

ENZO BIOCHEM INC
Form 10-Q
March 09, 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 January 31, 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

10022

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

(Address of Principal Executive office)

(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 March 2, 2016, the Registrant had approximately 46,093,000 shares of common stock outstanding.

ENZO BIOCHEM, INC.
FORM 10-Q
January 31, 2016

INDEX

PART I - FINANCIAL INFORMATION

<u>Item 1. Condensed Financial Statements</u>	3
<u>Consolidated Balance Sheets – January 31, 2016 (unaudited) and July 31, 2015 (audited)</u>	3
<u>Consolidated Statements of Operations for the three and six months ended January 31, 2016 and 2015 (unaudited)</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended January 31, 2016 and 2015 (unaudited)</u>	5
<u>Consolidated Statement of Stockholders' Equity for the six months ended January 31, 2016 (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the three and six months ended January 31, 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>	33
<u>Item 4. Controls and Procedures</u>	33
<u>Part II – OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	34
<u>Item 1A. Risk Factors</u>	34
<u>Item 6. Exhibits</u>	34
<u>Signatures</u>	34

Part 1 Financial Information**Item 1** Financial Statements**ENZO BIOCHEM, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except share data)**

	January 31, 2016 (unaudited)	July 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 37,016	\$ 18,109
Accounts receivable, net of allowances	12,877	12,109
Other receivables	—	6,650
Inventories	7,395	7,396
Prepaid expenses and other	1,866	2,222
Total current assets	59,154	46,486
Property, plant and equipment, net	8,730	7,948
Goodwill	7,452	7,452
Intangible assets, net	5,221	6,155
Other assets	349	353
Total assets	\$ 80,906	\$ 68,394
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Loan payable	\$ 3,013	\$ 3,013
Accounts payable – trade	9,459	8,762
Accrued liabilities	9,556	11,297
Other current liabilities	2,476	886
Total current liabilities	24,504	23,958
Deferred taxes	30	37
Other liabilities	1,925	1,793
Total liabilities	\$ 26,459	\$ 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: 46,092,518 at January 31, 2016 and 46,062,065 at July 31, 2015	461	461
Additional paid-in capital	325,253	324,966

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Accumulated deficit	(273,416)	(284,682)
Accumulated other comprehensive income	2,149	1,861
Total stockholders' equity	54,447	42,606
Total liabilities and stockholders' equity	\$ 80,906	\$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 January 31,		Six Months Ended January 31,	
	2016	2015	2016	2015
Revenues:				
Clinical laboratory services	\$ 17,523	\$ 14,725	\$ 34,613	\$ 30,547
Product revenues	6,578	7,723	14,265	15,725
Royalty and license fee income	459	644	859	1,644
Total revenues	24,560	23,092	49,737	47,916
Operating expenses:				
Cost of clinical laboratory services	10,535	9,246	20,867	19,376
Cost of product revenues	3,206	3,818	6,817	7,513
Research and development	861	834	1,728	1,625
Selling, general, and administrative	11,280	9,670	21,505	19,955
Provision for uncollectible accounts receivable	459	601	1,163	1,142
Legal fee expense	2,411	2,804	4,012	5,270
Legal settlements, net	(11,650)	—	(18,450)	—
Total operating expenses	17,102	26,973	37,642	54,881
Operating Income (loss)	7,458	(3,881)	12,095	(6,965)
Other income (expense):				
Interest	(42)	(49)	(82)	(118)
Other	11	(17)	65	2
Foreign exchange loss	(388)	(259)	(518)	(731)
Income (loss) before income taxes	7,039	(4,206)	11,560	(7,812)
(Provision) benefit for income taxes	(207)	115	(294)	(8)
Net income (loss)	\$ 6,832	\$ (4,091)	\$ 11,266	\$ (7,820)
Net income (loss) per common share:				
Basic	\$ 0.15	\$ (0.09)	\$ 0.24	\$ (0.17)
Diluted	\$ 0.15	\$ (0.09)	\$ 0.24	\$ (0.17)
Weighted average common shares outstanding:				
Basic	46,077	45,000	46,070	44,782
Diluted	46,518	45,000	46,353	44,782

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		Six Months	
	Ended		Ended	
	January 31,		January 31,	
	2016	2015	2016	2015
Net income (loss)	\$6,832	\$(4,091)	\$11,266	\$(7,820)
Other comprehensive income (loss):				
Foreign currency translation adjustments	226	35	288	143
Comprehensive income (loss)	\$7,058	\$(4,056)	\$11,554	\$(7,677)

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

ENZO BIOCHEM, INC.
CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY
Six months ended January 31, 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 January 31, 2016	—	—	—	11,266	—	11,266
Vesting of restricted stock	6,751	—	—	—	—	—
Exercise of stock options	23,702	—	66	—	—	66
Share-based compensation charges	—	—	221	—	—	221
Foreign currency translation adjustments	—	—	—	—	288	288
Balance at January 31, 2016	46,092,518	\$ 461	\$ 325,253	\$ (273,416)	\$ 2,149	\$ 54,447

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

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

	Six Months Ended January 31,	
	2016	2015
Cash flows from operating activities:		
Net income (loss)	\$11,266	\$(7,820)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization of property, plant and equipment	1,059	1,014
Amortization of intangible assets	843	859
Provision for uncollectible accounts receivable	1,170	1,142
Deferred income tax benefit	(5)	(48)
Share-based compensation charges	221	203
Accrual for share-based 401(k) employer match expense	439	296
Foreign exchange loss	333	570
Changes in operating assets and liabilities:		
Accounts receivable	(1,952)	(524)
Other receivables	6,650	—
Inventories	(20)	306
Prepaid expenses and other	350	524
Accounts payable – trade	693	(1,423)
Accrued liabilities, other current liabilities and other liabilities	(983)	(1,571)
Total adjustments	8,798	1,348
Net cash provided by (used in) operating activities	20,064	(6,472)
Cash flows from investing activities:		
Capital expenditures	(943)	(653)
Security deposits and other	2	—
Net cash used in investing activities	(941)	(653)
Cash flows from financing activities:		
Net proceeds from issuance of common stock	—	5,341
Proceeds from borrowings under Credit Agreement	44,378	43,362
Repayments under Credit Agreement	(44,378)	(43,362)
Installment loan and capital lease obligation payments	(258)	(230)
Proceeds from the exercise of stock options	66	—
Net cash (used in) provided by financing activities	(192)	5,111
Effect of exchange rate changes on cash and cash equivalents	(24)	(95)
Increase (decrease) in cash and cash equivalents	18,907	(2,109)
Cash and cash equivalents - beginning of period	18,109	17,455
Cash and cash equivalents - end of period	\$37,016	\$15,346

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

7

ENZO BIOCHEM, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

As of January 31, 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 January 31, 2016, the consolidated statements of operations, comprehensive income (loss), and cash flows for the three and six months ended January 31, 2016 and 2015, and the consolidated statement of stockholders’ equity for the six months ended January 31, 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 consolidated financial 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 six months ended January 31, 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

In February 2016, the FASB issued Accounting Standards Update (“ASU”) No. 2016-02 – Leases (Topic 842). The objective of the update is to increase transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The amendments of the ASU are effective for fiscal years beginning after December 31, 2018 and early application is permitted. We are currently evaluating the impact of this standard on our consolidated financial statements.

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.

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 six months ended January 31, 2015, 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 three and six months ended January 31, 2016, approximately 440,000 and 281,000 weighted average stock options were included in the calculation of diluted weighted average shares outstanding. For the three and six months ended January 31, 2015, the number of potential common shares (“in the money options”) and unvested restricted stock excluded from the calculation of diluted earnings per share were zero and 18,000.

For the three and six months ended January 31, 2016, the effect of approximately 235,000 and 305,000 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 six months ended January 31, 2015, the effect of approximately 52,000 and 97,000 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 six months ended January 31, 2016 and 2015, income taxes paid by the Company were \$53 and \$37, respectively.

For the six months ended January 31, 2016 and 2015, interest paid by the Company was \$77 and \$101, respectively.

For the six months ended January 31, 2016 and 2015, the Company financed \$76 and \$57 respectively, in machinery and transportation equipment under installment loans.

During the six months ended January 31, 2016 and 2015, there was a total of \$1,141 and \$155 in capital lease agreements.

Note 4 - Inventories

Inventories consist of the following:

	January 31, 2016	July 31, 2015
Raw materials	\$ 1,180	\$ 1,013
Work in process	1,975	2,002
Finished products	4,240	4,381
	\$ 7,395	\$ 7,396

Note 5 – Goodwill and intangible assets

At January 31, 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	—	(843)	(843)
Foreign currency translation	(350)	259	(91)
January 31, 2016	\$27,488	\$ (22,267)	\$5,221

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

	January 31, 2016			July 31, 2015		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents	\$11,027	\$ (10,888)	\$ 139	\$11,028	\$ (10,871)	\$ 157
Customer relationships	12,046	(7,785)	4,261	12,243	(7,398)	4,845
Website and acquired content	1,006	(1,006)	—	1,020	(1,020)	—
Licensed technology and other	499	(437)	62	518	(441)	77
Trademarks	2,910	(2,151)	759	3,029	(1,953)	1,076
Total	\$27,488	\$ (22,267)	\$5,221	\$27,838	\$ (21,683)	\$6,155

At January 31, 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 January 31, 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 January 31, 2016 and July 31, 2015, the borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$3.0 million.

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 January 31, 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:

- o The minimum balance the Company must borrow at any time is \$2.0 million. At January 31 2016, the loan balance was approximately \$3.0 million, with an additional availability of \$3.9 million.

o The Company must maintain a Minimum Liquidity, as defined in the Credit Agreement, of not less than \$3.0 million. At January 31, 2016, the Company's Minimum Liquidity was \$8.9 million.

o The quarterly Cash Burn, as defined in the Credit Agreement, must be greater than zero. During the six months ended January 31, 2016, the Cash Burn was positive in the amount of \$0.1 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 January 31, 2016, Liquidity as defined was \$37.9 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:

	January 31, 2016	July 31, 2015
Payroll, benefits, and commissions	\$ 3,837	\$ 3,907
Legal fee expense	2,320	4,183
Professional fees	485	678
Research and development	300	300
Other	2,614	2,229
	\$ 9,556	\$ 11,297

Other current liabilities consist of the following:

	January 31, 2016	July 31, 2015
Accrued legal settlement	\$ 1,908	\$ 406
Capital lease obligations	289	149
Installment loans	279	331
	\$ 2,476	\$ 886

Note 8 – Other Liabilities

Other liabilities consist of the following:

	January 31, 2016	July 31, 2015
Accrued legal settlement	\$ 800	\$ 1,220
Capital lease obligations, net of short term	923	210
Installment loans, net of short term	202	363
	\$ 1,925	\$ 1,793

As of January 31, 2016, future minimum payments under the capital leases, net of interest of \$253 aggregates \$1,212 including a short term debt portion of \$289 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 OfferingSM 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 six months ended January 31, 2016, the Company did not sell any shares of Common Stock under the Sales Agreement. For the six months ended January 31, 2015, the Company sold an aggregate of 1,126,804 shares of Common Stock under the Sales Agreement at an average price of \$4.89 per share and received proceeds of approximately \$5.3 million, net of expenses of \$169.

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:

	Three months ended January 31,		Six months ended January 31,	
	2016	2015	2016	2015
Stock options	\$104	\$91	\$208	\$176
Restricted stock	6	14	13	27
	\$110	\$105	\$221	\$203

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 January 31,		Six months ended January 31,	
	2016	2015	2016	2015
Cost of clinical laboratory services	\$2	\$2	\$3	\$3
Research and development	—	1	—	2
Selling, general and administrative	108	102	218	198
	\$110	\$105	\$221	\$203

No excess tax benefits were recognized during the three month periods ended January 31, 2016 and 2015.

Stock Option Plans

The following table summarizes stock option activity during the three month period ended January 31, 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	189,873	\$ 4.66		
Exercised	(23,702)	\$ 2.79		
Cancelled or expired	(6,000)	\$ 3.61		
Outstanding at end of period	1,518,275	\$ 3.25	2.0 years	\$ 2,269
Exercisable at end of period	1,098,307	\$ 2.95	1.4 years	\$ 1,963

As of January 31, 2016, the total future compensation cost related to non-vested options, not yet recognized in the statements of operations, was \$0.6 million and the weighted average period over which the remaining expense of these awards is expected to be recognized is seventeen 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 January 31, 2016 is as follows:

	Awards	Weighted Average Award Price
Outstanding at July 31, 2015	21,501	\$ 8.84
Awarded	—	\$ —
Vested	(6,751)	\$ (2.10)
Forfeited	(1,500)	\$ (2.86)
Unvested at end of period	13,250	\$ 4.04

The fair value of a restricted stock award is determined based on the closing stock price on the award date. As of January 31, 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 eighteen months.

The fair value of the awards that vested during the six months ended January 31, 2016 and 2015 was \$21 and \$43, respectively.

The total number of shares available for grant as equity awards from the 2011 Incentive Plan is approximately 1,118,000 shares as of January 31, 2016.

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 January 31, 2016 was (2.9%) compared to a benefit of 2.7% for the three months ended January 31, 2015. The Company's effective tax rate (provision) was (2.5%) and de minimus for the six months ended January 31, 2016 and 2015, 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 six months ended January 31, 2016 and 2015, the Company recorded royalty income under the agreement of approximately \$0.9 million and \$1.6 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

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

Three months ended January 31, 2016

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$17,523	—	—	—	\$ 17,523
Product revenues	—	\$6,578	—	—	6,578
Royalty and license fee income	—	459	—	—	459
	17,523	7,037	—	—	24,560
Operating expenses:					
Cost of clinical laboratory services	10,535	—	—	—	10,535
Cost of product revenues	—	3,206	—	—	3,206
Research and development	—	661	\$ 200	—	861
Selling, general and administrative	5,649	2,773	—	\$2,858	11,280
Provision for uncollectible accounts receivable	467	(8)	—	—	459
Legal fee expense	57	5	—	2,349	2,411
Legal settlements, net	1,500	(13,150)	—	—	(11,650)
Total operating expenses	18,208	(6,513)	200	5,207	17,102
Operating income (loss)	(685)	13,550	(200)	(5,207)	7,458
Other income (expense)					
Interest	(23)	17	—	(36)	(42)
Other	(1)	—	—	12	11
Foreign exchange loss	—	(388)	—	—	(388)
Income (loss) before income taxes	\$(709)	\$13,179	\$ (200)	\$(5,231)	\$ 7,039
Depreciation and amortization included above	\$411	\$524	\$ —	\$17	\$ 952
Share-based compensation included in above:					
Cost of clinical laboratory services	\$2	—	—	—	\$ 2
Research and development	—	—	—	—	—
Selling, general and administrative	9	\$5	—	\$94	108
Total	\$11	\$5	\$ —	\$94	\$ 110
Capital expenditures	\$354	\$84	\$ —	\$—	\$ 438

15

Three months ended January 31, 2015

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$14,725	—	—	—	\$ 14,725
Product revenues	—	\$ 7,723	—	—	7,723
Royalty and license fee income	—	644	—	—	644
	14,725	8,367	—	—	23,092
Operating expenses:					
Cost of clinical laboratory services	9,246	—	—	—	9,246
Cost of product revenues	—	3,818	—	—	3,818
Research and development	—	635	\$ 199	—	834
Selling, general and administrative	5,089	2,704	—	\$1,877	9,670
Provision for uncollectible accounts receivable	658	(57)	—	—	601
Legal fee expense	41	(53)	—	2,816	2,804
Total operating expenses	15,034	7,047	199	4,693	26,973
Operating income (loss)	(309)	1,320	(199)	(4,693)	(3,881)
Other income (expense)					
Interest	(12)	5	—	(42)	(49)
Other	4	(29)	—	8	(17)
Foreign exchange loss	—	(259)	—	—	(259)
Income (loss) before income taxes	\$(317)	\$ 1,037	\$ (199)	\$(4,727)	\$(4,206)
Depreciation and amortization included above	\$357	\$ 555	\$ 1	\$22	\$ 935
Share-based compensation included in above:					
Cost of clinical laboratory services	\$2	—	—	—	\$ 2
Research and development	—	\$ 1	—	—	1
Selling, general and administrative	12	3	—	\$87	102
Total	\$14	\$ 4	\$ —	\$87	\$ 105
Capital expenditures	\$338	\$ 51	\$ —	\$—	\$ 389

Six months ended January 31, 2016

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$34,613	—	—	—	\$ 34,613
Product revenues	—	\$14,265	—	—	14,265
Royalty and license fee income	—	859	—	—	859
	34,613	15,124	—	—	49,737
Operating expenses:					
Cost of clinical laboratory services	20,867	—	—	—	20,867
Cost of product revenues	—	6,817	—	—	6,817
Research and development	—	1,328	\$ 400	—	1,728
Selling, general and administrative	10,935	5,832	—	\$4,738	21,505
Provision for uncollectible accounts receivable	1,175	(12)	—	—	1,163
Legal fee expense	66	(17)	—	3,963	4,012
Legal settlements, net	1,500	(19,950)	—	—	(18,450)
Total operating expenses	34,543	(6,002)	400	8,701	37,642
Operating income (loss)	70	21,126	(400)	(8,701)	12,095
Other income (expense)					
Interest	(42)	31	—	(71)	(82)
Other	3	39	—	23	65
Foreign exchange loss	—	(518)	—	—	(518)
Income (loss) before income taxes	\$31	\$20,678	\$ (400)	\$(8,749)	\$ 11,560
Depreciation and amortization included above	\$808	\$1,054	\$ —	\$40	\$ 1,902
Share-based compensation included in above:					
Cost of clinical laboratory services	\$3	—	—	—	\$ 3
Research and development	—	—	—	—	—
Selling, general and administrative	19	\$10	—	\$189	218
Total	\$22	\$10	\$ —	\$189	\$ 221
Capital expenditures	\$791	\$152	\$ —	\$—	\$ 943

17

Six months ended January 31, 2015

	Clinical Labs	Life Sciences	Therapeutics	Other	Consolidated
Revenues:					
Clinical laboratory services	\$30,547	—	—	—	\$ 30,547
Product revenues	—	\$ 15,725	—	—	15,725
Royalty and license fee income	—	1,644	—	—	1,644
	30,547	17,369	—	—	47,916
Operating expenses:					
Cost of clinical laboratory services	19,376	—	—	—	19,376
Cost of product revenues	—	7,513	—	—	7,513
Research and development	—	1,183	\$ 442	—	1,625
Selling, general and administrative	10,157	5,853	—	\$3,945	19,955
Provision for uncollectible accounts receivable	1,189	(47)	—	—	1,142
Legal fee expense	131	(51)	—	5,190	5,270
Total operating expenses	30,853	14,451	442	9,135	54,881
Operating income (loss)	(306)	2,918	(442)	(9,135)	(6,965)
Other income (expense)					
Interest	(39)	7	—	(86)	(118)
Other	6	(35)	—	31	2
Foreign exchange gain	—	(731)	—	—	(731)
Income (loss) before income taxes	\$(339)	\$ 2,159	\$ (442)	\$(9,190)	\$(7,812)
Depreciation and amortization included above	\$714	\$ 1,113	\$ 2	\$44	\$ 1,873
Share-based compensation included in above:					
Cost of clinical laboratory services	\$3	—	—	—	\$ 3
Research and development	—	\$ 2	—	—	2
Selling, general and administrative	21	3	—	\$174	198
Total	\$24	\$ 5	\$ —	\$174	\$ 203
Capital expenditures	\$589	\$ 64	\$ —	\$—	\$ 653

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. (NASDAQ:LIFE) 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 intends to appeal 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.

On April 22, 2014, the Company as plaintiff finalized and executed a settlement agreement with Affymetrix, Inc. to settle patent litigation actions before the U.S. District Court, Southern District of New York (the “Agreement”) in the amount of \$5.1 million. Under terms of the Agreement, Affymetrix paid to the Company \$4.3 million and paid to the Company’s attorneys \$0.8 million.

On June 20, 2014, the Company, as plaintiff finalized and executed a settlement agreement with PerkinElmer, Inc., and PerkinElmer Health Sciences, Inc. (formerly known as PerkinElmer Life Sciences, Inc.) (together, “PerkinElmer”), with respect to an action between the Company and PerkinElmer before the U.S. District Court, Southern District of New York, Case No 03-CV-3817. PerkinElmer paid \$7.0 million in escrow pursuant to the agreement because of a former attorney’s charging lien for fees allegedly owed for past services rendered to the Company. Also put into escrow was an additional \$30 relating to the Molecular Probes settlement. On December 3, 2015, the Company entered into a Settlement Agreement with the former attorney pursuant to which the Company and the former attorney resolved their respective claims against each other. During the three months ended January 31, 2016, the Company received a total of \$7.03 million from the escrow referred to above in accordance with the terms of the Settlement Agreement. This settlement is included in the statement of operations under Legal settlements, net within the Life Science segment.

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 may be 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 January 31, 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.

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.

20

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 January 31, 2016 compared to January 31, 2015

(in 000s)

Comparative Financial Data for the Three Months Ended January 31,

Revenues:	2016	2015	Increase (Decrease)	% Change	
Clinical laboratory services	\$17,523	\$14,725	\$ 2,798	19	%
Product revenues	6,578	7,723	(1,145)	(15))
Royalty and license fee income	459	644	(185)	(29))
Total revenues	24,560	23,092	1,468	6	
Operating expenses:					
Cost of clinical laboratory services	10,535	9,246	1,289	14	
Cost of product revenues	3,206	3,818	(612)	(16))
Research and development	861	834	27	3	
Selling, general, and administrative	11,280	9,670	1,610	17	
Provision for uncollectible accounts receivable	459	601	(142)	(24))
Legal fee expense	2,411	2,804	(393)	(14))
Legal settlements, net	(11,650)	—	(11,650)	**	
Total operating expenses	17,102	26,973	(9,871)	(37))
Operating income (loss)	7,458	(3,881)	11,339	**	
Other income (expense):					
Interest	(42)	(49)	7	14	

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Other	11	(17)	28	**
Foreign exchange loss	(388)	(259)	(129)	(50)
Income (loss) before income taxes	\$7,039	\$(4,206)	\$ 11,245	**

**** not meaningful**

Consolidated Results:

The “2016 period” and the “2015 period” refer to the three months ended January 31, 2016 and 2015, respectively.

Clinical laboratory services revenues for the 2016 period were \$17.5 million compared to \$14.7 million in the 2015 period, an increase of \$2.8 million or 19%. 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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Product revenues for the 2016 period were \$6.6 million compared to \$7.7 million in the 2015 period, a decrease of \$1.1 million or 15%. 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 (\$0.1 million). Revenues decreased due to lower order volume and the timing of orders from selected customers and were negatively impacted by pricing due to competition and lower research funding, especially in academia.

Royalty and license fee income during the 2016 period was \$0.5 million compared to \$0.6 million in the 2015 period a decrease of \$0.2 million or 29%. 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 \$10.5 million as compared to \$9.2 million in the 2015 period, an increase of \$1.3 million or 14% due to the increase in Clinical laboratory services revenue of 19%.

The cost of product revenues during the 2016 period was \$3.2 million compared to \$3.8 million in the 2015 period, a decrease of \$0.6 million or 16% due to lower sales. The gross profit margin was 51% in the 2016 and 2015 periods.

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

Selling, general and administrative expenses were approximately \$11.3 million during the 2016 period versus \$9.7 million during the 2015 period, an increase of \$1.6 million or 17%. The Clinical Lab segment selling, general and administrative increased \$0.5 million primarily due to increases in selling and billing and collection expenses. The Life Sciences segment selling, general and administrative increased \$0.1 million due to an increase in selling expenses. Other segment selling, general and administrative increased \$1.0 million for contested proxy expenses of \$1.1 million relating to our annual stockholders' meeting which took place in January 2016, offset by a decrease of \$0.1 million of salary related expenses.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was \$0.5 million for the 2016 period as compared to \$0.6 million in the 2015 period, a decrease of \$0.1 million or 24%. The decrease is primarily due to enhanced collection procedures for self-pay patient receivables. 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 2.7% and 4.5%, respectively.

Legal fee expense was \$2.4 million during the 2016 period compared to \$2.8 million in the 2015 period, a decrease of \$0.4 million or 14% due to the timing of legal 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 \$(11.7) million in the 2016 period. During the 2016 period the Company as plaintiff finalized and executed a settlement agreement with Agilent Technologies, Inc. relating to a patent infringement claim and collected proceeds held in escrow relating to the PerkinElmer, Inc. and Molecular Probes, Inc. settlements, totaling \$13.2 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. There were no legal settlements during the 2015 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 and the 2015 periods, the foreign currency loss was \$0.4 million and \$0.3 million, respectively, an unfavorable change of \$0.1 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 depreciated approximately 7%, 3% and 2%, respectively versus the US dollar. During the 2015 period, the British pound and Euro depreciated 5% and 10%, respectively versus the US dollar. The Swiss franc appreciated 4% versus the US dollar.

Segment Results:

Clinical Labs

The Clinical Labs segment's loss before taxes was \$0.7 million for 2016 period as compared to a loss of \$0.3 million 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 \$17.5 million compared to \$14.7 in the 2015 period. The increase of \$2.8 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 \$10.5 million as compared to \$9.2 million in the 2015 period, an increase of \$1.3 million. Clinical Lab gross profit margin was 40% in the 2016 period and 37% in the 2015 period. The provision for uncollectable accounts was \$0.5 million as compared to \$0.7 million; the decrease is due to enhanced collection procedures for self-pay patient receivables.

Life Sciences

The Life Sciences segment's income before taxes was \$13.2 million for the 2016 period as compared to \$1.1 million for the 2015 period, an improvement of \$12.1 million over fiscal 2015. The 2016 period includes \$13.2 million for patent and other litigation settlements previously described. Product revenues decreased \$1.1 million or 15% 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 (\$0.1 million). Revenues decreased due to lower order volume and the timing of orders from selected customers and were negatively impacted by pricing due to competition and lower research funding, especially in academia. The segment's gross profit was \$3.8 million in the 2016 period, as compared \$4.5 million in the 2015 period, a decrease of \$0.7 million primarily due to a decrease in royalty and license fee income of \$0.2 million and a gross margin decrease of \$0.5 million on lower product revenues. The segment's other operating expenses, excluding legal and legal settlements, net, in the 2016 period increased \$0.1 million due to increased selling expenses. Due to 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 \$0.4 million compared to a \$0.3 million in the 2015 period, resulting in an unfavorable change of \$0.1 million in the 2016 period.

Therapeutics

Therapeutics loss before income taxes was approximately \$0.2 million in the 2016 and 2015 periods.

Other

The Other loss before taxes for the 2016 period was approximately \$5.2 million as compared to \$4.7 million for the 2015 period, an increase of \$0.5 million. The Company incurred \$1.5 million of consulting and legal fee expenses relating to a contested proxy for our annual stockholders' meeting which took place in January 2016, which was partially offset by a decrease of \$0.9 million in legal fee expense and related costs associated with ongoing patent litigation and a decrease of \$0.1 million of salary related expenses.

Results of Operations**Six months ended January 31, 2016 as compared to January 31, 2015***(in 000s)*

<u>Revenues:</u>	2016	2015	Increase (Decrease)	%	Change
Clinical laboratory services	\$34,613	\$30,547	\$ 4,066	13	%
Product revenues	14,265	15,725	(1,460)	(9)	
Royalty and license fee income	859	1,644	(785)	(48)	
Total revenues	49,737	47,916	1,821	4	
Operating expenses:					
Cost of clinical laboratory services	20,867	19,376	1,491	8	
Cost of product revenues	6,817	7,513	(696)	(9)	
Research and development	1,728	1,625	103	6	
Selling, general, and administrative	21,505	19,955	1,550	8	
Provision for uncollectible accounts receivable	1,163	1,142	21	2	
Legal fee expense	4,012	5,270	(1,258)	(24)	
Legal settlements, net	(18,450)	—	(18,450)	**	
Total operating expenses	37,642	54,881	(17,239)	(31)	
Operating income (loss)	12,095	(6,965)	19,060	**	
Other income (expense):					
Interest	(82)	(118)	36	(31)	
Other	65	2	63	**	
Foreign exchange loss	(518)	(731)	213	(29)	
Income (loss) before income taxes	\$11,560	\$(7,812)	\$ (19,372)	**	

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

The “2016 period” and the “2015 period” refer to the six months ended January 31, 2016 and 2015, respectively.

Clinical laboratory services revenues for the 2016 period were \$34.6 million compared to \$30.5 million in the 2015 period, an increase of \$4.1 million or 13%. 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 \$14.3 million compared to \$15.7 million in the 2015 period, a decrease of \$1.5 million or 9%. The decrease was due to declines in sales of products (\$1.1 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 the timing of orders from selected customers and were negatively impacted by pricing due to competition and lower research funding, especially in academia.

Royalty and license fee income during the 2016 period was \$0.8 million compared to \$1.6 million in the 2015 period a decrease of \$0.8 million or 48%. 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 \$20.9 million as compared to \$19.4 million in the 2015 period, an increase of \$1.5 million or 8% due to the increase in Clinical laboratory services revenue of 13%.

The cost of product revenues during the 2016 period was \$6.8 million compared to \$7.5 million in the 2015 period, a decrease of \$0.7 million or 9% due to lower sales. The gross profit margin was 52% in the 2016 and 2015 periods.

Research and development expenses were approximately \$1.7 million and \$1.6 million during the 2016 and 2015 periods, respectively.

Selling, general and administrative expenses were approximately \$21.5 million during the 2016 period versus \$20.0 million during the 2015 period, an increase of \$1.6 million or 8%. The Clinical Lab segment selling, general and administrative increased \$0.8 million primarily due to increases in selling, billing and collection expenses. The Life Sciences segment selling, general and administrative was unchanged. Other segment selling, general and administrative increased \$0.8 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 a decrease of \$0.2 million for other professional fees and \$0.1 million of miscellaneous expenses.

The provision for uncollectible accounts receivable, primarily related to the Clinical Labs segment, was approximately \$1.1 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 \$4.0 million during the 2016 period compared to \$5.3 million in the 2015 period, a decrease of \$1.3 million or 24% due to the timing of legal 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. 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 and 2015 periods due to interest incurred and fees relating to the credit agreement entered into in 2013.

During the 2016 and the 2015 periods, the foreign currency loss was \$0.5 million and \$0.7 million, respectively, a favorable change of \$0.2 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, British pound, and Euro depreciated approximately 9%, 5% and 1% respectively, versus the US dollar. During the 2015 period, the Swiss franc, British pound, and Euro depreciated approximately 2%, 11% and 16% respectively, versus the US dollar.

Segment Results:

Clinical Labs

The Clinical Labs segment's income before taxes was breakeven for 2016 period as compared to a loss of (\$0.3) million 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 \$34.6 million compared to \$30.5 in the 2015 period. The increase of \$4.1 million is attributed to increased molecular testing volume and higher value account acquisitions, which were offset in part by attrition and a decline in volume. Cost of sales during the 2016 period was \$20.9 million as compared to \$19.4 million in the 2015 period, an increase of \$1.5 million due to higher service revenues. Clinical Lab gross profit margin was 40% in the 2016 period and 37% in the 2015 period. The provision for uncollectable accounts was approximately \$1.1 million for both the 2016 and 2015 periods; and as a percent of revenues was 3.4% and 3.9% in the 2016 and 2015 periods, respectively. The decrease is due to enhanced collection procedures for self-pay patient receivables.

Life Sciences

The Life Sciences segment's income before taxes was \$20.7 million for the 2016 period as compared to \$2.2 million for the 2015 period, an improvement of \$18.5 million over fiscal 2015. The 2016 period includes \$20.0 million for patent and other litigation settlements previously described. Product revenues decreased \$1.5 million or 9% in the

2016 period due to declines in sales of products (\$1.1 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 the timing of orders from selected customers and were negatively impacted by pricing due to competition and lower research funding, especially in academia. The segment's gross profit was \$8.3 million in the 2016 period, as compared \$9.9 million in the 2015 period, a decrease of \$1.6 million primarily due to a decrease in royalty and license fee income of \$0.8 million and a gross margin decrease of \$0.8 million on lower product revenues. The segment's other operating expenses, excluding legal and legal settlements, net, in the 2016 period increased \$0.2 million due to increased research and development expenses. Due to slightly 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 \$0.5 million compared to a \$0.7 million in the 2015 period, resulting in an unfavorable change of \$0.2 million in the 2016 period.

Therapeutics

Therapeutics loss before income taxes was approximately \$0.4 million in the 2016 and 2015 periods.

Other

The Other loss before taxes for the 2016 period was approximately \$8.7 million as compared to \$9.1 million for the 2015 period, a decrease of \$0.4 million. During the 2016 period, legal fee expense associated with ongoing patent litigation declined \$1.6 million, professional fees declined \$0.2 million, and salary related expenses declined \$0.1 million. These declines were partially offset by \$1.5 million of consulting and legal fee expenses relating to the contested proxy costs for our annual stockholders' meeting which took place in January 2016.

Liquidity and Capital Resources

At January 31, 2016, the Company had cash and cash equivalents of \$37.0 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 \$34.7 million at January 31, 2016 compared to \$22.5 million at July 31, 2015. The increase in working capital of \$12.1 million was primarily due to net income of \$11.3 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 January 31, 2016 was approximately \$20.1 million as compared to cash used in operating activities of \$6.5 million in fiscal 2015, an increase of approximately \$26.5 million. The increase in the 2016 period was primarily due to a change in the net income of \$19.1 million, net change in operating assets and liabilities of \$7.4 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 2016.

Net cash used in investing activities in fiscal 2016 was approximately \$0.9 million as compared to \$0.7 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 \$0.2 million as compared to cash provided by financing activities of \$5.1 million in fiscal 2015. The decrease of \$5.3 million was primarily due to proceeds from the issuance of common stock under the Controlled Equity Offering program in the 2015 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 January 31, 2016 and July 31, 2015 borrowings under the Credit Agreement related to the Clinical Labs and Life Sciences receivables aggregated \$3.0 million, with an additional availability of \$3.9 million as of January 31, 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 January 31, 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 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 this 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 January 31, 2016		Three months ended January 31, 2015	
Revenue category				
Third-party payer	\$10,105	58 %	\$8,046	55 %
Patient self-pay	3,524	20	2,558	17
Medicare	2,756	16	3,024	21
HMO's	1,138	6	1,097	7
Total	\$17,523	100 %	\$14,725	100 %

	Six months ended January 31, 2016		Six months ended January 31, 2015	
Revenue category				
Third-party payer	\$19,798	57 %	\$16,765	55 %
Patient self-pay	6,763	20	5,220	17
Medicare	5,753	17	6,243	20
HMO's	2,299	6	2,319	8
Total	\$34,613	100 %	\$30,547	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 26% of the Clinical Labs segment net revenue for the three months ended January 31, 2016 and 2015 respectively, and 30% and 26% for the six months ended January 31, 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 January 31, 2016 and 2015, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 84.2% and 85.2%, respectively, of gross billings. During the six months ended January 31, 2016 and 2015, the contractual adjustment percentages, determined using current and historical reimbursements statistics, were 84.3% and 85.3%, 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 \$2.2 million and \$2.1 million for the six months ended January 31, 2016 and 2015, respectively, and a change in the net accounts receivable of approximately \$0.6 million as of January 31, 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

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 January 31, 2016, and July 31, 2015, approximately 75.4% 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 \$1.0 million or 30% and \$1.1 million or 28% represents foreign receivables as of January 31, 2016 and July 31, 2015, includes royalty receivables of \$0.1 million, as of January 31, 2016 and July 31, 2015, from Qiagen Corporation.

Net accounts receivable

Billing category	As of January 31, 2016		As of July 31, 2015	
Clinical Labs				
Third party payers	\$5,248	54 %	\$3,595	44 %
Patient self-pay	2,988	31	3,213	39
Medicare	1,110	11	1,081	13
HMO's	362	4	305	4
Total Clinical Labs	9,708	100%	8,194	100%
Total Life Sciences	3,169		3,915	
Total accounts receivable	\$12,877		\$12,109	

30

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

	January 31, 2016	July 31, 2015
Beginning balance	\$1,786	\$ 2,142
Provision for doubtful accounts	1,163	2,284
Write-offs, net	(969)	(2,640)
Ending balance	\$1,980	\$ 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 January 31, 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 January 31, 2016 and July 31, 2015 was 13.3% 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 January 31, 2016	Total	%	Third Party Payers	%	Self Pay	%	Medicare	%	HMO's	%
1-30 days	\$31,542	50	\$20,341	45	\$3,398	47	\$4,200	59	\$3,603	91
31-60 days	7,961	12	5,031	11	2,013	28	567	8	350	9
61-90 days	6,001	9	3,609	8	1,878	26	495	7	19	—
91-120 days	4,225	7	3,760	8	(2)	0	458	6	9	—
121-150 days	2,275	4	1,963	5	7	0	296	4	9	—
Greater than 150 days*	11,526	18	10,418	23	(60)	(1)	1,168	16	—	—
Totals	\$63,531	100%	\$45,122	100%	\$7,234	100%	\$7,184	100%	\$3,990	100%

31

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 \$7,324 fully reserved over 210 days as of January 31, 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 January 31, 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 \$0.3 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 January 31, 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 January 31, 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

Exhibit No.	Exhibit
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.

