	45,797	46,450	45,120

The accompanying notes are an integral part of these consolidated financial statements.

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)**  
**(UNAUDITED)**  
**(in thousands)**

	Three Months		Nine Months	
	Ended		Ended	
	April 30,		April 30,	
	2016	2015	2016	2015
Net income (loss)	\$(2,115)	\$(2,907)	\$9,151	\$(10,727)
Other comprehensive income (loss):				
Foreign currency translation adjustments	(222 )	(20 )	66	123
Comprehensive income (loss)	\$(2,337)	\$(2,927)	\$9,217	\$(10,604)

The accompanying notes are an integral part of these consolidated financial statements.

**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**  
**Nine months ended April 30, 2016**  
**(UNAUDITED)**  
**(in thousands, except share data)**

	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 31, 2015	46,062,065	\$ 461	\$ 324,966	\$ (284,682 )	\$ 1,861	\$ 42,606
Net income for the period ended April 30, 2016	—	—	—	9,151	—	9,151
Vesting of restricted stock	8,751	—	—	—	—	—
Exercise of stock options	23,702	—	66	—	—	66
Share-based compensation charges	—	—	370	—	—	370
Issuance of common stock 401(K) plan match	160,352	2	707	—	—	709
Foreign currency translation adjustments	—	—	—	—	66	66
Balance at April 30, 2016	46,254,870	\$ 463	\$ 326,109	\$ (275,531 )	\$ 1,927	\$ 52,968

The accompanying notes are an integral part of these consolidated financial statements



**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(UNAUDITED)**  
**(in thousands)**

	Nine Months Ended April 30,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$9,151	\$(10,727)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,602	1,513
Amortization of intangible assets	1,260	1,284
Provision for uncollectible accounts receivable	1,170	1,731
Deferred income tax benefit	(8 )	(71 )
Share-based compensation charges	370	319
Accrual for share-based 401(k) employer match expense	560	511
Foreign exchange loss	14	640
Changes in operating assets and liabilities:		
Accounts receivable	(3,040 )	(940 )
Other receivables	6,650	—
Inventories	447	597
Prepaid expenses and other	402	16
Accounts payable – trade	396	(957 )
Accrued liabilities, other current liabilities and other liabilities	(1,970 )	(2,086 )
Total adjustments	7,853	2,557
Net cash provided by (used in) operating activities	17,004	(8,170 )
Cash flows from investing activities:		
Capital expenditures	(1,389 )	(1,168 )
Security deposits and other	(1 )	(1 )
Net cash used in investing activities	(1,390 )	(1,169 )
Cash flows from financing activities:		
Net proceeds from issuance of common stock	—	6,687
Proceeds from borrowings under Credit Agreement	67,343	65,389
Repayments under Credit Agreement	(68,356)	(65,389)
Installment loan and capital lease obligation payments	(424 )	(316 )
Proceeds from the exercise of stock options	66	—
Net cash (used in) provided by financing activities	(1,371 )	6,371
Effect of exchange rate changes on cash and cash equivalents	8	(112 )
Increase (decrease) in cash and cash equivalents	14,251	(3,080 )
Cash and cash equivalents - beginning of period	18,109	17,455
Cash and cash equivalents - end of period	\$32,360	\$14,375

The accompanying notes are an integral part of these consolidated financial statements.

7

**ENZO BIOCHEM, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**As of April 30, 2016**  
**(Unaudited)**  
**(Dollars in thousands, except share data)**

Note 1 – Basis of Presentation

The accompanying consolidated financial statements include the accounts of Enzo Biochem, Inc. and its wholly-owned subsidiaries, Enzo Life Sciences, Enzo Clinical Labs, Enzo Therapeutics and Enzo Realty LLC, collectively or with one or more of its subsidiaries referred to as the “Company” or “Companies”. The consolidated balance sheet as of April 30, 2016, the consolidated statements of operations, comprehensive income (loss), and cash flows for the three and nine months ended April 30, 2016 (the “interim statements”) and 2015, and the consolidated statement of stockholders’ equity for the nine months ended April 30, 2016 are unaudited. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position and operating results for the interim periods have been made. Certain information and footnote disclosure, normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. The interim statements should be read in conjunction with the consolidated financial statements for the year ended July 31, 2015 and notes thereto contained in the Company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission. The consolidated balance sheet at July 31, 2015 has been derived from the audited financial statements at that date. The results of operations for the three and nine months ended April 30, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending July 31, 2016.

Effect of New Accounting Pronouncements

Leases - In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02 – Leases (Topic 842). The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. While we are evaluating the impact of adopting the new standard on our consolidated financial statements, we expect that upon adoption we will recognize ROU assets and lease liabilities in amounts that could be material.

Revenue recognition - In May 2014, the FASB issued Accounting Standards Codification (“ASC”) Topic 606, Revenue from Contracts with Customers, which supersedes ASC 605, Revenue Recognition. The new standard requires companies to recognize revenues upon transfer of goods or services to customers in amounts that reflect the

consideration which the company expects to receive in exchange for those goods or services. In July 2015, the FASB delayed the effective date of the standard by one year. The new guidance is effective for financial statements issued for annual reporting periods beginning after December 15, 2017 and early application is not permitted before the original effective date of annual reporting periods beginning after December 15, 2016. We are currently evaluating the impact of this standard on our consolidated financial statements.

**Inventory** – In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory,” which is intended to simplify the subsequent measurement of inventories by replacing the current lower of cost or market test with a lower of cost and net realizable value test. Application of the standard, which should be applied prospectively, is required for the annual and interim periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

**Stock Compensation** – In March 2016, the FASB issued ASU 2016-09, “Improvements to Employee Share-Based Payment Accounting,” which requires all excess tax benefits or deficiencies to be recognized as income tax expense or benefit in the income statement. In addition, excess tax benefits should be classified along with other income tax cash flows as an operating activity in the statement of cash flows. Application of the standard is required for the annual and interim periods beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this new standard on our consolidated financial statements.

Note 2 – Net income (loss) per share

Basic net income (loss) per share represents net income (loss) divided by the weighted average number of common shares outstanding during the period. As a result of the net loss for the three and nine months ended April 30, 2015, and the three months ended April 30, 2016 diluted weighted average shares outstanding are the same as basic weighted average shares outstanding, and do not include the potential common shares from stock options and unvested restricted stock because to do so would be antidilutive.

For the nine months ended April 30, 2016, approximately 337,000 weighted average stock options were included in the calculation of diluted weighted average shares outstanding. For the three and nine months ended April 30, 2015 and the three months ended April 30, 2016, the number of potential common shares (“in the money options”) and unvested restricted stock excluded from the calculation of diluted earnings per share were 1,384,000, 1,139,000 and 444,000, respectively.

For the three and nine months ended April 30, 2016, the effect of approximately 235,000 and 282,000 respectively, of outstanding “out of the money” options to purchase common shares were excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive. For the three and nine months ended April 30, 2015, the effect of approximately 384,000 and 192,000 respectively, of outstanding “out of the money” options to purchase common shares were excluded from the calculation of diluted net income (loss) per share because their effect would be anti-dilutive.

Note 3 - Supplemental disclosure for statement of cash flows

For the nine months ended April 30, 2016 and 2015, income taxes paid by the Company were \$207 and \$103, respectively.

For the nine months ended April 30, 2016 and 2015, interest paid by the Company was \$112 and \$153, respectively.

For the nine months ended April 30, 2016 and 2015, the Company financed \$76 and \$388 respectively, in machinery and transportation equipment under installment loans.

During the nine months ended April 30, 2016 and 2015, there was a total of \$1,186 and \$147 in new capital lease agreements.

During the nine months ended April 30, 2016 and 2015, the Company issued shares of common stock in connection with its share-based 401(k) employer match in the amount of \$709 and \$663.

Note 4 - Inventories

Inventories consist of the following:

	April 30, 2016	July 31, 2015
Raw materials	\$920	\$1,013
Work in process	1,811	2,002
Finished products	4,247	4,381
	\$6,978	\$7,396

Note 5 – Goodwill and intangible assets

At April 30, 2016 and July 31, 2015, the Company's net carrying amount of goodwill, related to the Clinical Labs segment, is \$7,452.

The Company's change in the net carrying amount of intangible assets, all in the Life Sciences segment is as follows:

	Gross	Accumulated Amortization	Net
July 31, 2015	\$27,838	\$ (21,683 )	\$6,155
Amortization expense	—	(1,260 )	(1,260)
Foreign currency translation	4	(15 )	(11 )
April 30, 2016	\$27,842	\$ (22,958 )	\$4,884

9

Intangible assets, all finite lived, consist of the following:

	April 30, 2016			July 31, 2015		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents	\$11,027	\$ (10,896)	) \$131	\$11,028	\$ (10,871)	) \$157
Customer relationships	12,238	(8,158)	) 4,080	12,243	(7,398)	) 4,845
Website and acquired content	1,018	(1,018)	) —	1,020	(1,020)	) —
Licensed technology and other	504	(447)	) 57	518	(441)	) 77
Trademarks	3,055	(2,439)	) 616	3,029	(1,953)	) 1,076
Total	\$27,842	\$ (22,958)	) \$4,884	\$27,838	\$ (21,683)	) \$6,155

At April 30, 2016, information with respect to intangibles assets acquired is as follows:

	Useful life assigned	Weighted average remaining useful life
Customer relationships	8-15 years	4.5 years
Trademarks	5 years	1.5 years
Other intangibles	10 years	3.5 years

At April 30, 2016, the weighted average useful life of amortizable intangible assets is approximately four years.

#### Note 6 - Loan Payable

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the “Credit Agreement”) among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and Healthcare Finance Group, LLC (the “Lender”). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Lab and Life Science segments up to \$8.0 million at defined eligibility percentages and provides for additional borrowings of \$4.0 million for increased eligible assets. Debt issuance costs of \$281 are being amortized over the life of the Credit Agreement. If the amount of borrowings outstanding under the revolving credit facility exceeds the borrowing base then in effect, or the Lender requires a reserve, the Company will be required to repay such borrowings in an amount sufficient to eliminate such excess. Interest on advances, payable monthly, is based on the three month LIBOR rate, with a floor of 1.25% plus an applicable margin of 4.0%. In the event of any default, the interest rate may be increased 3.0% over the current rate. The facility also carries a non-utilization fee of 0.50% per annum, payable monthly, on the unused portion of the Credit Agreement. At each of April 30, 2016 and July 31, 2015, the borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$2.0 million and \$3.0 million, respectively.

The Company's obligations under the Credit Agreement are secured by primarily all the unencumbered U.S. assets of the Company, excluding buildings and intellectual property which the Lender has a negative pledge, and the capital stock of subsidiaries. The Credit Agreement includes customary affirmative and negative covenants and events of default and requires maximum levels of cash usage and minimum levels of liquidity, as defined, and provides for increased liquidity levels if operating results are not achieved. Negative covenants include among others, limitations on additional debt, liens, loans or investments, distributions, asset sales and affiliate transactions. Events of default include non-payment of principal and interest on debt outstanding, non-performance of covenants, material change in business, breach of representations, bankruptcy and insolvency, material judgments and changes in control. In July 31, 2013, the lender modified various financial covenants relating to fiscal 2014. As of April 30, 2016, the Company is in compliance with the financial covenants.

The Credit Agreement includes customary affirmative and negative covenants and events of default. The terms of the debt covenants include:

The minimum balance the Company must borrow at any time is \$2.0 million. At April 30 2016, the loan balance was approximately \$2.0 million, with an additional availability of \$4.8 million.

The Company must maintain a Minimum Liquidity, as defined in the Credit Agreement, of not less than \$3.0 million. At April 30, 2016, the Company's Minimum Liquidity was \$10.9 million.



The quarterly Cash Burn, as defined in the Credit Agreement, must be greater than zero. During the nine months ended April 30, 2016, the Cash Burn was positive in the amount of \$1.0 million.

As of October 31, 2015, the Credit Agreement was amended to redefine Cash Burn and add a definition for Liquidity (the “amendment”). Under the amendment, the determination of Cash Burn during a fiscal quarter excludes capital expenditures provided that Liquidity exceeds \$7 million as of the last day of the fiscal quarter. As of April 30, 2016, Liquidity as defined was \$37.2 million.

Based on its current level of Minimum Liquidity and Cash Burn, the Company believes it will continue to be in compliance with the financial covenants in future periods; however there are no assurances of such compliance. Based on our ability to comply with financial covenants in the past, our ability to obtain covenant waivers previously, and our expected future performance, we believe we would be able to cure a non-compliance event and obtain a Lender waiver. The Company currently believes that the Lender would be willing to negotiate and provide waivers to the Company in the event of non-compliance with covenants, although there can be no assurances. In addition, the Company believes the effects of non-compliance with the covenants would not have a material effect on our financial condition and liquidity due to cash provided by operating cash flows and funds available under the Company’s Controlled Equity Offering program.

Note 7 – Accrued Liabilities and Other Current Liabilities

Accrued liabilities consist of the following:

	April 30, 2016	July 31, 2015
Payroll, benefits, and commissions	\$3,636	\$3,907
Legal fee expense	1,770	4,183
Professional fees	576	678
Research and development	300	300
Other	1,774	2,229
	\$8,056	\$11,297

Other current liabilities consist of the following:

	April 30, 2016	July 31, 2015
Accrued legal settlement	\$1,909	\$406
Capital lease obligations	298	149

Installment loans	257	331
	\$2,464	\$ 886

Note 8 – Other Liabilities

Other liabilities consist of the following:

	April 30, 2016	July 31, 2015
Accrued legal settlement	\$803	\$1,220
Capital lease obligations, net of short term	869	210
Installment loans, net of short term	148	363
	\$1,820	\$1,793

As of April 30, 2016, future minimum payments under the capital leases, net of interest of \$229 aggregates \$1,167 including a short term debt portion of \$298 included in other current liabilities. A total of \$2.7 million is included in other current liabilities and in other liabilities as accrued legal settlement which is further discussed in Note 13 - Contingencies.

Note 9 – Stockholders' Equity

***Controlled Equity Offering***

On March 28, 2013, the Company entered into a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"). Under the Sales Agreement, the Company may offer and sell, from time to time, through Cantor, shares of the Company's common stock, par value \$0.01 per share (the "Common Stock"), having an aggregate offering price of up to \$20.0 million (the "Shares"). The Company will pay Cantor a commission of 3.0% of the aggregate gross proceeds received under the Sales Agreement. The Company is not obligated to make any sales of the Shares under the Sales Agreement. The offering of Shares pursuant to the Sales Agreement will terminate upon the earlier of (a) the sale of all of the Shares subject to the Sales Agreement or (b) the termination of the Sales Agreement by Cantor or the Company, as permitted therein. The Shares were initially issued pursuant to the Company's Registration Statement on Form S-3 which was declared effective on August 5, 2010 and a prospectus supplement, dated March 28, 2013, and more recently under the Company's current Registration Statement on Form S-3 which was declared effective on August 13, 2013 and a prospectus supplement dated August 1, 2013, filed by the Company with the Securities and Exchange Commission (the "SEC").

On December 31, 2014, the Sales Agreement was amended in order for the Company to offer and sell, through Cantor, acting as agent, additional shares of Common Stock having an aggregate offering price of \$20.0 million. In connection with the amendment to the Sales Agreement, the Company also filed with the SEC a prospectus supplement dated December 31, 2014.

During the nine months ended April 30, 2016, the Company did not sell any shares of Common Stock under the Sales Agreement. For the nine months ended April 30, 2015, the Company sold an aggregate of 1,588,480 shares of Common Stock under the Sales Agreement at an average price of \$4.34 per share and received proceeds of approximately \$6.7 million, net of expenses of \$207.

***Share-based compensation***

The Company has an incentive stock option and restricted stock award plan (the "2005 Plan"), and a long term incentive share award plan, (the "2011 Incentive Plan"), which are more fully described in Note 10 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2015. The 2011 Plan, which is the only plan from which awards may now be granted, provides for the award to eligible employees, officers, directors, consultants and other persons of stock options, stock appreciation rights (SARs), restricted stock, restricted stock units, performance awards, and other stock-based awards.

The amounts of share-based compensation expense recognized in the periods presented are as follows:

	<b>Three months ended April 30,</b>		Nine months ended April 30,	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Stock options	\$143	\$104	\$351	\$283
Restricted stock	6	9	19	36
	\$149	\$113	\$370	\$319

The following table sets forth the amount of expense related to share-based payment arrangements included in specific line items in the accompanying statements of operations:

	Three months ended April 30,		Nine months ended April 30,	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Cost of clinical laboratory services	\$2	\$3	\$5	\$9
Research and development	—	—	—	2
Selling, general and administrative	147	110	365	308
	\$149	\$113	\$370	\$319

No excess tax benefits were recognized during the three month periods ended April 30, 2016 and 2015.

**Stock Option Plans**

The following table summarizes stock option activity during the three month period ended April 30, 2016:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (000s)
Outstanding at July 31, 2015	1,358,104	\$ 3.04		
Awarded	488,473	\$ 4.47		
Exercised	(23,702 )	\$ 2.79		
Cancelled or expired	(6,000 )	\$ 3.61		
Outstanding at end of period	1,816,875	\$ 3.43	1.9 years	\$ 2,386
Exercisable at end of period	1,104,974	\$ 2.95	1.1 years	\$ 1,976

As of April 30, 2016, the total future compensation cost related to non-vested options, not yet recognized in the statements of operations, was \$0.9 million and the weighted average period over which the remaining expense of these awards is expected to be recognized is nineteen months.

The intrinsic value of in the money stock option awards that are vested at the end of the period represents the Company's closing stock price on the last trading day of the period in excess of the exercise price multiplied by the number of options that vested.

**Restricted Stock Awards**

A summary of the activity pursuant to the Company's unvested restricted stock awards for the six months ended April 30, 2016 is as follows:

	Awards	Weighted Average Award Price
Outstanding at July 31, 2015	21,501	\$ 8.84
Awarded	—	\$ —
Vested	(8,751 )	\$ (2.32 )
Forfeited	(1,500 )	\$ (2.86 )
Unvested at end of period	11,250	\$ 4.21

The fair value of a restricted stock award is determined based on the closing stock price on the award date. As of April 30, 2016, there was approximately \$0.1 million of unrecognized compensation cost related to unvested restricted stock-based compensation to be recognized over a weighted average remaining period of approximately seventeen months.

The fair value of the awards that vested during the nine months ended April 30, 2016 and 2015 was \$30 and \$67, respectively.

The total number of shares available for grant as equity awards from the 2011 Incentive Plan is approximately 820,000 shares as of April 30, 2016.

During the nine months ended April 30, 2016, the Company contributed \$709 to match its employees' 401(k) contributions by issuing 160,352 shares, representing the fair value of the shares at the date of issuance, and adjusted common stock and additional paid in capital by the same amount.

During the nine months ended April 30, 2015, the Company contributed \$663 to match its employees' 401(k) contributions by issuing 214,984 shares, representing the fair value of the shares at the date of issuance, and adjusted common stock and additional paid in capital by the same amount.

Note 10 - Income taxes

At the end of each interim reporting period, the Company estimates its effective income tax rate expected to be applicable for the full year. This estimate is used to determine the income tax provision or benefit on a year-to-date basis and may change in subsequent interim periods.

The Company's effective tax rate (provision) for the three months ended April 30, 2016 was de minimus compared to a benefit of 3.2% for the three months ended April 30, 2015. The Company's effective tax rate (provision) for the nine months ended April 30, 2016 and 2015 was (3.1%) and de minimus, respectively. The tax provision for the periods was based on state, local and foreign taxes, net of the benefit for amortization of foreign intangibles. The Company's effective tax rate for both periods differed from the expected net operating loss carryforward benefit at the U.S. federal statutory rate of 34% primarily due to the inability to recognize such benefit. The carryforward benefit cannot be recognized because of uncertainties relating to future taxable income in terms of both its timing and its sufficiency, which would enable the Company to realize the federal carryforward benefit.

The Company files a consolidated Federal income tax return. The Company files combined returns with California, Michigan and New York State and City for certain subsidiaries. Other subsidiaries file separate state and foreign tax returns.

Note 11 – Royalty and licensing income

The Company's Life Science segment has a license agreement with Qiagen that began in 2005, whereby the Company earns quarterly royalties on the net sales of Qiagen products subject to the license until the expiration of the patent on April 24, 2018. During the nine months ended April 30, 2016 and 2015, the Company recorded royalty income under the agreement of approximately \$1.1 million and \$2.1 million respectively, which is included in the Life Sciences segment.

Note 12 – Segment reporting

The Company has three reportable segments: Clinical Labs, Life Sciences, and Therapeutics. The Clinical Labs segment provides diagnostic services to the health care community. The Company's Life Sciences segment develops, manufactures, and markets products to research and pharmaceutical customers. The Company's Therapeutic segment conducts research and development activities for therapeutic drug candidates.

The Company evaluates segment performance based on segment income (loss) before taxes. Costs excluded from segment income (loss) before taxes and reported as “Other” consist of corporate general and administrative costs which are not allocable to the three reportable segments. Legal fee expense incurred to defend the Company’s intellectual property and other general corporate matters is considered a component of the Other segment. Legal fee expense specific to other segments’ activities has been allocated to those segments. Legal settlements, net represent activities for which royalties would have been received by the Company’s Life Sciences segment had the Company had agreements in place with plaintiffs for the patents or products covered by the settlements.

Management of the Company assesses assets on a consolidated basis only and, therefore, assets by reportable segment have not been included in the reportable segments below. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies contained in the Company’s Annual Report on Form 10-K for the year ended July 31, 2015.



The following financial information represents the operating results of the reportable segments of the Company:

**Three months ended April 30, 2016**

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$18,162	—	—	—	\$ 18,162
Product revenues	—	\$ 8,001	—	—	8,001
Royalty and license fee income	—	270	—	—	270
	18,162	8,271	—	—	26,433
Operating expenses:					
Cost of clinical laboratory services	11,142	—	—	—	11,142
Cost of product revenues	—	3,846	—	—	3,846
Research and development	—	674	\$ 208	—	882
Selling, general and administrative	6,008	2,877	—	\$1,984	10,869
Provision for uncollectible accounts receivable	612	(36 )	—	—	576
Legal fee expense	54	11	—	1,567	1,632
Legal settlements, net	—	—	—	—	—
Total operating expenses	17,816	7,372	208	3,551	28,947
Operating income (loss)	346	899	(208 )	(3,551)	(2,514 )
Other income (expense):					
Interest	(33 )	7	—	(14 )	(40 )
Other	2	4	—	16	22
Foreign exchange gain	—	419	—	—	419
Income (loss) before income taxes	\$315	\$ 1,329	\$ (208 )	\$(3,549)	\$(2,113 )
Depreciation and amortization included above	\$418	\$ 514	\$ —	\$28	\$ 960
Share-based compensation included in above:					
Cost of clinical laboratory services	\$2	—	—	—	\$ 2
Research and development	—	—	—	—	—
Selling, general and administrative	14	\$ 9	—	\$124	147
Total	\$16	\$ 9	\$ —	\$124	\$ 149
Capital expenditures	\$331	\$ 115	\$ —	\$—	\$ 446

## Three months ended April 30, 2015

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$15,657	—	—	—	\$ 15,657
Product revenues	—	\$ 7,906	—	—	7,906
Royalty and license fee income	—	423	—	—	423
	15,657	8,329	—	—	23,986
Operating expenses:					
Cost of clinical laboratory services	9,724	—	—	—	9,724
Cost of product revenues	—	3,779	—	—	3,779
Research and development	—	704	\$ 105	—	809
Selling, general and administrative	4,935	3,031	—	\$2,180	10,146
Provision for uncollectible accounts receivable	631	(42 )	—	—	589
Legal fee expense	42	(22 )	—	1,935	1,955
Legal settlement, net	—	(170 )	—	—	(170 )
Total operating expenses	15,332	7,280	105	4,115	26,832
Operating income (loss)	325	1,049	(105 )	(4,115)	(2,846 )
Other income (expense):					
Interest	(23 )	6	—	(41 )	(58 )
Other	11	2	—	13	26
Foreign exchange loss	—	(125 )	—	—	(125 )
Income (loss) before income taxes	\$313	\$ 932	\$ (105 )	\$(4,143)	\$(3,003 )
Depreciation and amortization included above	\$358	\$ 543	\$ —	\$22	\$ 923
Share-based compensation included in above:					
Cost of clinical laboratory services	\$3	—	—	—	\$ 3
Research and development	—	\$—	—	—	—
Selling, general and administrative	9	6	—	\$95	110
Total	\$12	\$ 6	\$ —	\$95	\$ 113
Capital expenditures	\$453	\$ 58	\$ —	\$4	\$ 515

16

## Nine months ended April 30, 2016

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$52,775	—	—	—	\$ 52,775
Product revenues	—	\$22,266	—	—	22,266
Royalty and license fee income	—	1,129	—	—	1,129
	52,775	23,395	—	—	76,170
Operating expenses:					
Cost of clinical laboratory services	32,009	—	—	—	32,009
Cost of product revenues	—	10,663	—	—	10,663
Research and development	—	2,002	\$ 608	—	2,610
Selling, general and administrative	16,943	8,709	—	\$6,722	32,374
Provision for uncollectible accounts receivable	1,787	(48 )	—	—	1,739
Legal fee expense	120	(6 )	—	5,530	5,644
Legal settlements, net	1,500	(19,950)	—	—	(18,450 )
Total operating expenses	52,359	1,370	608	12,252	66,589
Operating income (loss)	416	22,025	(608 )	(12,252)	9,581
Other income (expense):					
Interest	(75 )	38	—	(85 )	(122 )
Other	5	35	—	47	87
Foreign exchange loss	—	(99 )	—	—	(99 )
Income (loss) before income taxes	\$346	\$21,999	\$ (608 )	\$(12,290)	\$ 9,447
Depreciation and amortization included above	\$1,226	\$1,568	\$ —	\$68	\$ 2,862
Share-based compensation included in above:					
Cost of clinical laboratory services	\$5	—	—	—	\$ 5
Research and development	—	—	—	—	—
Selling, general and administrative	33	\$19	—	\$313	365
Total	\$38	\$19	\$ —	\$313	\$ 370
Capital expenditures	\$1,122	\$267	\$ —	\$—	\$ 1,389

## Nine months ended April 30, 2015

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$46,204	—	—	—	\$ 46,204
Product revenues	—	\$ 23,631	—	—	23,631
Royalty and license fee income	—	2,067	—	—	2,067
	46,204	25,698	—	—	71,902
Operating expenses:					
Cost of clinical laboratory services	29,100	—	—	—	29,100
Cost of product revenues	—	11,292	—	—	11,292
Research and development	—	1,887	\$ 547	—	2,434
Selling, general and administrative	15,090	8,886	—	\$6,125	30,101
Provision for uncollectible accounts receivable	1,820	(89 )	—	—	1,731
Legal fee expense	174	(74 )	—	7,125	7,225
Legal settlement, net	—	(170 )	—	—	(170 )
Total operating expenses	46,184	21,732	547	13,250	81,713
Operating income (loss)	20	3,966	(547 )	(13,250)	(9,811 )
Other income (expense):					
Interest	(63 )	13	—	(126 )	(176 )
Other	18	(34 )	—	44	28
Foreign exchange loss	—	(856 )	—	—	(856 )
Income (loss) before income taxes	\$(25 )	\$ 3,089	\$ (547 )	\$(13,332)	\$(10,815 )
Depreciation and amortization included above	\$ 1,072	\$ 1,656	\$ 2	\$ 67	\$ 2,797
Share-based compensation included in above:					
Cost of clinical laboratory services	\$ 9	—	—	—	\$ 9
Research and development	—	\$ 2	—	—	2
Selling, general and administrative	30	9	—	\$ 269	308
Total	\$ 39	\$ 11	\$ —	\$ 269	\$ 319
Capital expenditures	\$ 1,042	\$ 122	\$ —	\$ 4	\$ 1,168

18

Note 13 – Contingencies

On June 7, 2004, the Company and Enzo Life Sciences, Inc., filed suit in the United States District Court for the District of Connecticut against Applera Corporation and its wholly-owned subsidiary Tropix, Inc., which became Life Technologies, Inc. and was acquired by Thermo Fisher Scientific, Inc. (NYSE:TMO) on February 3, 2014. The complaint alleged infringement of six patents relating to DNA sequencing systems, labeled nucleotide products, and other technology. Yale University is the owner of four of the patents and the Company is the exclusive licensee. These four patents are commonly referred to as the “Ward” patents. On November 12, 2012, a jury in New Haven found that one of these patents (United States Patent No. 5,449,667) was infringed and not proven invalid. The jury awarded \$48.5 million for this infringement. On January 6, 2014, the judge awarded prejudgment interest of approximately \$12.5 million and additional post-interest on the full amount will also be awarded starting November 7, 2012 until the total award is satisfied. The final award to the Company could be reduced or be subject to possible claims from third parties. On March 16, 2015, the Court of Appeals for the Federal Circuit vacated that judgment in a decision remanding the matter to the district court for further proceedings. On February 22, 2016, the Connecticut District Court granted Applera’s motion for summary judgment of non-infringement. The Company appealed that decision. There can be no assurance that the Company will be successful in this litigation. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

As of August 1, 2014 the Company was engaged in litigation in the United States District Court for the Southern District of New York against Roche Diagnostic GmbH and its related company Roche Molecular Systems, Inc. (“Roche”), as declaratory judgment defendant. This case was commenced in May 2004. Roche seeks a declaratory judgment of non-breach of contract and patent invalidity against the Company. Roche has also asserted tort claims against the Company. The Company has asserted breach of contract and patent infringement causes of action against Roche. There has been extensive discovery in the case. In 2011, Roche moved for summary judgment of non-infringement regarding the Company’s patent claims. In 2012, the motion was granted in part and denied in part. In December 2012, Roche moved for summary judgment on the Company’s non-patent claims. Additional discovery was taken and the Company responded to the motions in May 2013. On December 6, 2013, the Court granted in part and denied in part Roche’s summary judgment motion. On October 22, 2014, the Court ordered that damages discovery concerning the Company’s remaining contract and patent claims and Roche’s claims should be completed by January 30, 2015, and expert discovery should be completed following the Court’s not-yet-issued claim construction ruling concerning the Company’s patent infringement claim against Roche. Roche dropped its tort claims during damages discovery. On April 28, 2015, the Court heard oral argument on claim construction issues. On May 8, 2015, Roche and the Company jointly moved the Court to extend the schedule for damages discovery until May 29, 2015, and the Court granted that motion. The litigation in the United States District Court for the Southern District of New York between the Company and Molecular Probes, Inc. terminated on May 11, 2015, with a settlement, upon the parties’ joint stipulation for dismissal.

In 2012, the Company received a Subpoena Duces Tecum (the “Subpoena”) from the Department of Health and Human Services, Office of Inspector General (“OIG”). The Subpoena was issued as part of an investigation being conducted by the US Attorney’s Office for the Eastern District of New York in conjunction with the OIG. While a number of potential issues were raised initially by the government, the investigation came to focus primarily on an alleged failure to collect diagnosis codes from physicians who ordered tests through Enzo Clinical Labs. The time period initially covered by the investigation was from 2004 through 2011. In response to the Subpoena, the Company cooperated with the government. On September 22, 2014, the Company and the U.S. Department of Justice reached a settlement agreement to resolve this matter, in substantive form as disclosed in the Company’s fiscal quarter ended April 30,

2014. During the quarter ended April, 30, 2014, the Company recorded a charge of \$2.0 million in the statement of operations under legal settlements, net within the Clinical Labs segment. The settlement amount will be paid with interest over a five-year period. Under certain circumstances, the Company was required to accelerate payments and/or pay up to an additional \$1.5 million based upon (i) a favorable recovery and collection related to the judgment in the Life Technologies matter discussed above, (ii) receipt of additional capital greater than \$10.0 million in a fiscal year (in that case, the Company is required to pay 20% of any amount over \$10.0 million plus interest, or (iii) sale of the Company. The final settlement covers the time period 2004-2014. During the three months ended January 31, 2016, the Company accrued an additional \$1.5 million, due to the Company's achievement of certain financial milestones. As of April 30, 2016, the total liability for this settlement is \$2.7 million, of which \$1.9 million is included in other current liabilities and \$0.8 million included in other liabilities.

On July 2, 2015, the Company as Plaintiff executed a settlement agreement with Luminex Corporation with respect to an action between the Company and Abbott Laboratories and Abbott Molecular, Inc (Defendants) and Luminex Corporation (Intervening Defendant) before the United States District Court for the District of Delaware for alleged patent infringement. Luminex paid the Company a total of \$7.1 million as consideration for this agreement and the dismissal of the litigation against Luminex.

On July 20, 2015, the Company as a Plaintiff finalized and executed a settlement agreement with Siemens Healthcare Diagnostics Inc. (“Siemens”) to settle a patent litigation lawsuit before the U.S. District Court for the District of Delaware in the amount of \$6.7 million, net. Under terms of the agreement, Siemens will also pay the Company additional royalties of \$1.0 million per annum on sales of its molecular products manufactured and/or sold in the United States during the its fiscal years 2015 through 2019 if sales of such products exceed a contractual amount. The net settlement amount was included in other receivables in the consolidated balance sheet as of July 31, 2015 and was received in August 2015.

On October 9, 2015, the Company reached and finalized a settlement with Affymetrix, Inc. in the amount of \$6.8 million, net in a patent infringement action brought by the Company. On January 4, 2016, the Company reached and finalized a settlement agreement with Agilent Technologies, Inc. in the amount of \$6.1 million, net in a patent infringement action brought by the Company. Both cases were originally brought by the Company in the United States District Court for the District of Delaware. The settlements are included in the statement of operations under Legal settlements, net within the Life Science segment.

On May 16, 2016, the Company reached and finalized a settlement with Life Technologies Corporation in the amount of \$35.0 million in an infringement action brought by the Company regarding its US Patents no. 6,992,180 and 7,064,197. The case was originally brought by the Company in the United States District Court for the District of Delaware. This settlement will be recorded in the fourth quarter of fiscal year 2016.

The Company is party to other claims, legal actions, complaints, and contractual disputes that arise in the ordinary course of business. The Company believes that any liability that may ultimately result from the resolution of these matters will not, individually or in the aggregate, have a material adverse effect on its financial position or results of operations

## **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 consolidated financial statements and related notes and other information included elsewhere in this Quarterly Report on Form 10-Q.

### Forward-Looking Statements

Our disclosure and analysis in this report, including but not limited to the information discussed in this Item 2, contain forward-looking information about our Company’s financial results and estimates, business prospects and products in research and development that involve substantial risks and uncertainties. From time to time, we also may provide oral or written forward-looking statements in other materials we release to the public. Forward-looking statements give our

current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historic or current facts. They use words such as “anticipate”, “estimate”, “expect”, “project”, “intend”, “plan”, “believe”, “will”, and other words and terms of similar meaning in connection with any discussion of future operations or financial performance.

In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign currency rates, intellectual property matters, the outcome of contingencies, such as legal proceedings, and financial results.

We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. Achievement of future results is subject to risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. As a result, investors are cautioned not to place undue reliance on any of our forward-looking statements. Investors should bear this in mind as they consider forward-looking statements. We do not assume any obligation to update or revise any forward-looking statement that we make, even if new information becomes available or other events occur in the future. We are also affected by other factors that may be identified from time to time in our filings with the Securities and Exchange Commission, some of which are set forth in Item 1A - Risk Factors in our Form 10-K filing for the July 31, 2015 fiscal year. You are advised to consult any further disclosures we make on related subjects in our Forms 10-Q, 8-K and 10-K reports to the Securities and Exchange Commission. Although we have attempted to provide a list of important factors which may affect our business, investors are cautioned that other factors may prove to be important in the future and could affect our operating results. You should understand that it is not possible to predict or identify all such factors or to assess the impact of each factor or combination of factors on our business. Consequently, you should not consider any such list to be a complete set of all potential risks or uncertainties.



## Overview

Enzo Biochem, Inc. (the “Company” “we”, “our” or “Enzo”) is a growth-oriented biotechnology company focusing on delivering and applying advanced technology capabilities to produce affordable reliable products and services to allow our customers to meet their clinical needs. We develop, manufacture and sell our proprietary technology solutions and platforms to clinical laboratories, specialty clinics and researchers and physicians globally. Our pioneering work in genomic analysis coupled with our extensive patent estate and enabling platforms have positioned the Company to continue to play an important role in the rapidly growing molecular medicine marketplaces.

Enzo technology solutions and platforms and unique operational structure is designed to reduce overall healthcare costs to both government and private insurers. Our proprietary technology platforms reduces our customers’ need for multiple, specialized instruments, and offer a variety of throughput capabilities together with a demonstrated high level of accuracy and reproducibility. Our genetic test panels are focused on large and growing markets primarily in the areas of personalized medicine, women’s health, infectious diseases and genetic disorders.

For example, our Ampiprobe™ technology platform can lead to the development of an entire line of nucleic acid clinical products that can allow laboratories to offer a complete menu of services at a cost that allows them to enjoy an acceptable margin. In November 2015, New York State approved our first assay based on the Ampiprobe platform aimed at providing affordable molecular diagnostics in light of reimbursement pressure. Our technology solutions provide tools to physicians, clinicians and other health care providers to improve detection, treatment and monitoring of a broad spectrum of diseases and conditions. In addition, reduced patient to physician office visits translates into lower healthcare processing costs and greater patient services.

We are comprised of three interconnected operating segments which have evolved out of our core competencies involving the use of nucleic acids as informational molecules and the use of compounds for immune modulation. Information concerning sales by geographic area and business segments for fiscal year ended July 31, 2015 can be found in our Form 10-K Note 15 in the Notes to Consolidated Financial Statements.

Below are brief descriptions of each of our operating segments (See Note 12 in the Notes to Consolidated Financial Statements):

**Enzo Clinical Labs** is a clinical reference laboratory providing a wide range of clinical services to a physicians, medical centers, other clinical labs and pharmaceutical companies. The Company believes having a College of American Pathologists (“CAP”) certified medical laboratory located in New York provides us to the opportunity to more rapidly introduce cutting edge products and services to the clinical marketplace. Enzo Clinical Labs offers an extensive menu of molecular and other clinical laboratory tests or procedures used in patient care by physicians to establish or support a diagnosis, monitor treatment or medication, and search for an otherwise undiagnosed condition. Our laboratory is equipped with state of the art communication and connectivity solutions enabling the rapid transmission, analysis and interpretation of generated data. We operate a full service clinical laboratory in

Farmingdale, New York, a network of over 30 patient service centers throughout New York and New Jersey, a free standing “STAT” or rapid response laboratory in New York City and a full service phlebotomy, in-house logistics department, and information technology department.

**Enzo Life Sciences** manufactures, develops and markets products and tools to clinical research, drug development and bioscience research customers worldwide. Underpinned by broad technological capabilities, Enzo Life Sciences has developed proprietary products used in the identification of genomic information by laboratories around the world. Information regarding our technologies can be found in the “Core Technologies” section. We are internationally recognized and acknowledged as a leader in the development, manufacturing validation and commercialization of numerous products serving not only the clinical research market but life sciences researchers in the fields of cellular analysis and drug discovery, among others. Our operations are supported by global operations allowing for the efficient marketing and delivery of our products around the world.

**Enzo Therapeutics** is a biopharmaceutical venture that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases, many of which are derived from the pioneering work of Enzo Life Sciences. Enzo Therapeutics has focused its efforts on developing treatment regimens for diseases and conditions for which current treatment options are ineffective, costly, and/or cause unwanted side effects. This focus has generated a clinical and preclinical pipeline, as well as more than 111 patents and patent applications.

**Results of Operations****Three months ended April 30, 2016 compared to April 30, 2015***(in 000s)*Comparative Financial Data for the Three Months Ended April 30,

	2016	2015	Increase (Decrease)	% Change	
<b>Revenues:</b>					
Clinical laboratory services	\$18,162	\$15,657	\$ 2,505	16	%
Product revenues	8,001	7,906	95	1	
Royalty and license fee income	270	423	(153 )	(36 )	)
Total revenues	26,433	23,986	2,447	10	
<b>Operating expenses:</b>					
Cost of clinical laboratory services	11,142	9,724	1,418	15	
Cost of product revenues	3,846	3,779	67	2	
Research and development	882	809	73	9	
Selling, general, and administrative	10,869	10,146	723	7	
Provision for uncollectible accounts receivable	576	589	(13 )	(2 )	)
Legal fee expense	1,632	1,955	(323 )	(17 )	)
Legal settlements, net	—	(170 )	170	**	
Total operating expenses	28,947	26,832	2,115	8	
Operating loss	(2,514 )	(2,846 )	332	12	
<b>Other income (expense):</b>					
Interest	(40 )	(58 )	18	31	
Other	22	26	(4 )	(15 )	)
Foreign exchange gain (loss)	419	(125 )	544	**	
Income (loss) before income taxes	\$(2,113 )	\$(3,003 )	\$ 890	30	

**\*\* not meaningful****Consolidated Results:**

The “2016 period” and the “2015 period” refer to the three months ended April 30, 2016 and 2015, respectively.

Clinical laboratory services revenues for the 2016 period were \$18.2 million compared to \$15.7 million in the 2015 period, an increase of \$2.5 million or 16%. The increase is attributed to increased molecular testing volume and higher value account acquisitions, which were offset in part by attrition and a slight decline in routine test volume.

Product revenues for the 2016 period were \$8.0 million compared to \$7.9 million in the 2015 period, an increase of \$0.1 million or 1%. Revenues increased \$0.2 million in the United States and decreased \$0.1 million in European markets in the 2016 period versus the 2015 period.

Royalty and license fee income during the 2016 period was \$0.3 million compared to \$0.4 million in the 2015 period a decrease of \$0.1 million or 36%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. Qiagen is experiencing declines in its US sales of HPV products which in turn reduced our royalty income. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2016 period was \$11.1 million as compared to \$9.7 million in the 2015 period, an increase of \$1.4 million or 15% due to the increase in Clinical laboratory services revenue for molecular testing of 16%.

The cost of product revenues during the 2016 period was approximately \$3.8 million in both the 2016 and 2015 periods. The gross profit margin was 52% in both periods.

Research and development expenses were approximately \$0.9 million and \$0.8 million during the 2016 and 2015 periods, respectively.

Selling, general and administrative expenses were approximately \$10.9 million during the 2016 period versus \$10.2 million during the 2015 period, an increase of \$0.7 million or 7%. The Clinical Lab segment selling, general and administrative increased \$1.1 million primarily due to increases in sales commission, payroll and related costs and billing and collection expenses in support of greater molecular testing. The Life Sciences segment selling, general and administrative decreased \$0.2 million due to a decrease in compensation related expenses. Other segment selling, general and administrative decreased \$0.2 million due to lower salary related expenses and professional fees.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was \$0.6 million for both the 2016 and 2015 periods. As a percent of Clinical laboratory services, the provision for uncollectible accounts receivable relating to the Clinical Labs segment in the 2016 and 2015 periods was 3.4% and 4.0%, respectively. The decrease is primarily due to enhanced collection procedures for self-pay patient receivables.

Legal fee expense was \$1.6 million during the 2016 period compared to \$1.9 million in the 2015 period, a decrease of \$0.3 million or 17% due to the timing of legal activity and fees and related costs associated with ongoing patent litigation.

Legal settlements, net were \$(0.2) million in the 2015 period from a small settlement which occurred in that period.

Interest expense was \$0.1 million during the 2016 and 2015 periods due to interest incurred and fees relating to the credit agreement entered into in 2013.

During the 2016 period, the foreign currency exchange gain was \$0.4 million versus a loss of \$0.1 million, a favorable change of \$0.5 million. The Company has loans and receivables with its foreign subsidiaries which may be denominated in US dollars or a foreign currency. When re-measuring these amounts into the respective entities' functional currency, the Company recognizes a loss if those foreign currencies, including the Swiss Franc, British pound and Euro depreciate relative to the US dollar during the period and a gain if those foreign currencies appreciate relative to the US dollar. During the 2016 period, the British pound, Swiss franc, and Euro appreciated approximately 3%, 7% and 6%, respectively versus the US dollar. During the 2015 period, the Euro and Swiss franc each depreciated 3% versus the US dollar, and the British pound appreciated 2% versus the US dollar.

## **Segment Results:**

### **Clinical Labs**

The Clinical Labs segment's operating income before taxes was \$0.3 million for the 2016 and 2015 periods. Revenue from laboratory services for the 2016 period were \$18.2 million compared to \$15.7 in the 2015 period. The increase of \$2.5 million is attributed to increased molecular testing volume and higher value account acquisitions, which were offset in part by attrition and a slight decline in routine test volume. Cost of sales during the 2016 period was \$11.1 million as compared to \$9.7 million in the 2015 period, an increase of \$1.4 million due to higher molecular testing. Clinical Lab gross profit margin was approximately 39% in the 2016 period and approximately 38% in the 2015 period. As a percentage of revenues, the provision for uncollectable accounts declined to 3.4% versus 4.0% in the 2015 period and is due to enhanced collection procedures for self-pay patient receivables.

### **Life Sciences**

The Life Sciences segment's operating income before taxes was \$1.3 million for the 2016 period as compared to \$0.9 million for the 2015 period, an improvement of \$0.4 million. The 2015 period includes a \$0.2 million benefit for a minor litigation settlement. Product revenues increased \$0.1 million or 1% in the 2016 period. The segment's gross profit was \$4.4 million in the 2016 period, as compared \$4.5 million in the 2015 period, a decrease of \$0.1 million due to a decrease in royalty and license fee income. The segment's other operating expenses, excluding legal and legal settlements, net, in the 2016 period decreased \$0.1 million due to decreased selling expenses. Due to appreciation of foreign currencies versus the US dollar, including the Swiss Franc, British pound and Euro during the 2016 period, the foreign currency gain was \$0.4 million compared to a loss of \$0.1 million in the 2015 period, resulting in a favorable change of \$0.5 million in the 2016 period.

### **Therapeutics**

Therapeutics segment's operating loss before income taxes was approximately \$0.2 million and \$0.1 million in the 2016 and 2015 periods.

**Other**

The Other segment's operating loss before taxes for the 2016 period was approximately \$3.5 million as compared to \$4.1 million for the 2015 period, a decrease of \$0.6 million due to lower legal fee and compensation related expenses.

**Results of Operations**

*Nine months ended April 30, 2016 as compared to April 30, 2015*

*(in 000s)*

	2016	2015	Increase (Decrease)	% Change
<b>Revenues:</b>				
Clinical laboratory services	\$52,775	\$46,204	\$ 6,571	14 %
Product revenues	22,266	23,631	(1,365 )	(6 )
Royalty and license fee income	1,129	2,067	(938 )	(45 )
Total revenues	76,170	71,902	4,268	6
<b>Operating expenses:</b>				
Cost of clinical laboratory services	32,009	29,100	2,909	10
Cost of product revenues	10,663	11,292	(629 )	(6 )
Research and development	2,610	2,434	176	7
Selling, general, and administrative	32,374	30,101	2,273	8
Provision for uncollectible accounts receivable	1,739	1,731	8	—
Legal fee expense	5,644	7,225	(1,581 )	(22 )
Legal settlements, net	(18,450)	(170 )	(18,280 )	**
Total operating expenses	66,589	81,713	(15,124 )	(9 )
Operating income (loss)	9,581	(9,811 )	19,392	**
<b>Other income (expense):</b>				
Interest	(122 )	(176 )	54	31
Other	87	28	59	**
Foreign exchange loss	(99 )	(856 )	757	88
Income (loss) before income taxes	\$9,447	\$(10,815)	\$ 20,262	**

**\*\* not meaningful**

**Consolidated Results:**

The “2016 period” and the “2015 period” refer to the nine months ended April 30, 2016 and 2015, respectively.

Clinical laboratory services revenues for the 2016 period were \$52.8 million compared to \$46.2 million in the 2015 period, an increase of \$6.6 million or 14%. The increase is attributed to increased molecular testing volume and higher value account acquisitions which were offset in part by attrition and a decline in routine test volume.

Product revenues for the 2016 period were \$22.3 million compared to \$23.6 million in the 2015 period, a decrease of \$1.4 million or 6%. The decrease was due to declines in sales of products (\$1.0 million) in both the United States and foreign markets and the negative impact of translating revenues denominated in the euro, pound sterling and Swiss franc which depreciated versus the US dollar in the 2016 period compared to the 2015 period (\$0.4 million). Revenues decreased due to lower order volume and were also negatively impacted by pricing due to competition and lower research funding, especially in academia.

Royalty and license fee income during the 2016 period was \$1.1 million compared to \$2.0 million in the 2015 period a decrease of \$0.9 million or 45%. Royalties are primarily earned from the reported sales of Qiagen products subject to a license agreement. Qiagen is experiencing declines in its US sales of HPV products which in turn reduced our royalty income. There are no direct expenses relating to royalty and licensing income.

The cost of clinical laboratory services during the 2016 period was \$32.0 million as compared to \$29.1 million in the 2015 period, an increase of \$2.9 million or 10% due to the increase in Clinical laboratory services revenue for molecular testing of 14%.



The cost of product revenues during the 2016 period was \$10.7 million compared to \$11.3 million in the 2015 period, a decrease of \$0.6 million or 6% due to lower sales. The gross profit margin was 52% in the 2016 and 2015 periods.

Research and development expenses were approximately \$2.6 million and \$2.4 million during the 2016 and 2015 periods, respectively.

Selling, general and administrative expenses were approximately \$32.4 million during the 2016 period versus \$30.1 million during the 2015 period, an increase of \$2.3 million or 8%. The Clinical Lab segment selling, general and administrative increased \$1.9 million primarily due to increases in sales commissions and compensation related expenses in support of greater molecular testing volume. The Life Sciences segment selling, general and administrative declined approximately \$0.2 million due to declines in payroll and facilities expense. Other segment selling, general and administrative increased \$0.6 million due to an increase of \$1.1 million for contested proxy expenses relating to our annual stockholders' meeting which took place in January 2016, partially offset by decreases of \$0.3 million for professional fees and \$0.2 million of payroll related expenses.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was approximately \$1.7 million for both the 2016 and 2015 periods. As a percent of Clinical laboratory services, the provision for uncollectible accounts receivable relating to the Clinical Labs segment in the 2016 and 2015 periods was 3.4% and 3.9%, respectively. The decrease is primarily due to enhanced collection procedures for self-pay patient receivables.

Legal fee expense was \$5.6 million during the 2016 period compared to \$7.2 million in the 2015 period, a decrease of \$1.6 million or 22% due to the timing of legal activity fees and related costs associated with ongoing patent litigation. Legal fee expense in the 2016 period includes \$0.4 million for contested proxy costs relating to our annual stockholders meeting which took place in January 2016.

Legal settlements, net was \$(18.5) million in the 2016 period versus \$(0.2) million in the 2015 period. During the 2016 period the Company as plaintiff finalized and executed settlement agreements with Affymetrix and Agilent Technologies, Inc. relating to patent infringement claims and collected proceeds held in escrow relating to the PerkinElmer, Inc. and Molecular Probes, Inc. settlements, totaling \$20.0 million. The Company also recorded an additional charge of \$1.5 million relating to the settlement with the U.S. Department of Justice, due to the achievement of certain financial milestones. See Note 13 Contingencies.

Interest expense was \$0.1 million during the 2016 versus \$0.2 million in the 2015 periods. During the 2015 period there were some additional fees relating to the credit agreement, which was entered into in 2013.

During the 2016 and the 2015 periods, the foreign currency loss was \$0.1 million and \$0.9 million, respectively, a favorable change of \$0.8 million. The Company has loans and receivables with its foreign subsidiaries which may be

denominated in US dollars or a foreign currency. When re-measuring these amounts into the respective entities' functional currency, the Company recognizes a loss if those foreign currencies, including the Swiss Franc, British pound and Euro depreciate relative to the US dollar during the period and a gain if those foreign currencies appreciate relative to the US dollar. During the 2016 period, the Swiss franc and Euro appreciated approximately 1%, and 4.5% respectively, versus the US dollar. The British pound depreciated 6.4%.

**Segment Results:**

**Clinical Labs**

The Clinical Labs segment's operating income before taxes was \$0.4 million for 2016 period as compared to breakeven in the 2015 period. The 2016 period includes an additional \$1.5 million charge for the legal settlement with the U.S. Department of Justice, due to the achievement of certain financial milestones. Revenue from laboratory services for the 2016 period were \$52.8 million compared to \$46.2 million in the 2015 period. The increase of \$6.6 million is attributed to increased molecular testing volume and higher value account acquisitions, which were offset in part by attrition and a decline in routine test volume. Cost of sales during the 2016 period was \$32.0 million as compared to \$29.1 million in the 2015 period, an increase of \$2.9 million due to higher molecular testing service revenues. Clinical Lab gross profit margin was 39% in the 2016 period and 37% in the 2015 period. As a percentage of revenues, the provision for uncollectable accounts declined to 3.4% versus 3.9% in the 2015 period and is due to enhanced collection procedures for self-pay patient receivables.

## **Life Sciences**

The Life Sciences segment's operating income before taxes was \$22.0 million for the 2016 period as compared to \$3.1 million for the 2015 period, an improvement of \$18.9 million. The 2016 period includes \$20.0 million for patent and other litigation settlements previously described and \$0.2 million in the 2015 period. Product revenues decreased \$1.4 million or 6% in the 2016 period due to declines in sales of products (\$1.0 million) in both the United States and foreign markets and the negative impact of translating revenues denominated in the euro, pound sterling and Swiss franc which depreciated versus the US dollar in the 2016 period compared to the 2015 period (\$0.4 million). Revenues decreased due to lower order volume and were negatively impacted by pricing due to competition and lower research funding, especially in academia. The segment's gross profit was \$12.7 million in the 2016 period, as compared \$14.4 million in the 2015 period, a decrease of \$1.7 million primarily due to lower royalty and license fee income of \$0.9 million and a gross margin decrease of \$0.8 million on lower product revenues. Due to significantly smaller depreciation of foreign currencies versus the US dollar, including the Swiss Franc, British pound and Euro during the 2016 period, the foreign currency loss was \$0.1 million compared to a loss of \$0.9 million in the 2015 period, resulting in a favorable change of \$0.8 million in the 2016 period.

## **Therapeutics**

Therapeutics segment's operating loss before income taxes was approximately \$0.6 and \$0.5 million in the 2016 and 2015 periods, respectively.

## **Other**

The Other segment's operating loss before taxes for the 2016 period was approximately \$12.3 million as compared to \$13.3 million for the 2015 period, a decrease of \$1.0 million. During the 2016 period, legal fee expense associated with ongoing patent litigation declined \$2.0 million, professional fees declined \$0.3 million, and salary related expenses declined \$0.2 million. These declines were partially offset by \$1.5 million of consulting and legal fee expenses relating to contested proxy costs for our annual stockholders' meeting which took place in January 2016.

## **Liquidity and Capital Resources**

At April 30, 2016, the Company had cash and cash equivalents of \$32.4 million of which \$0.5 million was in foreign accounts, as compared to cash and cash equivalents of \$18.1 million, of which \$0.5 million was in foreign accounts at July 31, 2015. It is the Company's current intent to permanently reinvest these funds outside of the United States, and its current plans do not demonstrate a need to repatriate them to fund its United States operations. The Company had working capital of \$33.5 million at April 30, 2016 compared to \$22.5 million at July 31, 2015. The increase in working capital of \$11.0 million was primarily due to net income of \$9.2 million, which includes the recognition of

\$18.5 million in income from Legal settlements, net from patent litigation settlement agreements, offset by net changes in operating assets and liabilities.

Net cash provided by operating activities as of April 30, 2016 was approximately \$17.0 million as compared to cash used in operating activities of \$8.2 million in fiscal 2015, an increase of approximately \$25.2 million. The increase in the 2016 period was primarily due to the change in net income of \$19.9 million, and the net change in operating assets and liabilities of \$6.3 million, which includes the collection of other receivables of \$6.7 million from the settlement agreement with Siemens Healthcare Diagnostics Inc. in the first quarter of fiscal 2016.

Net cash used in investing activities in fiscal 2016 was approximately \$1.4 million as compared to \$1.2 million in the 2015 period, an increase of \$0.2 million. The increase in the 2016 period is primarily due to increased capital expenditures.

Net cash used in financing activities in fiscal 2016 was approximately \$1.4 million as compared to cash provided by financing activities of \$6.4 million in fiscal 2015. The decrease of \$7.7 million was primarily due to proceeds from the issuance of common stock under the Controlled Equity Offering program in the 2015 period and a \$1.0 million reduction in the loan payable under the Credit Agreement in the 2016 period.

On June 7, 2013, the Company entered into a secured Revolving Loan and Security Agreement (the "Credit Agreement") among the Company and certain of its subsidiaries, with Enzo Therapeutics as a guarantor, and MidCap Financial Services, LLC (formerly Healthcare Finance Group, LLC). The Credit Agreement, which expires in December 2016, provides for borrowings against eligible US receivables, as defined, of the Clinical Labs and Life Sciences segments up to \$8.0 million at defined eligibility percentages and provides for additional borrowings of \$4.0 million for increased eligible assets.

At April 30, 2016 and July 31, 2015 borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$2.0 million and \$3.0 million, respectively, with an additional availability of \$4.8 million as of April 30, 2016. As of October 31, 2015, the Credit Agreement was amended to add and redefine certain terms used in the Cash Burn covenant calculation, principally the elimination of capital expenditures from the calculation when Liquidity exceeds \$7.0 million.

As of April 30, 2016, the Company is in compliance with the modified financial covenants. See Note 6 to the Consolidated Financial Statements herein for a further description of the Credit Agreement's terms, the amendment and financial covenants.

The Company continued to review all operating units to further reduce annual operating expenditures in fiscal 2016. While revenues and operating results at the Clinical Labs segment improved, revenues for the Life Sciences segment declined slightly versus fiscal 2015. If revenues were to significantly decline, the segment could be required to record impairments of its intangible assets, which last occurred in fiscal 2012. The Company believes that its current cash and cash equivalents level, utilization of the Controlled Equity Offering program if necessary, as disclosed in Form 10-K Note 10 to the financial statements, which resulted in net proceeds of \$6.7 million during the fiscal year ended July 31, 2015, and available borrowings under the aforementioned Revolving Loan and Security Agreement disclosed in Note 6 to the financial statements herein are sufficient for its foreseeable liquidity and capital resource needs over the next twelve (12) months, although there can be no assurance that future events will not alter such view. Although there can be no assurances, in the event additional capital is required, the Company believes it has the ability to raise additional funds through equity offerings or other sources of funds. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the Item 1A. "Risk Factors" section of our Form 10-K for the year ended July 31, 2015, some of which are outside our control. Macroeconomic conditions could limit our ability to successfully execute our business plans and therefore adversely affect our liquidity plans.

See our Form 10-K for the fiscal year ended July 31, 2015 for Forward Looking Cautionary Statements.

### **Contractual Obligations**

There have been no material changes to our Contractual Obligations as reported in our Form 10-K for the fiscal year ended July 31, 2015.

Management is not aware of any material claims, disputes or settled matters concerning third party reimbursement that would have a material effect on our financial statements, except as disclosed in Note 13 to the Consolidated Financial Statement.

### **Off-Balance Sheet Arrangements**

The Company does not have any “off-balance sheet arrangements” as such term is defined in Item 303(a)(4) of Regulation S-K.

### **Critical Accounting Policies**

The Company’s discussion and analysis of its financial condition and results of operations are based upon Enzo Biochem, Inc.’s consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires the Company to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and judgments also affect related disclosure of contingent assets and liabilities.

On an on-going basis, we evaluate our estimates, including those related to contractual expense, allowance for uncollectible accounts, inventory, intangible assets and income taxes. The Company bases its estimates on experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

#### Product revenues

Revenues from product sales are recognized when the products are shipped and title transfers, the sales price is fixed or determinable and collectability is reasonably assured.

Royalties

Royalty revenues are recorded in the period earned. Royalties received in advance of being earned are recorded as deferred revenues.

Revenues – Clinical laboratory services

Revenues from Clinical Labs are recognized upon completion of the testing process for a specific patient and reported to the ordering physician. These revenues and the associated accounts receivable are based on gross amounts billed or billable for services rendered, net of a contractual adjustment, which is the difference between amounts billed to payers and the expected approved reimbursable settlements from such payers.

The following table represents the clinical laboratory segment's net revenues and percentages by revenue category:

	Three months ended April 30, 2016		Three months ended April 30, 2015	
Revenue category				
Third-party payer	\$10,250	57 %	\$9,172	59 %
Patient self-pay	4,357	24	2,667	17
Medicare	2,421	13	2,543	16
HMO's	1,134	6	1,275	8
Total	\$18,162	100 %	\$15,657	100 %

	Nine months ended April 30, 2016		Nine months ended April 30, 2015	
Revenue category				
Third-party payer	\$30,049	57 %	\$25,937	56 %
Patient self-pay	11,120	21	8,910	19
Medicare	8,174	15	7,763	17
HMO's	3,432	7	3,594	8
Total	\$52,775	100 %	\$46,204	100 %

The Company provides services to certain patients covered by various third-party payers, including the Federal Medicare program. Laws and regulations governing Medicare are complex and subject to interpretation for which action for noncompliance includes fines, penalties and exclusion from the Medicare programs. See Note 13 in the Notes to Consolidated Financial Statements.

Other than the Medicare program, one provider whose programs are included in the “Third-party payers” and “Health Maintenance Organizations” (“HMO’s”) categories represents approximately 31% and 30% of the Clinical Labs segment net revenue for the three months ended April 30, 2016 and 2015 respectively, and 30% and 27% for the nine months ended April 30, 2016 and 2015, respectively.

Contractual Adjustment

The Company’s estimate of contractual adjustment is based on significant assumptions and judgments, such as its interpretation of payer reimbursement policies, and bears the risk of change. The estimation process is based on the experience of amounts approved as reimbursable and ultimately settled by payers, versus the corresponding gross amount billed to the respective payers. The contractual adjustment is an estimate that reduces gross revenue, based on gross billing rates, to amounts expected to be approved and reimbursed. Gross billings are based on a standard fee schedule we set for all third party payers, including Medicare, HMO’s and managed care. The Company adjusts the contractual adjustment estimate quarterly, based on its evaluation of current and historical settlement experience with payers, industry reimbursement trends, and other relevant factors.

The other relevant factors that affect our contractual adjustment include the monthly and quarterly review of: 1) current gross billings and receivables and reimbursement by payer, 2) current changes in third party arrangements and 3) the growth of in-network provider arrangements and managed care plans specific to our Company.

Our clinical laboratory business is primarily dependent upon reimbursement from third-party payers, such as Medicare (which principally serves patients 65 and older) and insurers. We are subject to variances in reimbursement rates among different third-party payers, as well as constant changes of reimbursement rates.



Changes that decrease reimbursement rates or coverage would negatively impact our revenues. The number of individuals covered under managed care contracts or other similar arrangements has grown over the past several years and may continue to grow in the future. In addition, Medicare and other government healthcare programs continue to shift to managed care. These trends will continue to reduce our revenues.

During the three months ended April 30, 2016 and 2015, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 84.6% and 85.5%, respectively, of gross billings. During the nine months ended April 30, 2016 and 2015, the contractual adjustment percentages, determined using current and historical reimbursements statistics, were 84.4% and 85.4%, respectively, the decrease is due to the increase in molecular testing performed. In general, the Company believes a decline in reimbursement rates or a shift to managed care or similar arrangements may be offset by the positive impact of an increase in the number of molecular tests we perform. However, there can be no assurance that we can increase the number of tests we perform or that if we do increase the number of tests we perform, that we can maintain that higher number of tests performed, or that an increase in the number of tests we perform would result in increased revenue.

The Company estimates (by using a sensitivity analysis) that each 1% point change in the contractual adjustment percentage could result in a change in clinical laboratory services revenues of approximately \$3.4 million and \$3.2 million for the nine months ended April 30, 2016 and 2015, respectively, and a change in the net accounts receivable of approximately \$0.6 million as of April 30, 2016.

Our clinical laboratory financial billing system records gross billings using a standard fee schedule for all payers and does not record contractual adjustment by payer at the time of billing. Therefore, we are unable to quantify the effect of contractual adjustment recorded during the current period that relate to revenue recorded in a previous period. However, we can reasonably estimate our monthly contractual adjustment to revenue on a timely basis based on our quarterly review process, which includes:

- an analysis of industry reimbursement trends;

• an evaluation of third-party reimbursement rates changes and changes in reimbursement arrangements with third-party payers;

• a rolling monthly analysis of current and historical claim settlement and reimbursement experience statistics with payers;

- an analysis of current gross billings and receivables by payer.

Accounts Receivable and Allowance for Doubtful Accounts

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Accounts receivable are reported at realizable value, net of allowances for doubtful accounts, which is estimated and recorded in the period of the related revenue.

The following is a table of the Company's net accounts receivable by segment. The Clinical Labs segment's net receivables are detailed by billing category and as a percent to its total net receivables. At April 30, 2016, and July 31, 2015, approximately 73% and 68%, respectively, of the Company's net accounts receivable relates to its Clinical Labs business, which operates in the New York, New Jersey, and Eastern Pennsylvania medical communities.

The Life Sciences segment's accounts receivable, of which \$1.2 million or 32% and \$1.1 million or 28% represents foreign receivables as of April 30, 2016 and July 31, 2015, includes royalty receivables of \$0.1 million, as of April 30, 2016 and July 31, 2015, from Qiagen Corporation.

Net accounts receivable

Billing category	As of April 30, 2016		As of July 31, 2015	
Clinical Labs				
Third party payers	\$6,882	67 %	\$3,595	44 %
Patient self-pay	1,835	18	3,213	39
Medicare	1,205	12	1,081	13
HMO's	334	3	305	4
Total Clinical Labs	10,256	100 %	8,194	100 %
Total Life Sciences	3,744		3,915	
Total accounts receivable	\$14,000		\$12,109	

Changes in the Company's allowance for doubtful accounts are as follows:

	April 30, 2016	July 31, 2015
Beginning balance	\$1,786	\$2,142
Provision for doubtful accounts	1,739	2,284
Write-offs, net	(603 )	(2,640)
Ending balance	\$2,922	\$1,786

For the Clinical Labs segment, the allowance for doubtful accounts represents amounts that the Company does not expect to collect after the Company has exhausted its collection procedures. The Company estimates its allowance for doubtful accounts in the period the related services are billed and reduces the allowance in future accounting periods based on write-offs during those periods. It bases the estimate for the allowance on the evaluation of historical experience of accounts going to collections and the net amounts not received. Accounts going to collection include the balances, after receipt of the approved settlements from third party payers, for the insufficient diagnosis information received from the ordering physician which result in denials of payment, and our estimate of the uncollected portion of receivables from self-payers, including deductibles and copayments, which are subject to credit risk and patients' ability to pay.

As at April 30, 2016 and 2015, the Company recategorized to collections customers whose accounts receivable had been outstanding more than 210 days. The Company fully reserves through its contractual allowances amounts that have not been written off because the payer's filing date deadline has not occurred or the collection process has not been exhausted. The Company's collection experience on Medicare receivables beyond 210 days has been insignificant. The Company adjusts the historical collection analysis for recoveries, if any, on an ongoing basis.

The Company's ability to collect outstanding receivables from third party payers is critical to its operating performance and cash flows. The primary collection risk lies with uninsured patients or patients for whom primary insurance has paid but a patient portion remains outstanding. The Company also assesses the current state of its billing functions in order to identify any known collection or reimbursement issues in order to assess the impact, if any, on the allowance estimates, which involves judgment. The Company believes that the collectability of its receivables is directly linked to the quality of its billing processes, most notably, those related to obtaining the accurate patient information in order to bill effectively for the services provided. Should circumstances change (e.g. shift in payer mix, decline in economic conditions or deterioration in aging of receivables), our estimates of net realizable value of receivables could be reduced by a material amount.

Billing for laboratory services is complicated because of many factors, especially: the differences between our standard gross fee schedule for all payers and the reimbursement rates of the various payers we deal with, disparity of coverage and information requirements among the various payers, and disputes with payers as to which party is responsible for reimbursement.

The allowance for doubtful accounts as a percentage of total accounts receivable at April 30, 2016 and July 31, 2015 was 17.3% and 12.9%, respectively. During fiscal 2015, the contractual allowance applied to the Clinical Labs segment's patient self-pay revenues was increased based on collections trends, which has the effect of reducing the allowance for doubtful patient pay accounts receivable. We continue to improve our patient pay collection process by billing patients sooner and by giving past due accounts to collection agencies sooner.

The following table indicates the Clinical Labs aged gross receivables by payer group which is prior to adjustment to gross receivables for: 1) contractual adjustment, 2) fully reserved balances not yet written off, and 3) other revenue adjustments.

As of April 30, 2016	Total	%	Third Party Payers	%	Self Pay	%	Medicare	%	HMO's	%
1-30 days	\$31,705	52	\$19,340	44	\$4,525	66	\$4,761	71	\$3,079	97
31-60 days	9,926	16	7,777	18	1,457	21	595	9	97	3
61-90 days	6,696	11	5,281	12	910	13	501	7	4	—
91-120 days	4,002	7	3,775	9	(2 )	—	227	4	2	—
121-150 days	2,667	5	2,507	5	(4 )	—	160	2	4	—
Greater than 150 days*	5,509	9	5,125	12	(62 )	—	438	7	8	—
Totals	\$60,505	100%	\$43,805	100%	\$6,824	100%	\$6,682	100%	\$3,194	100%

30

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

As of July 31, 2015	Total	%	Third Party Payers	%	Medicare Payers	%	Self Pay	%	HMO's	%
1-30 days	\$28,157	53	\$17,527	50	\$ 4,048	52	\$2,991	47	\$3,591	95
31-60 days	6,650	13	4,109	12	802	10	1,718	27	21	1
61-90 days	4,191	8	2,313	7	578	7	1,276	20	24	1
91-120 days	3,651	7	2,534	7	604	8	474	7	39	1
121-150 days	2,856	4	2,426	7	399	5	(3 )	0	34	1
Greater than 150 days**	7,187	14	5,878	17	1,329	18	(40 )	-1	20	1
Totals	\$52,692	100%	\$34,787	100%	\$ 7,760	100%	\$6,416	100%	\$3,729	100%

\* Total includes \$2,432 fully reserved over 210 days as of April 30, 2016.

\*\* Total includes \$4,072 fully reserved over 210 days as of July 31, 2015.

### *Income Taxes*

The Company accounts for income taxes under the liability method of accounting for income taxes. Under the liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The liability method requires that any tax benefits recognized for net operating loss carry forwards and other items be reduced by a valuation allowance where it is not more likely than not the benefits will be realized in the foreseeable future. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. Under the liability method, the effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. To the extent the Company prevails in matters for which a liability for an unrecognized tax benefit is established or is required to pay amounts in excess of the liability, the Company's effective tax rate in a given financial statement period may be affected.

### *Inventory*

The Company values inventory at the lower of cost (first-in, first-out) or market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. Write downs of inventories to market value are based on a review of inventory quantities on hand and estimated sales forecasts based on sales history and anticipated future demand. Unanticipated changes in demand could have a significant impact on the value of our inventory and require additional write downs of inventory which would impact our results of operations.

*Goodwill and Intangible Assets*

Goodwill represents the excess of the cost of an acquisition over the fair value of the net assets acquired. Intangible assets (exclusive of patents), arose primarily from acquisitions, and primarily consist of customer relationships, trademarks, licenses, and website and database content. Finite-lived intangible assets are amortized according to their estimated useful lives, which range from 4 to 15 years. Patents represent capitalized legal costs incurred in pursuing patent applications. When such applications result in an issued patent, the related capitalized costs are amortized over a ten year period or the life of the patent, whichever is shorter, using the straight-line method. The Company reviews its issued patents and pending patent applications, and if it determines to abandon a patent application or that an issued patent no longer has economic value, the unamortized balance in deferred patent costs relating to that patent is immediately expensed.

The Company tests goodwill and long-lived assets annually as of the first day of the fourth quarter, or more frequently if indicators of potential impairment exist. In assessing goodwill and long-lived assets for impairment, the Company has the option to first perform a qualitative assessment to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If the Company determines that it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, the Company is not required to perform any additional tests in assessing goodwill and long-lived assets for impairment. However, if the Company concludes otherwise or elects not to perform the qualitative assessment, then it is required to perform the first step of a two-step quantitative impairment review process.

The first step of the quantitative impairment test requires the identification of the reporting units and comparison of the fair value of each of these reporting units to their respective carrying value. If the carrying value of the reporting unit is less than its fair value, no impairment exists and the second step is not performed. If the carrying value of the reporting unit is higher than its fair value, the second step must be performed to compute the amount of the goodwill impairment, if any. In the second step, the impairment is computed by comparing the implied fair value of the reporting unit goodwill with the carrying amount of that goodwill. If the carrying amount of the reporting unit goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized for the excess

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risk from changes in foreign currency exchange rates resulting from acquisitions with foreign locations (See Item 1A. Risk Factors section of the Form 10-K for the fiscal year ended July 31, 2015) that could impact our results of operations and financial position. We do not currently engage in any hedging or market risk management tools.

#### *Foreign Currency Exchange Rate Risk*

The financial reporting of our non-U.S. subsidiaries is denominated in currencies other than the U.S. dollar. Since the functional currency of our non-U.S. subsidiaries is the local currency, foreign currency translation adjustments are accumulated as a component of accumulated other comprehensive income in stockholders' equity. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies at April 30, 2016, our assets and liabilities would decrease by \$0.5 million and \$0.1 million, respectively, and our net sales and net earnings (loss) would decrease by \$0.8 million and \$0.2 million, respectively, on an annual basis.

We also maintain intercompany balances and loans with subsidiaries in different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$1.0 million on an annual basis.

#### *Interest Rate Risk*

We are exposed to interest rate risk with our variable rate Credit Agreement which bears interest at the three month LIBOR with a floor of 1.25% plus 4% per annum. A 3% change in the LIBOR rate would impact our interest expense by \$0.1 million.

As of April 30, 2016, we have fixed interest rate financing on transportation and equipment leases.

#### **Item 4. Controls and Procedures**

##### **(a) Evaluation of Disclosure Controls and Procedures**

As of the end of the period covered by this report, the Company's management conducted an evaluation (as required under Rules 13a-15(b) and 15d-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) of the Company's "disclosure controls and procedures" (as such term is defined under the Exchange Act), under the supervision and with the participation of the principal executive officer and the principal financial officer. Based on this evaluation, the principal executive officer and the principal financial officer concluded that the Company's disclosure controls and procedures are effective as of the end of the period covered by this report. Notwithstanding the foregoing, a control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that it will detect or uncover failures within the Company to disclose material information otherwise required to be set forth in the Company's periodic reports.

##### **(b) Changes in Internal Controls over Financial Reporting**

There was no change in the Company's internal controls over financial reporting during the fiscal quarter covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



**PART II – OTHER INFORMATION**

Item 1. Legal Proceedings

There have been no other material developments with respect to previously reported legal proceedings discussed in the annual report on Form 10-K for the fiscal year ended July 31, 2015 filed with the Securities and Exchange Commission, other than as noted in Note 13 to the Consolidated Financial Statements as of April 30, 2016.

Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in Part 1, Item 1A of the Company’s Annual Report on Form 10-K for the fiscal year ended July 31, 2015.

Item 6. Exhibits

<b>Exhibit No.</b>	<b>Exhibit</b>
10.1	Settlement and Release Agreement between the Company and Agilent Technologies, Inc.
10.2	Settlement and Release Agreement between the Company and Life Technologies Corporation
31.1	Certification of Elazar Rabbani, Ph.D. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Barry Weiner pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Elazar Rabbani, Ph.D. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Barry Weiner pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definitions Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\*XBRL (Extensible Business Reporting Language) information is being furnished and not filed for purposes of Sections 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934.

## **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ENZO BIOCHEM, INC.  
(Registrant)

Date: June 8, 2016 by: /s/ Barry Weiner  
President, Chief Financial Officer, Principal Accounting Officer, Treasurer and Director

33