

ENZO BIOCHEM INC
Form 10-Q
March 11, 2019
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, 2019

or

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

For the transition period from _____ to _____

Commission File Number 001-09974

ENZO BIOCHEM, INC.

(Exact name of registrant as specified in its charter)

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

13-2866202
(IRS. Employer
Identification No.)

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

10022
(Zip Code)

212-583-0100

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant has required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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

Yes No

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

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if smaller reporting company) Smaller reporting company
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Yes No

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 1, 2019, the Registrant had 47,241,335 shares of common stock outstanding.

ENZO BIOCHEM, INC.
FORM 10-Q
January 31, 2019

INDEX

PART I - FINANCIAL INFORMATION

<u>Item 1. Financial Statements</u>	3
<u>Consolidated Balance Sheets – January 31, 2019 (unaudited) and July 31, 2018</u>	3
<u>Consolidated Statements of Operations for the three and six months ended January 31, 2019 and 2018 (unaudited)</u>	4
<u>Consolidated Statements of Comprehensive Income (Loss) for the three and six months ended January 31, 2019 and 2018 (unaudited)</u>	5
<u>Consolidated Statement of Stockholders' Equity for the six months ended January 31, 2019 and 2018 (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the six months ended January 31, 2019 and 2018 (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>	29
<u>Item 4. Controls and Procedures</u>	30
<u>Part II – OTHER INFORMATION</u>	
<u>Item 1. Legal Proceedings</u>	31
<u>Item 1A. Risk Factors</u>	31
<u>Item 6. Exhibits</u>	31
<u>Signatures</u>	32

Part 1 Financial Information
Item 1 Financial Statements

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

	January 31, 2019 (unaudited)	July 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 41,978	\$ 60,041
Accounts receivable, net of allowances	11,665	13,147
Inventories	7,514	7,278
Prepaid expenses and other	2,483	2,734
Total current assets	63,640	83,200
Property, plant and equipment, net	13,925	7,636
Goodwill	7,452	7,452
Intangible assets, net	1,388	1,886
Other assets, including restricted cash of \$750 at January 31, 2019	2,715	1,486
Total assets	\$ 89,120	\$ 101,660
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	\$ 7,773	\$ 9,516
Accrued liabilities	8,559	10,054
Other current liabilities	264	616
Total current liabilities	16,596	20,186
Loan payable	4,464	—
Other liabilities	563	353
Total liabilities	\$ 21,623	\$ 20,539
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: 47,241,335 at January 31, 2019 and 47,182,254 at July 31, 2018	472	472
Additional paid-in capital	331,463	330,770
Accumulated deficit	(266,610)	(252,221)
Accumulated other comprehensive income	2,172	2,100
Total stockholders' equity	67,497	81,121
Total liabilities and stockholders' equity	\$ 89,120	\$ 101,660

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,	
	2019	2018	2019	2018
Revenues	\$19,327	\$26,152	\$40,587	\$53,028
Operating costs and expenses:				
Cost of revenues	14,748	15,607	28,987	31,038
Research and development	833	812	1,561	1,559
Selling, general and administrative	11,497	11,049	22,467	21,954
Legal fee expense	1,142	1,700	2,443	2,131
Total operating costs and expenses	28,220	29,168	55,458	56,682
Operating loss	(8,893)	(3,016)	(14,871)	(3,654)
Other income (expense):				
Interest	227	185	501	342
Other	132	33	179	69
Foreign exchange gain (loss)	126	800	(198)	605
Loss before income taxes	(8,408)	(1,998)	(14,389)	(2,638)
Benefit for income taxes	—	1,097	—	1,097
Net loss	\$(8,408)	\$(901)	\$(14,389)	\$(1,541)
Net loss per common share:				
Basic and diluted	\$(0.18)	\$(0.02)	\$(0.30)	(0.03)
Weighted average common shares outstanding:				
Basic and diluted	47,199	46,941	47,197	46,806

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 Ended January 31,		Six Months Ended January 31,	
	2019	2018	2019	2018
Net loss	\$(8,408)	\$(901)	\$(14,389)	\$(1,541)
Other comprehensive (loss) gain:				
Foreign currency translation adjustments	(198)	(578)	72	(495)
Comprehensive loss	\$(8,606)	\$(1,479)	\$(14,317)	\$(2,036)

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, 2019 and 2018
(UNAUDITED)
(in thousands, except share data)

	Common Stock Shares Issued	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 31, 2018	47,182,254	\$ 472	\$ 330,770	\$ (252,221)	\$ 2,100	\$ 81,121
Net loss for the period ended January 31, 2019	—	—	—	(14,389)	—	(14,389)
Vesting of restricted stock	986	—	—	—	—	—
Exercise of stock options	34,719	—	94	—	—	94
Share-based compensation charges	—	—	526	—	—	526
Net issuance of common stock for options exercised by Directors	23,376	—	73	—	—	73
Foreign currency translation adjustments	—	—	—	—	72	72
Balance at January 31, 2019	47,241,335	\$ 472	\$ 331,463	\$ (266,610)	\$ 2,172	\$ 67,497

	Common Stock Shares Issued	Treasury Stock Shares	Common Stock Amount	Additional Paid-in Capital	Treasury Stock Amount	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
Balance at July 31, 2017	46,506,176	—	\$ 465	\$ 328,294	\$—	\$ (241,900)	\$ 2,013	\$ 88,872
Net loss for the period ended January 31, 2018	—	—	—	—	—	(1,541)	—	(1,541)
Cashless options exercise	340,898	106,911	—	1,014	(1,014)	—	—	—
Vesting of restricted stock	2,062	—	—	—	—	—	—	—
Exercise of stock options	228,704	—	6	704	—	—	—	710
Share-based compensation charges	—	—	—	413	—	—	—	413
Foreign currency translation adjustments	—	—	—	—	—	—	(495)	(495)
Balance at January 31, 2018	47,077,840	106,911	\$ 471	\$ 330,425	\$ (1,014)	\$ (243,441)	\$ 1,518	\$ 87,959

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

6

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

	Six Months Ended January 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$(14,389)	\$(1,541)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization of property, plant and equipment	1,040	1,051
Amortization of intangible assets	494	484
Share-based compensation charges	526	413
Accrual for share-based 401(k) employer match expense	393	358
Foreign exchange loss (gain)	159	(595)
Changes in operating assets and liabilities:		
Accounts receivable	1,471	206
Inventories	(254)	(430)
Prepaid expenses and other assets	(208)	(522)
Accounts payable – trade	(1,746)	(809)
Accrued liabilities, other current liabilities and other liabilities	(2,331)	2,220
Total adjustments	(456)	2,376
Net cash (used in) provided by operating activities	(14,845)	835
Cash flows from investing activities:		
Capital expenditures	(6,988)	(1,066)
Security deposits and other	—	(10)
Net cash used in investing activities	(6,988)	(1,076)
Cash flows from financing activities:		
Proceeds from borrowing under mortgage loan	4,500	—
Repayments under loans and capital lease obligations	(140)	(190)
Proceeds from exercise of stock options	166	710
Net cash provided by financing activities	4,526	520
Effect of exchange rate changes on cash and cash equivalents	(6)	22
(Decrease) increase in cash and cash equivalents	(17,313)	301
Cash and cash equivalents - beginning of period	60,041	64,167
Cash and cash equivalents - end of period	\$42,728	\$64,468
The composition of cash and cash equivalents and restricted cash is as follows:		
Cash and cash equivalents	41,978	64,167
Restricted cash included in other assets	750	—
Total cash and cash equivalents (including restricted cash)	\$42,728	\$64,167

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, 2019
(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, Enzo Realty LLC and Enzo Realty II 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, 2019, the consolidated statements of operations and comprehensive income (loss) for the three and six months ended January 31, 2019 and 2018, the consolidated statements of cash flows for the six months ended January 31, 2019 and 2018 and the consolidated statement of stockholders’ equity for the six months ended January 31, 2019 and 2018 (the “interim statements”) are unaudited. In the opinion of management, all adjustments (which include normal recurring adjustments) necessary to present fairly the financial position and operating results for the interim periods have been made. Certain information and footnote disclosure, normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States, have been condensed or omitted. The interim statements should be read in conjunction with the consolidated financial statements for the year ended July 31, 2018 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, 2018 has been derived from the audited financial statements at that date. The results of operations for the three and six months ended January 31, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending July 31, 2019.

Effect of New Accounting Pronouncements

Adoption of New Accounting Standards

On August 1, 2018, the Company adopted a new accounting standard issued by the Financial Accounting Standards Board (“FASB”) on revenue recognition using the full retrospective method. This new accounting standard outlines a single comprehensive model to use in accounting for revenue arising from contracts with customers. This standard supersedes existing revenue recognition requirements and eliminates most industry-specific revenue recognition guidance from GAAP. The core principle of the revenue recognition standard is to require an entity to recognize as revenue the amount that reflects the consideration which it expects to be entitled to when control of goods or services are transferred to its customers.

As a result of the Company's adoption of this standard, the majority of the amounts that were historically classified as bad debt expense, primarily related to patient responsibility, are now considered an implicit price concession in determining net revenues from clinical services. Accordingly, the Company reports estimated uncollectible balances associated with patient responsibility as a reduction of the transaction price and therefore as a reduction in net revenues, when historically these amounts were classified and separately reported as a provision for uncollectible accounts receivable. The adoption of this standard has no impact on revenues reported for life sciences products. The adoption of this new accounting standard resulted in increased disclosure, including qualitative and quantitative disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. For further details, see Note 3.

The impact of the adoption of the standard on prior period consolidated operations, cash flows and balance sheet is presented in the table below:

	As Previously Reported	Adjustment for New Accounting Standard on Revenue Recognition	Reclassification of Residual	As Restated
Consolidated Statements of Operations for the three months ended January 31, 2018:				
Total Revenues	\$26,952	\$(800)	—	\$26,152
Provision for uncollectible accounts receivable	779	(800)	\$21	—
Selling, general and administrative expenses	11,070	—	(21)	11,049
Net loss	(901)	—	—	\$(901)
Consolidated Statements of Operations for the six months ended January 31, 2018:				
Total Revenues	54,628	(1,600)	—	53,028
Provision for uncollectible accounts receivable	1,593	(1,600)	7	—
Selling, general and administrative expenses	21,961	—	(7)	21,954
Net loss	(1,541)	—	—	(1,541)
Consolidated Statements of Cash Flows January 31, 2018:				
Provision for uncollectible accounts receivable	1,593	(1,600)	7	—
Changes in operating assets and liabilities: Accounts receivable	(1,387)	1,600	(7)	206
Consolidated balance sheet July 31, 2018:				
Accounts receivable	15,815	(2,523)	—	13,292
Less: Allowance for doubtful accounts	2,668	(2,523)	—	145
Accounts receivable, net of allowance for doubtful accounts	13,147	—	—	13,147

On August 1, 2018, the Company adopted a new accounting standard issued by FASB which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. Adoption of this standard requires amendments in the update applied prospectively to an award modified on or after the adoption date. For the foreseeable future, any excess income tax benefits or deficiencies from stock-based compensation, which would be recognized as discrete items within income tax expense rather than additional paid in capital, will be offset by an equivalent adjustment to the deferred tax valuation allowance. Accordingly, adoption of this standard had no impact on our reported operations.

Pronouncements Issued but Not Yet Adopted

In February 2016, FASB issued ASU No. 2016-02 – *Leases (Topic 842)*, as amended. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for our fiscal year beginning August 1, 2019 including interim periods within that fiscal year. We will adopt the standard using a modified retrospective transition approach and will not restate our comparative periods. Given the size of our lease portfolio, we expect the adoption of this standard will materially impact our consolidated financial statements by

significantly increasing our non-current assets and non-current liabilities on our consolidated balance sheets when we record the right of use assets and related lease liabilities for our existing operating leases. We will recognize expense in the consolidated statement of operations similar to current lease accounting, in the cost of revenues and selling, general and administrative.

In June 2016, FASB issued ASU No. 2016-13 *Financial Instruments – Credit Losses (Topic 326)*. This standard changes the impairment model for most financial instruments, including trade receivables, from an incurred loss method to a new forward-looking approach, based on expected losses. The estimate of expected credit losses will require entities to incorporate considerations of historical information, current information and reasonable and supportable forecasts. Adoption of this standard is required for our annual and interim periods beginning August 1, 2020 and must be adopted using a modified retrospective transition approach. We are currently assessing the impact of the adoption of this standard on our results of operations, financial position and cash flows.

We reviewed all other recently issued accounting pronouncements and have concluded they are not applicable or not expected to be significant to the accounting for our operations.

Concentration Risk

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 42% and 38% of Clinical Services net revenue for the three months ended January 31, 2019 and 2018 respectively, and 42% and 39% for the six months ended January 31, 2019 and 2018, respectively. As of January 31, 2019, other than the Medicare program, two providers whose programs are included in either “Third-party payers” and/or “Health Maintenance Organizations” (“HMO’s”) categories represent approximately 24% of Clinical Services net receivables. As of July 31, 2018, other than the Medicare program, three providers whose programs are included in either “Third-party payers” and/or “Health Maintenance Organizations” (“HMO’s”) categories represent approximately 29% of Clinical Services net receivables.

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, 2019 and 2018 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, 2019, the number of potential common shares (“in the money options”) and unvested restricted stock excluded from the calculation of diluted earnings per share was 78,000 and 108,000,

respectively, because their effect would be antidilutive. For the three and six months ended January 31, 2018, approximately 719,000, and 825,000, respectively of potential common shares (“in the money options”) and unvested restricted stock were excluded from the calculation of diluted earnings per share.

For the three and six months ended January 31, 2019, the effect of approximately 1,652,000 and 1,491,000 of outstanding “out of the money” options to purchase common shares were excluded from the calculation of diluted net income per share because their effect would be anti-dilutive. For the three and six months ended January 31, 2018, there were no outstanding “out of the money” options to purchase common shares.

Note 3 – Revenue Recognition

Clinical Services Revenue

Net revenues in the Company’s clinical services business accounted for 65% and 72% of the Company’s total net revenues for the six months ended January 31, 2019 and 2018, respectively and are primarily comprised of a high volume of relatively low-dollar transactions. The services business, which provides clinical testing services, satisfies its performance obligation and recognizes revenues upon completion of the testing process for a specific patient and reporting to the ordering physician. The Company may also perform clinical testing services for other laboratories and will recognize revenue from those services when reported to the ordering laboratory. The Company estimates the amount of consideration it expects to receive from customer groups using the portfolio approach. These estimates of the expected consideration include the impact of contractual allowances and price concessions on our customer group portfolios consisting of healthcare insurers, government payers, client payers and patients as described below. Contracts with customers in our laboratory services business do not contain a financing component, based on the typically limited period of time between performance of services and collection of consideration. The transaction price includes variable consideration in the form of the contractual allowance and price concessions as well as the collectability of the transaction based on the patient intent and ability to pay. The Company uses the expected value method in estimating the amount of the variability included in the transaction price.

The following are descriptions of our laboratory services business portfolios:

Third party payers and Health Maintenance Organizations (HMO's)

Reimbursements from third party payers, primarily healthcare insurers, and HMO's are based on negotiated fee-for-service schedules and on capitated payment rates. Revenues consist of amounts billed net of contractual allowances for differences between amounts billed and the estimated consideration the Company expects to receive from such payers, which considers historical collection and denial experience and the terms of the Company's contractual arrangements. Adjustments to the allowances, based on actual receipts from the third-party payers, are recorded upon settlement.

Collection of the consideration the Company expects to receive is normally a function of providing complete and correct billing information to these third party payers within the various filing deadlines, and typically occurs within 60 to 90 days of billing. Provided the Company has billed healthcare insurers accurately with complete information prior to the established filing deadline, there has historically been little to no collection risk. If there has been a delay in billing, the Company determines if the amounts in question will likely go past the filing deadline, and if so, will reserve accordingly for the billing.

Government Payer - Medicare

Reimbursements from Medicare are based on fee-for-service schedules set by Medicare, which is funded by the government. Revenues consist of amounts billed net of contractual allowances for differences between amounts billed and the estimated consideration the Company expects to receive from Medicare, which considers historical collection and denial experience and other factors. Adjustments to the allowances, based on actual receipts from the government payers, are recorded upon settlement.

Collection of consideration the Company expects to receive is normally a function of providing the complete and correct billing information within the various filing deadlines and typically occurs within 60 days of billing. Provided the Company has billed the government payer accurately with complete information prior to the established filing deadline, there has historically been little to no collection risk. If there has been a delay in billing, the Company determines if the amounts in question will likely go past the filing deadline, and, if so, it will reserve accordingly for the billing.

Patient self pay

Uninsured patients are billed based on established patient fee schedules or fees negotiated with physicians on behalf of their patients. Coinsurance and deductible responsibilities based on fees negotiated with healthcare insurers are also billed to insured patients and included in this portfolio. Collection of billings from patients is subject to credit risk and ability of the patients to pay. Revenues consist of amounts billed net of discounts provided to uninsured patients in accordance with the Company's policies and implicit price concessions. Implicit price concessions represent differences between amounts billed and the estimated consideration the Company expects to receive from patients, which considers historical collection experience and other factors including current market conditions. Adjustments to the estimated allowances, based on actual receipts from the patients, are recorded upon settlement. Patient billings are generally fully reserved for when the related billing reaches 210 days outstanding. Balances are automatically written off when they are sent to collection agencies. Allowances are further adjusted for estimated recoveries of amounts sent to collection agencies based on historical collection experience, which is regularly monitored. Collection of consideration the Company expects to receive typically occurs within 180 days of billing.

The following table represents clinical services net revenues and percentages by type of customer:

	Three months ended January 31, 2019			Three months ended January 31, 2018		
<u>Revenue category</u>						
Third-party payer	\$ 6,509	54	%	\$ 11,102	59	%
Medicare	2,338	20		3,230	17	
Patient self-pay	1,797	15		1,583	9	
HMO's	1,356	11		2,815	15	
Total	\$ 12,000	100	%	\$ 18,730	100	%

11

Six months ended Six months ended
January 31, 2019 January 31, 2018

Revenue category				
Third-party payer	\$ 14,415	55 %	\$ 22,762	60 %
Medicare	5,089	19	6,215	16
Patient self-pay	3,771	14	3,642	9
HMO's	3,022	12	5,645	15
Total	\$ 26,297	100 %	\$ 38,264	100

For the three and six months ended January 31, 2019 and 2018, all of the Company's services were provided within the United States.

Products Revenue and royalty income

Products revenues consist of the sale of single-use products used in the identification of genomic information and are recognized at a point in time following the transfer of control of such products to the customer, which generally occurs upon shipment. Payment terms for shipments to end-user and distributor customers may range from 30 to 90 days. Any claims for credit or return of goods may be made generally within 30 days of receipt. Revenues are reduced to reflect estimated credits and returns, although historically these adjustments have not been material. Taxes collected from customers relating to product sales and remitted to governmental authorities are excluded from revenue. Amounts billed to customers for shipping and handling are included in revenue, while the related shipping and handling costs are reflected in cost of products.

Royalty income is based on net sales of the Company's licensed products by a third party. We recognize royalty income in the period the sales occur based on third party evidence received. During the three and six months ended January 31, 2019 there was no royalty income. For the three and six months ended January 31, 2018, royalty income was \$300 and \$561, respectively.

Products revenue by geography is as follows:

	Three Months Ended January 31		Six Months Ended January 31	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
United States	\$4,106	\$3,634	\$7,985	\$7,370
Europe	1,408	1,551	2,750	3,183
Rest of the world	1,813	1,937	3,555	3,650
Products revenue	7,327	\$7,122	14,290	\$14,203

Note 4 - Supplemental disclosure for statement of cash flows

For the six months ended January 31, 2019 and 2018, income taxes paid by the Company were \$80 and \$15, respectively.

For the six months ended January 31, 2019 and 2018, interest paid by the Company was \$66 and \$45, respectively.

For the six months ended January 31, 2019 and 2018, the Company did not finance any machinery or transportation equipment under installment loans.

During the six months ended January 31, 2019, there was a total of \$381 in capital lease agreements. During the six months ended January 31, 2018, the Company did not enter into any capital lease agreements.

During the three months ended January 31, 2019 certain directors and officers of the Company exercised 203,511 stock options in a non-cash transaction. The officers and directors received 23,376 net shares of common stock. The Company did not receive any proceeds from this exercise. The net shares issued represent the difference between the fair market value of the options on the date of exercise less the strike price cost to exercise the options.

Note 5 – Inventories

Inventories consist of the following:

	January 31, 2019	July 31, 2018
Raw materials	\$ 788	\$ 754
Work in process	2,315	2,174
Finished products	4,411	4,350
	\$ 7,514	\$ 7,278

Note 6 – Goodwill and intangible assets

At January 31, 2019 and July 31, 2018, the Company has goodwill of \$7,452 allocated to the Clinical Services reporting unit.

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

	Gross	Accumulated Amortization	Net
July 31, 2018	\$27,347	\$ (25,461)	\$ 1,886
Amortization expense	—	(494)	(494)
Foreign currency translation	(41)	37	(4)
January 31, 2019	\$27,306	\$ (25,918)	\$ 1,388

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

	January 31, 2019			July 31, 2018		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents	\$ 11,027	\$ (10,987)	\$ 40	\$ 11,027	\$ (10,980)	\$ 47
Customer relationships	11,814	(10,466)	1,348	11,836	(9,997)	1,839
Website and acquired content	1,008	(1,008)	—	1,008	(1,008)	—
Licensed technology and other	483	(483)	—	483	(483)	—
Trademarks	2,974	(2,974)	—	2,993	(2,993)	—
Total	\$ 27,306	\$ (25,918)	\$ 1,388	\$ 27,347	\$ (25,461)	\$ 1,886

At January 31, 2019, information with respect to intangibles assets acquired is as follows:

	Useful life assigned	Weighted average remaining useful life
Customer relationships	8 -15 years	2 years
Other intangibles	10 years	4 years

At January 31, 2019, the weighted average remaining useful life of intangible assets is approximately two years.

Note 7 - Loan Payable

In connection with the purchase of our new facility, on November 27, 2018 a wholly owned subsidiary (the “mortgagor subsidiary”) of the Company entered into a Fee Mortgage and Security Agreement (the “mortgage agreement”) with Citibank, N.A. (the “mortgagee”). The mortgage agreement provides for a loan of \$4,500 for a term of 10 years, bears a fixed interest rate of 5.09% per annum and requires monthly mortgage payments of \$30. Debt issuance costs of \$56 are being amortized over the life of the mortgage agreement. The balance of unamortized debt issuance cost was \$55 at January 31, 2019. At January 31, 2019, the balance owed by the subsidiary under the mortgage agreement was \$4.5 million. The Company’s obligations under the mortgage agreement are secured by the new facility and by a \$750 cash collateral deposit with the mortgagee as additional security. This restricted cash is included in other assets as of January 31, 2019.

The mortgage agreement includes affirmative and negative covenants and events of default, as defined. Events of default include non-payment of principal and interest on debt outstanding, non-performance of covenants, material changes in business, breach of representations, bankruptcy or insolvency, and changes in control. The mortgage includes certain financial covenants. As of January 31, 2019, required financial covenants have been met.

We assumed from the seller an operating lease for a current tenant at the facility which runs to December 2019. Rental income from the assumed lease is included in other income.

Note 8 – Accrued Liabilities

Accrued liabilities consist of the following:

	January 31, 2019	July 31, 2018
Payroll, benefits, and commissions	\$4,516	\$4,870
Legal fee expense	1,013	2,121
Professional fees	667	811
Other	2,363	2,252
	\$8,559	\$10,054

Note 9 – Stockholders’ Equity***Controlled Equity Offering***

The Company has 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”). The Company pays 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 initial agreement contemplated the sale of shares of the Company’s common stock having an aggregate offering price of up to \$20.0 million. In December 2014, the Sales Agreement was amended in order for the Company to offer and sell additional shares of Common Stock having an aggregate offering price of \$20.0 million.

On September 1, 2017, the Company filed with the SEC a “shelf” registration and sales agreement prospectus covering the offering, issuance and sale of our Common Stock that may be issued and sold under the existing Sales Agreement in an aggregate amount of up to \$19.15 million. A total of \$150 million of securities may be sold under this shelf registration, which was declared effective September 15, 2017.

During the six months ended January 31, 2019 and 2018, the Company did not sell any shares of Common Stock under the Sales Agreement.

Share-based compensation

On January 14, 2011, the Company’s stockholders approved the adoption of the 2011 Incentive Plan (the “2011 Plan”) which provides for the issuance of equity awards, including among others, options, restricted stock and restricted stock units for up to 3,000,000 Common Shares. The exercise price of options granted under the 2011 Plan, and consistent with other Plans, is equal to or greater than fair market value of the Common Stock on the date of grant. Unless terminated earlier by the Board of Directors, the 2011 Plan will terminate at the earliest of; (a) such time as no shares of Common Stock remain available for issuance under the 2011 Plan or (b) tenth anniversary of the effective date of the 2011 Plan. On January 5, 2018, the Company’s stockholders approved the amendment and restatement of the 2011 Plan to increase the number of shares available for issuance by 2,000,000 bringing the total number of shares available for award under the 2011 Plan to 5,000,000. Awards outstanding upon expiration of the 2011 Plan shall remain in effect until they have been exercised, terminated, or have expired.

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,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Stock options	\$289	\$205	\$521	\$407
Restricted stock	2	3	5	6
	\$291	\$208	\$526	\$413

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

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,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Selling, general and administrative	\$291	\$208	\$526	\$413
	\$291	\$208	\$526	\$413

No excess tax benefits were recognized during the six month periods ended January 31, 2019 and 2018.

Stock Option Plans

The following table summarizes stock option activity during the six month period ended January 31, 2019:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (000s)
Outstanding at July 31, 2018	1,882,116	\$ 4.96		
Awarded	725,821	\$ 2.81		
Exercised	(238,230)	\$ 2.69		\$ 117
Cancelled or expired	(2,000)	\$ 4.51		
Outstanding at end of period	2,367,707	\$ 4.53	3.4 years	\$ 811
Exercisable at end of period	1,148,101	\$ 5.23	1.1 years	\$ 112

As of January 31, 2019, the total future compensation cost related to non-vested options, not yet recognized in the statements of operations, was \$1.4 million and the weighted average period over which the remaining expense of these awards is expected to be recognized is eighteen months.

The intrinsic value of in the money stock option awards 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.

During the three months ended January 31, 2019 certain directors and officers of the Company exercised 203,511 stock options in non-cash transactions. The officers and directors received 23,376 net shares of common stock. The Company did not receive any proceeds from this exercise. The net shares issued represent the difference between the fair market value of the options on the date of exercise less the strike price cost to exercise the options.

Performance Stock Units

To better align the long-term interest of executives with growing U.S. practices, beginning in fiscal 2018, the Company granted long-term incentive awards in the form of time based stock options and performance-based restricted stock units (“Performance Stock Units” or “PSUs”). The PSUs earned will be determined over a three-year performance period. The primary performance metrics will be revenue and Adjusted EBITDA growth. Payouts based on revenue and adjusted EBITDA goals will be modified based on Total Shareholder Return (“TSR”) performance relative to Enzo’s peer group.

During fiscal year 2018 and 2019, the Company awarded PSUs to its executive officers, this award provides for the grant of shares of our common stock at the end of a three-year period based on the achievement of average revenue growth and adjusted EBITDA growth over that period. As of January 31, 2019, the Company did not accrue any compensation expense for these PSU’s as the three-year performance period has just begun and achievement of the growth goals is currently not probable.

Period Ending	Total Grant	Fair Market Value Grant Date (000s)
7/31/2018	32,000	\$ 141
1/31/2019	81,500	\$ 229

Restricted Stock Awards

The fair value of a restricted stock award is determined based on the closing stock price on the award date. As of January 31, 2019, there were 1,626 shares of unvested restricted stock which have a weighted average award price of \$1.74 per share. As of January 31, 2019, there was approximately \$11 of unrecognized compensation cost related

to these unvested shares of restricted stock to be recognized over a weighted average remaining period of approximately twenty-four months. There were no awards made during the six months ended January 31, 2019. During the six months ended January 31, 2019, 985 restricted stock awards vested whose fair value was approximately \$4.

The total number of shares available for grant as equity awards from the 2011 Incentive Plan is approximately 1,208,000 shares as of January 31, 2019.

Note 10 – Segment reporting

The Company has three reportable segments: Products, Clinical Services and Therapeutics. The Company’s Products segment develops, manufactures, and markets products to research and pharmaceutical customers. The Clinical Services segment provides diagnostic services to the health care community. The Company’s Therapeutics 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, which may result in settlements recognized in another segment and other general corporate matters are considered a component of the Other segment. Legal fee expense specific to other segments’ activities have been allocated to those segments.

Legal settlements, net, represent activities for which royalties would have been received in the Company’s Products segment and expenses related to an investigation within the Clinical Services segment. 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.

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

Three months ended January 31, 2019

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	\$ 12,000	\$ 7,327	—	—	\$ 19,327

Operating costs and expenses:

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Cost of revenues	11,025	3,723	—	—	14,748
Research and development	—	611	\$ 222	—	833
Selling, general and administrative	6,200	2,981	—	\$2,316	11,497
Legal fee expense	38	1	—	1,103	1,142
Total operating costs and expenses	17,263	7,316	222	3,419	28,220
Operating income (loss)	(5,263)	11	(222)	(3,419)	(8,893)
<u>Other income (expense):</u>					
Interest	(15)	14	—	228	227
Other	(29)	(4)	—	165	132
Foreign exchange loss	—	126	—	—	126
(Loss) income before income taxes	\$(5,307)	\$ 147	\$ (222)	\$(3,026)	\$(8,408)
Depreciation and amortization included above	\$ 374	\$ 343	\$ —	\$ 51	\$ 768
<u>Share-based compensation included in above:</u>					
Selling, general and administrative	\$ 40	\$ 26	\$ —	\$ 225	\$ 291
Total	\$ 40	\$ 26	\$ —	\$ 225	\$ 291
Capital expenditures	\$ 409	\$ 26	\$ —	\$ 6,147	\$ 6,582

Three months ended January 31, 2018

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	\$ 18,730	\$ 7,422	—	—	\$ 26,152
<u>Operating costs and expenses:</u>					
Cost of revenues	11,730	3,877	—	—	15,607
Research and development	—	591	\$ 221	—	812
Selling, general and administrative	6,107	2,878	—	\$2,064	11,049
Legal fee expense	8	25	—	1,667	1,700
Total operating costs and expenses	17,845	7,371	221	3,731	29,168
Operating income (loss)	885	51	(221)	(3,731)	(3,016)
<u>Other income (expense):</u>					
Interest	(23)	11	—	197	185
Other	3	1	—	29	33
Foreign exchange loss	—	800	—	—	800
Income (loss) before income taxes	\$ 865	\$ 863	\$ (221)	\$(3,505)	\$ (1,998)
Depreciation and amortization included above	\$ 413	\$ 355	\$ —	\$ 18	\$ 786
<u>Share-based compensation included in above:</u>					
Selling, general and administrative	28	\$ 21	—	\$ 159	208
Total	\$ 28	\$ 21	\$ —	\$ 159	\$ 208
Capital expenditures	\$ 576	\$ 28	\$ —	\$ —	\$ 604

Six months ended January 31, 2019

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	\$ 26,297	\$ 14,290	—	—	\$ 40,587
<u>Operating costs and expenses:</u>					
Cost of revenues	21,993	6,994	—	—	28,987
Research and development	—	1,118	\$ 443	—	1,561
Selling, general and administrative	12,260	5,905	—	\$ 4,302	22,467
Legal fee expense	74	8	—	2,361	2,443
Total operating costs and expenses	34,327	14,025	443	6,663	55,458
Operating income (loss)	(8,030)	265	(443)	(6,663)	(14,871)
<u>Other income (expense):</u>					
Interest	(33)	30	—	504	501
Other	11	—	—	168	179
Foreign exchange loss (gain)	—	(198)	—	—	(198)
(Loss) income before income taxes	\$ (8,052)	\$ 97	\$ (443)	\$ (5,991)	\$ (14,389)
Depreciation and amortization included above	\$ 777	\$ 685	\$ —	\$ 72	\$ 1,534
<u>Share-based compensation included in above:</u>					
Selling, general and administrative	78	\$ 50	—	\$ 398	526
Total	\$ 78	\$ 50	\$ —	\$ 398	\$ 526
Capital expenditures	\$ 763	\$ 78	\$ —	\$ 6,147	\$ 6,988

Six months ended January 31, 2018

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	\$ 38,264	\$ 14,764	—	—	\$ 53,028
<u>Operating costs and expenses:</u>					
Cost of revenues	23,772	7,266	—	—	31,038
Research and development	—	1,114	\$ 445	—	1,559
Selling, general and administrative	12,202	5,506	—	\$ 4,246	21,954
Legal fee expense	21	28	—	2,082	2,131
Total operating costs and expenses	35,995	13,914	445	6,328	56,682
Operating income (loss)	2,269	850	(445)	(6,328)	(3,654)
<u>Other income (expense):</u>					
Interest	(48)	23	—	367	342
Other	17	8	—	44	69
Foreign exchange loss	—	605	—	—	605
Income (loss) before income taxes	\$ 2,238	\$ 1,486	\$ (445)	\$ (5,917)	\$ (2,638)

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Depreciation and amortization included above	\$ 817	\$ 681	\$ —	\$ 37	\$ 1,535
<u>Share-based compensation included in above:</u>					
Selling, general and administrative	60	\$ 44	—	\$ 309	413
Total	\$ 60	\$ 44	\$ —	\$ 309	\$ 413
Capital expenditures	\$ 994	\$ 72	\$ —	\$ —	\$ 1,066
18					

Note 11 – Contingencies

There are seven cases that are either stayed or on appeal, which were originally brought by the Company in the United States District Court for the District of Delaware (“the Court”), alleging patent infringement against various companies. On June 28, 2017, the Court issued an opinion in the Gen-Probe case, granting Gen-Probe’s motion for summary judgment that the asserted claims of the ’180 patent are invalid for nonenablement. The Court entered final judgment of invalidity of the asserted claims of the ’180 patent on July 19, 2017 in the Gen-Probe and Hologic cases. The Court entered partial final judgment of invalidity of the asserted claims of the ’180 patent and stayed the remainder of the cases in the Becton Dickinson and Roche cases on July 31, 2017 and August 2, 2017, respectively. The Company filed notices of appeal in each of the Gen-Probe, Hologic, Becton Dickinson, and Roche cases, which were docketed by the United States Court of Appeals for the Federal Circuit (“Federal Circuit”). In the Abbott case, the parties agreed that the Court’s summary judgment ruling in the Gen-Probe case invalidated all of the ’180 patent claims asserted against the Abbott Defendants. On August 15, 2017, the Court granted Abbott’s motion for summary judgment that the asserted claims of the ’405 patent are invalid for nonenablement. On September 1, 2017, the Court entered final judgment of invalidity of the asserted claims of the ’180 and ’405 patents for nonenablement in the Abbott case. Enzo subsequently filed a notice of appeal in the Abbott case on September 14, 2017. The Federal Circuit docketed the appeal on September 15, 2017. The Federal Circuit consolidated the appeals from the Abbott, Becton Dickinson, Gen-Probe, Hologic, and Roche litigations (“Consolidated Appeals”). We disagree with the Court’s invalidity decisions regarding the ’180 and ’405 patents in the pending cases as set forth in our briefing in the Consolidated Appeals pending in the Federal Circuit. In the Consolidated Appeals, we have asked the Federal Circuit to reverse the Court’s grants of final and summary judgment of invalidity of the asserted claims of the ’180 and ’405 patents and to remand the cases against Abbott, Becton Dickinson, Gen-Probe, Hologic, and Roche to the Court. Although the Federal Circuit heard oral argument in the Consolidated Appeals on January 7, 2019, it has not yet issued a ruling in the appeal. In the other two cases involving Hologic, one of the cases is stayed (Hologic II), while the other case (Hologic III) that involves U.S. Patent No. 6,221,581 (“the ’581 patent”) is on appeal to the Federal Circuit. In Hologic III, the Court issued a claim construction order on October 15, 2018. On October 31, 2018, Enzo and Hologic entered a stipulation that the asserted claims of the ’581 Patent are not infringed under the Court’s claim construction for certain of the claim terms. The Court entered final judgment of non-infringement on November 5, 2018. Enzo filed a notice of appeal on November 28, 2018. The Federal Circuit docketed the appeal and issued a schedule on December 3, 2018. Enzo’s opening brief is due on April 2, 2019. Regarding Hologic’s petition requesting institution of an inter partes review proceeding of the ’581 patent filed with the United States Patent and Trademark Office (“PTO”), the Patent Trial and Appeals Board (“the Board”) denied institution of Hologic’s petition on April 18, 2018. On May 18, 2018, Hologic filed with the Board, a request for rehearing of the order denying institution of inter partes review of the ’581 patent. The Board denied Hologic’s request for rehearing on November 28, 2018.

Enzo Biochem, Inc. (the "Company"), along with its subsidiary Enzo Life Sciences, Inc. entered into a Settlement Agreement as of February 5, 2019 (the "Agreement") with Roche Diagnostics GmbH and Roche Molecular Systems, Inc. (together, "Roche") with respect to an action between the Company and Roche before the U.S. District Court, Southern District of New York, Case No 04-CV-4046. Roche has agreed to pay \$21 million in settlement pursuant to the Agreement. This settlement does not affect Enzo's civil action for patent infringement against Roche in the U.S. District Court for the State of Delaware, *Enzo Life Sciences Inc. v. Roche Molecular Systems Inc., et al.*, civil action no. 12-cv-00106, which remains pending on appeal. See Note 12 – Subsequent Event.

There can be no assurance that the Company will be successful in these litigations. Even if the Company is not successful, management does not believe that there will be a significant adverse monetary impact on the Company.

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

Note 12 – Subsequent Event

Enzo Biochem, Inc. (the "Company"), along with its subsidiary Enzo Life Sciences, Inc. entered into a Settlement Agreement as of February 5, 2019 (the "Agreement") with Roche Diagnostics GmbH and Roche Molecular Systems, Inc. (together, "Roche") with respect to an action between the Company and Roche before the U.S. District Court, Southern District of New York, Case No 04-CV-4046. Roche has agreed to pay \$21 million in settlement pursuant to the Agreement. This settlement does not affect Enzo's civil action for patent infringement against Roche in the U.S. District Court for the State of Delaware, *Enzo Life Sciences Inc. v. Roche Molecular Systems Inc., et al.*, civil action no. 12-cv-00106, which remains pending on appeal.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes and other information included elsewhere in this Quarterly Report on Form 10-Q.

Forward-Looking Statements

Our disclosure and analysis in this report, including but not limited to the information discussed in this Item 2, contain forward-looking information about our Company's financial results and estimates, business prospects and products in research and development that involve substantial risks and uncertainties. From time to time, we also may provide oral or written forward-looking statements in other materials we release to the public. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historic or current facts. They use words such as "anticipate", "estimate", "expect", "project", "intend", "plan", "believe", "will", and other words and terms of similar meaning in connection with any discussion of future operations or financial performance.

In particular, these include statements relating to future actions, prospective products or product approvals, future performance or results of current and anticipated products, sales efforts, expenses, interest rates, foreign currency rates, intellectual property matters, the outcome of contingencies, such as legal proceedings, and financial results. We cannot guarantee that any forward-looking statement will be realized, although we believe we have been prudent in our plans and assumptions. Achievement of future results is subject to risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected. As a result, investors are cautioned not to place undue reliance on any of our forward-looking statements. Investors should bear this in mind as they consider forward-looking statements. We do not assume any obligation to update or revise any forward-looking statement that we make, even if new information becomes available or other events occur in the future. We are also affected by other factors that may be identified from time to time in our filings with the Securities and Exchange Commission, some of which are set forth in Item 1A - Risk Factors in our Form 10-K filing for the July 31, 2018 fiscal year and updated in Item 1A. "Risk Factors in this Form 10-Q, 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 an integrated diagnostic bioscience 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 are leading the convergence of clinical laboratories, life sciences, and intellectual property through the development of unique diagnostic platform technologies that provide numerous advantages over previous standards. Utilizing cross-functional teams, we develop, manufacture and sell our proprietary technology solutions and platforms to clinical laboratories, specialty clinics and researchers and physicians globally. Enzo’s structure and business strategy represent the culmination of years of extensive planning and work.

The Company now has the unique ability to offer low cost, high performance products and services in molecular diagnostics, which ideally positions us to capitalize on the reimbursement pressures facing diagnostic labs. 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 are designed to reduce overall healthcare costs for both government and private insurers. Our proprietary technology platforms reduces our customers’ need for multiple, specialized instruments, and offer a variety of high 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. Our technology solutions provide tools to physicians, clinicians and other healthcare 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.

In the course of our research and development activities, we have built a substantial portfolio of intellectual property assets, comprised of 343 issued patents worldwide and over 157 pending patent applications, along with extensive enabling technologies and platforms.

Below are brief descriptions of each of our operating segments (See Note 10 in the Notes to Consolidated Financial Statements):

Clinical Services is a clinical reference laboratory providing a wide range of clinical services to physicians, medical centers, other clinical labs and pharmaceutical companies. The Company believes having a CLIA-certified and a College of American Pathologists (“CAP”) accredited medical laboratory located in New York provides us the opportunity to more rapidly introduce cutting edge products and services to the clinical marketplace. Enzo Clinical Services offers an extensive menu of molecular and other clinical laboratory tests and 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, New Jersey and expanding into Connecticut, a free standing “STAT” or rapid response laboratory in New York City and a full service phlebotomy, in-house logistics department, and an information technology department. Given our license in New York State, we are able to offer testing services to clinical laboratories and physicians in the majority of states nationwide.

Products manufactures, develops and markets products and tools for 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 of our Form 10-K. 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 also the life sciences markets 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.

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 154 patents and patent applications.

Results of Operations**Three months ended January 31, 2019 compared to January 31, 2018****(in 000s)**Comparative Financial Data for the Three Months Ended January 31,

	2019	2018	Increase (Decrease)	% Change
Revenues	\$19,327	\$26,152	\$ (6,825)	(26)
Operating costs and expenses:				
Cost of revenues	14,748	15,607	(859)	(6)
Research and development	833	812	21	3
Selling, general and administrative	11,497	11,049	448	4
Legal fee expense	1,142	1,700	(558)	(33)
Total operating costs and expenses	28,220	29,168	(948)	(3)
Operating loss	(8,893)	(3,016)	5,877	**
Other income:				
Interest	227	185	42	23
Other	132	33	99	**
Foreign currency gain	126	800	(674)	(84)
Loss before income taxes	\$(8,408)	\$(1,998)	\$ 6,410	**

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

The “2019 period” and the “2018 period” refer to the three months ended January 31, 2019 and 2018, respectively.

Clinical services revenues for the 2019 period were \$12.0 million compared to \$18.7 million in the 2018 period, a decrease of \$6.7 million or 36%. Services revenues were negatively affected by lower volume in genetic testing approximating \$3.0 million as a result of increased competition and by reduced genetics reimbursements of \$1.5 million as a result of an increase in denial rates and changes to medical and procedural requirements. Services revenues for the 2019 period were also negatively affected by a payer overpayment claim of approximately \$0.4 million, and reduced clinical reimbursements of \$0.3 million due to reimbursement pressure from the Protecting Access to Medicare Act (“PAMA”). Diagnostic testing volume, measured by the number of accessions, decreased approximately 3% period over period or \$0.4 million. Estimated collection amounts are subject to the complexities and ambiguities of third party payer billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when

estimating variable consideration in the recognition of revenue in the period that the related services are rendered. During the 2019 period, adjustments to estimated collection amounts from third party payers and HMO's decreased Services revenues by \$0.8 million. There were no adjustments in the 2018 period.

Products revenues for the 2019 period was \$7.3 million compared to \$7.1 million in the 2018 period, an increase of \$0.2 million or 3% due to higher product order volume in the U.S. market. There was no royalty income in the 2019 period as the license agreement expired in the prior year. Royalty income in the 2018 period was \$0.3 million.

The cost of clinical services during the 2019 period was \$11.0 million as compared to \$11.7 million in the 2018 period, a decrease of \$0.7 million or 6% primarily due to test mix. The components of the decrease are \$1.0 million for outside reference lab testing costs and internalizing the use of our AMPIPROBE® technology platform, partially offset by a \$0.1 million increase in testing supplies and an increase of \$0.2 million in compensation related expenses.

Clinical services gross profit margin was 8.1% in the 2019 period and 37.4% in the 2018 period. The decline was primarily due to a change in the mix of tests from higher reimbursed genetic testing in the 2018 period to lower reimbursed routine or esoteric testing in the 2019 period. In addition, gross margin was also negatively impacted by reimbursement pressure from PAMA which has resulted in declining government and third party payer reimbursement rates, and by adjustments described above. PAMA calls for further downward revision of reimbursement rates effective January 1, 2020 and so we expect reimbursement rate pressure to continue to impact our industry and our operations.

The cost of products revenues was \$3.7 million in the 2019 period and \$3.9 million in the 2018 period, a decrease of \$0.2 million or 4% due to the mix of products sold. The gross profit margin on products was 49.2% in the 2019 period and 45.6% in the 2018 period due to mix of products sold.

Research and development expenses were \$0.8 million in the 2019 and 2018 periods. The expense for Life Sciences Products was \$0.6 million in both periods and the expense for the Enzo Therapeutics was \$0.2 million in both periods.

Selling, general and administrative expenses were approximately \$11.5 million during the 2019 period versus \$11.1 million during the 2018 period, an increase of \$0.4 million or 3%. Clinical Services expense increased \$0.1 million as the cost of increased headcount to market our new molecular diagnostic products for use by other reference labs, and other marketing and information technology costs were offset in part by lower billing operations costs. The Products expense increased \$0.1 million due to increased headcount focused on sales, marketing and business development of our diagnostic platform technologies. The Other segment expense increased \$0.2 million, due to an increase in compensation and administrative expenses.

Legal fee expense was \$1.1 million during the 2019 period compared to \$1.7 million in the 2018 period, a decrease of \$0.6 million due to the timing of legal activity and related costs associated with on-going litigation and contract dispute where the Company is the plaintiff.

Interest income, net increased \$0.1 million in the 2019 period from rising interest rates earned on cash and cash equivalents.

The foreign currency gain during the 2019 period was \$0.1 million compared to \$0.8 million in the 2018 period, a decrease of \$0.7 million or 84%, due to the significant appreciation of foreign currencies versus the U.S. dollar experienced within the Products segment during the 2018 period compared to that of the 2019 period.

Results of Operations**Six months ended January 31, 2019 compared to January 31, 2018****(in 000s)**Comparative Financial Data for the Six Months Ended January 31,

	2019	2018	Increase (Decrease)	% Change
Revenues	\$40,587	\$53,028	\$ (12,441)	(23)
Operating costs and expenses:				
Cost of revenues	28,987	31,038	(2,051)	(7)
Research and development	1,561	1,559	2	-
Selling, general and administrative	22,467	21,954	513	2
Legal fee expense	2,443	2,131	312	15
Total operating costs and expenses	55,458	56,682	(1,224)	(2)
Operating loss	(14,871)	(3,654)	(11,217)	**
Other income (expense):				
Interest	501	342	159	46
Other	179	69	110	159
Foreign currency (loss) gain	(198)	605	(803)	**
Loss before income taxes	\$(14,389)	\$(2,638)	\$ 11,751	**

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

The “2019 period” and the “2018 period” refer to the six months ended January 31, 2019 and 2018, respectively.

Clinical services revenues for the 2019 period were \$26.3 million compared to \$38.3 million in the 2018 period, a decrease of \$12.0 million or 31%. Services revenues were negatively affected by lower volume in genetic testing approximating \$6.8 million as a result of increased competition and by reduced genetics reimbursements of \$2.1 million as a result of an increase in denial rates and changes to medical and procedural requirements. Services revenues for the 2019 period were also negatively affected by a payer overpayment claim of approximately \$0.4 million, and reduced clinical reimbursements of \$0.3 million due to reimbursement pressure from PAMA. Diagnostic testing volume measured by the number of accessions, decreased approximately 4% period over period or \$1.3 million. Estimated collection amounts are subject to the complexities and ambiguities of third party payer billing, reimbursement regulations and claims processing, as well as issues unique to Medicare and Medicaid programs, and require us to consider the potential for retroactive adjustments when estimating variable consideration in the

recognition of revenue in the period that the related services are rendered. During the 2019 period, adjustments to estimated collection amounts from third party payers and HMO's decreased Services revenues by \$1.1 million. There were no adjustments in the 2018 period.

Products revenues for the 2019 period was \$14.3 million compared to \$14.2 million in the 2018 period, an increase of \$0.1 million or 1% due to slightly higher product order volume in the U.S. market.

There was no royalty income in the 2019 period as the license agreement expired in the prior year. Royalty income in 2018 was \$0.6 million.

The cost of clinical services during the 2019 period was \$22.0 million as compared to \$23.8 million in the 2018 period, a decrease of \$1.8 million or 7% primarily due to the change in test mix. The components of the decrease are \$2.3 million for outside reference lab testing costs and internalizing the use of our AMPIPROBE® technology platform, partially offset by an increase in compensation related expenses of \$0.3 million and other lab expenses of \$0.2 million.

Gross profit margin was 16.4% in the 2019 period and 37.9% in the 2018 period. The decline was primarily due to a change in the mix of tests from higher reimbursed genetic testing in the 2018 period to lower reimbursed routine or esoteric testing in the 2019 period. In addition, gross margin was also negatively impacted by reimbursement pressure from PAMA which has resulted in declining government and third party payer reimbursement rates and by adjustments described above. PAMA calls for further downward revision of reimbursements rates effective January 1, 2020 and so we expect reimbursement rate pressure to continue to impact our industry and our operations.

The cost of products revenues was \$7.0 million in the 2019 period and \$7.3 million in the 2018 period, a decrease of \$0.3 million or 4% due to the mix of products sold and lower compensation expense. The gross profit margin on products was 51.1% in the 2019 period and 48.8% in the 2018 period due to mix of products sold.

Research and development expenses were \$1.5 million in the 2019 and 2018 periods. The expense for Life Sciences Products was \$1.1 million in both periods and the expense for the Enzo Therapeutics was \$0.4 million in both periods.

Selling, general and administrative expenses were approximately \$22.5 million during the 2019 period versus \$22.0 million during the 2018 period, an increase of \$0.5 million or 2%. Clinical Services expense increased \$0.1 million, as the cost of increased headcount to market our new molecular diagnostic products for use by other reference labs was nearly offset by lower administrative expenses. The Products expense increased \$0.4 million due to increased headcount focused on sales, marketing and business development of our diagnostic platform technologies. The Other segment expense was unchanged.

Legal fee expense was \$2.4 million during the 2019 period compared to \$2.1 million in the 2018 period, an increase of \$0.3 million due to the timing of legal activity and related costs associated with on-going litigation and contract dispute where the Company is the plaintiff.

Interest income, net increased \$0.2 million in the 2019 period from rising interest rates earned on cash and cash equivalents.

The foreign currency loss during the 2019 period was \$0.2 million compared to \$0.6 million gain in the 2018 period, a decrease of \$0.8 million, due to the significant appreciation of foreign currencies versus the U.S. dollar experienced within the Products segment during the 2018 period compared to that of the 2019 period.

Liquidity and Capital Resources

At January 31, 2019, the Company had cash and cash equivalents and restricted cash of \$42.7 million of which \$0.4 million was in foreign accounts, as compared to cash and cash equivalents of \$60.0 million, of which \$0.4 million was in foreign accounts at July 31, 2018. 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 \$47.0 million at January 31, 2019 compared to \$63.0 million at July 31, 2018. The decrease in working capital of \$16.0 million was primarily due to the period loss and net changes in operating assets and liabilities.

Net cash used in operating activities during the 2019 period was approximately \$14.8 million as compared to cash provided by operating activities of \$0.8 million during the 2018 period, a decrease of approximately \$15.6 million. The decrease is mainly due to the net loss increase of \$12.8 million and net change in assets and liabilities of \$2.8 million.

Net cash used in investing activities in fiscal 2019 and 2018 was approximately \$7.0 million and \$1.1 million, respectively. The increase in the 2019 period is mainly due to the purchase of our new facility.

Net cash provided by financing activities in fiscal 2019 was \$4.5 million as compared to \$0.5 million in fiscal 2018. The change of \$4.0 million is mainly due to a mortgage agreement entered into for the purchase of our new facility.

The mortgage agreement, which provides for a loan of \$4.5 million for a term of 10 years, bears a fixed interest rate of 5.09% per annum and requires monthly mortgage payments of \$30,106. At January 31, 2019, the balance owed under the mortgage agreement was \$4.5 million. The Company's obligations under the mortgage agreement are secured by the new facility and by a \$750 cash collateral deposit with the mortgagee as additional security. This restricted cash is included in other assets as of January 31, 2019. See Note 7 – Loan Payable.

The Company believes that its current cash and cash equivalents level, utilization of the Controlled Equity Offering program if necessary, and the net proceeds received under the \$21 million settlement agreement with Roche on February 5, 2019 are sufficient for its foreseeable liquidity and capital resource needs over at least the next twelve (12) months, although there can be no assurance that future events will not alter such view. We expect our cash reserves will be reduced over the next four quarters as we implement our strategy of developing innovative diagnostic platforms and assays for use by independent labs. 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. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the Item 1A. "Risk Factors" section of our Form 10-K for the year ended July 31, 2018, and updated in Item 1A. "Risk Factors" in this

Form 10-Q, 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.

Contractual Obligations

The Company completed the \$6 million purchase of a 36,000 square foot commercial facility and as part of the purchase entered into a mortgage of \$4.5 million with a 10 year term and bearing a fixed interest rate of 5.09%. See Note 7 – Loan Payable. There have been no other material changes to our Contractual Obligations as reported in our Form 10-K for the fiscal year ended July 31, 2018.

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 10 to the Consolidated Financial Statements.

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.

Revenues – Clinical Services

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 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 from these programs.

During the three months ended January 31, 2019 and 2018, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 88.6% and 84.1%, respectively, of gross billings. During the six months ended January 31, 2019 and 2018, the contractual adjustment percentages, determined using current and historical reimbursements statistics, were 88.0% and 84.5%, respectively. 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 services revenues of approximately \$2.2 million and \$2.6 million for the six months ended January 31, 2019 and 2018, respectively, and a change in the net accounts receivable of approximately \$0.4 million as of January 31, 2019.

Our clinical services 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 contractual adjustments recorded during the current period have on 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; and

- 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 services and by products. Net receivables for Clinical Services are detailed by billing category and as a percent to its total net receivables. At January 31, 2019, and July 31, 2018, approximately 71% and 75%, respectively, of the Company's net accounts receivable relates to its services business, which operates in the New York, New Jersey and Connecticut medical communities.

The accounts receivable balance for Products includes \$0.9 million or 27% of foreign receivables as of January 31, 2019 and July 31, 2018.

Net accounts receivable

Billing category	As of January 31, 2019		As of July 31, 2018	
Clinical Services				
Third party payers	\$4,147	50 %	\$4,692	48 %
Patient self-pay	2,149	26	2,010	20
Medicare	1,324	16	1,740	18
HMO's	623	8	1,329	14
Total Clinical Services	8,243	100%	9,771	100%
Total Products	3,422		3,376	
Total accounts receivable	\$11,665		\$13,147	

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.

Edgar Filing: ENZO BIOCHEM INC - Form 10-Q

Billing for clinical 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 following table indicates the Clinical Services 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, 2019	Total	%	Third Party Payers	%	Medicare	%	Self-Pay	%	HMO's	%
1-30 days	\$22,195	51	\$14,828	56	\$ 3,543	44	\$ 1,307	24	\$2,517	93
31-60 days	5,265	12	3,557	13	843	11	779	15	86	3
61-90 days	3,819	9	2,563	9	592	7	642	12	22	1
91-120 days	2,980	7	1,729	6	564	7	666	12	21	1
121-150 days	1,835	4	892	3	442	6	482	9	19	1
Greater than 150 days	7,158	17	3,578	13	2,034	25	1,515	28	31	1
Totals	\$43,252	100%	\$27,147	100%	\$ 8,018	100%	\$ 5,391	100%	\$2,696	100%

As of July 31, 2018	Total	%	Third Party Payers	%	Medicare	%	Self-Pay	%	HMO's	%
1-30 days	\$22,788	47	\$14,886	48	\$ 4,102	46	\$ 864	15	\$2,936	90
31-60 days	6,821	14	4,540	15	1,069	12	995	17	217	7
61-90 days	4,526	9	2,877	9	784	9	843	15	22	1
91-120 days	3,460	7	2,307	8	463	5	666	11	24	1
121-150 days	2,705	6	1,602	5	490	6	601	10	12	—
Greater than 150 days	8,357	17	4,481	15	1,976	22	1,862	32	38	1
Totals	\$48,657	100%	\$30,693	100%	\$ 8,884	100%	\$ 5,831	100%	\$3,249	100%

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 net realizable value, which approximates market. Work-in-process and finished goods inventories consist of material, labor, and manufacturing overhead. Write downs of inventories to net realizable 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, 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.

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 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 a quantitative test 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 identifies the reporting units and compares the fair value of each of these reporting units to their respective carrying amount. If the carrying amount of the reporting unit is less than its fair value, no impairment exists. If the carrying amount of the reporting unit is higher than its fair value, the impairment charge is the amount by which the carrying amount exceeds its fair value, not to exceed the total amount of goodwill and intangibles allocated to the reporting unit. As of January 31, 2019, the Company determined that indicators of potential impairment of goodwill existed for the Clinical Services unit due to the recent decline of its revenues. The Company determined that no impairment charge was necessary, based on a quantitative analysis.

Restricted Cash

As of January 31, 2019 the Company had a mortgage collateralized by a money market account of \$750 to the benefit of the mortgagee of the Company's recently purchased building. This restricted cash was classified as other assets as of January 31, 2019.

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, 2018) 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, 2019, our assets and liabilities would decrease by \$0.4 million and \$0.1 million, respectively, and our net sales and net earnings (loss) would decrease by \$0.8 million and \$0.2 million, respectively, on an annual basis.

We also maintain intercompany balances and loans with subsidiaries in different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$1.5 million on an annual basis.

Interest Rate Risk

As of January 31, 2019, we have fixed interest rate financing on a building mortgage and 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 not effective as of the end of the period covered by this report as management identified deficiencies in internal control over financial reporting that were determined to be material weaknesses. 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 were no changes in our internal control over financial reporting that occurred during the quarter ended January 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Plan to Remediate Material Weaknesses

As of January 31, 2019, we are in the process of remediating the material weaknesses over financial reporting identified and reported in our Form 10-K for the fiscal year ended July 31, 2018 related to (1) insufficient controls to fully and timely take into account changes in the business environment and experience with ultimate collection from third-party payers in the determination of contractual adjustment amounts and collectability of accounts receivable and (2) inadequate information technology controls intended to control change management, program access and monitoring; however, the material weaknesses cannot be considered remediated until the procedures designed to address the deficient controls have been tested for effectiveness.

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, 2018 filed with the Securities and Exchange Commission, other than as noted in Note 10 to the Consolidated Financial Statements as of January 31, 2019.

Item 1A. Risk Factors

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, 2018 are updated to include the following:

Risk relating to our debt

Our use of leverage may expose us to substantial risks

As of January 31, 2019, we had \$4.5 million in borrowings under a ten year mortgage agreement with Citibank, N.A., which bears a fixed interest rate of 5.09% per annum. We may incur additional indebtedness in the future. Accordingly, we are exposed to the typical risks associated with the use of leverage. Increased leverage makes it more difficult for us to withstand adverse economic conditions or business plan variances, to take advantage of new business opportunities, or to make necessary capital expenditures. The mortgage agreement includes customary affirmative and negative covenants and events of default, as defined. Events of default include non-payment of principal and interest on debt outstanding, non-performance of covenants, material changes in business, breach of representations, bankruptcy or insolvency, and changes in control. Our ability to maintain our compliance with these covenants is dependent on our financial performance, which is influenced by a number of factors. Violation of any of these covenants would result in an event of default under the mortgage agreement. Upon the occurrence of an event of default that is not cured or waived, the lender would have the ability to accelerate the repayment of all amounts then outstanding under the mortgage agreement.

Item 6. Exhibits

Exhibit No.	Exhibit
31.1	<u>Certification of Elazar Rabbani, Ph.D. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>

- 31.2 Certification of Barry Weiner pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1 Certification of Elazar Rabbani, Ph.D. pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Barry Weiner pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101.INS* XBRL Instance Document
- 101.SCH* XBRL Taxonomy Extension Schema Document
- 101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document
- 101.DEF* XBRL Taxonomy Extension Definitions Linkbase Document
- 101.LAB* XBRL Taxonomy Extension Label Linkbase Document
- 101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

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

SIGNATURES

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

ENZO
BIOCHEM,
INC.
(Registrant)

Date: March 11, 2019 by: /s/ Barry
Weiner
President,
Chief
Financial
Officer,
Principal
Accounting
Officer,
Treasurer
and
Director