

ENZO BIOCHEM INC  
Form 10-Q  
December 10, 2018  
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 October 31, 2018

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)

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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

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As of December 1, 2018, the Registrant had 47,192,429 shares of common stock outstanding.

ENZO BIOCHEM, INC.  
FORM 10-Q  
October 31, 2018

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

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

	October 31, 2018 (unaudited)	July 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 52,777	\$60,041
Accounts receivable, net of allowances	12,836	13,147
Inventories	7,588	7,278
Prepaid expenses and other	2,307	2,734
Total current assets	75,508	83,200
Property, plant and equipment, net	7,503	7,636
Goodwill	7,452	7,452
Intangible assets, net	1,625	1,886
Other assets	2,095	1,486
Total assets	\$ 94,183	\$101,660
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable – trade	\$ 7,155	\$9,516
Accrued liabilities	10,848	10,054
Other current liabilities	190	616
Total current liabilities	18,193	20,186
Other liabilities	320	353
Total liabilities	\$ 18,513	\$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: 47,192,429 at October 31, 2018 and 47,182,254 at July 31, 2018	472	472
Additional paid-in capital	331,030	330,770
Accumulated deficit	(258,202 )	(252,221)
Accumulated other comprehensive income	2,370	2,100
Total stockholders' equity	75,670	81,121
Total liabilities and stockholders' equity	\$ 94,183	\$101,660

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

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

	Three Months Ended October 31,	
	2018	2017
Revenues	21,260	26,876
Operating costs and expenses:		
Cost of revenues	14,239	15,431
Research and development	728	747
Selling, general and administrative	10,970	10,905
Legal fee expense	1,301	431
Total operating costs and expenses	27,238	27,514
Operating loss	(5,978 )	(638 )
Other income (expense):		
Interest	274	157
Other	47	36
Foreign exchange loss	(324 )	(195 )
Loss before income taxes	(5,981 )	(640 )
Benefit for income taxes	—	—
Net loss	\$(5,981 )	\$(640 )
Net loss per common share:		
Basic and diluted	\$(0.13 )	\$(0.01 )
Weighted average common shares outstanding:		
Basic and diluted	47,186	46,914

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 October 31,	
	2018	2017
Net loss	\$(5,981)	\$(640)
Other comprehensive income (loss):		
Foreign currency translation adjustments	270	83
Comprehensive loss	\$(5,711)	\$(557)

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



**ENZO BIOCHEM, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**  
**Three Months Ended October 31, 2018 and 2017**  
**(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 October 31, 2018	—	—	—	(5,981 )	—	(5,981 )
Vesting of restricted stock	175	—	—	—	—	—
Exercise of stock options	10,000	—	25	—	—	25
Share-based compensation charges	—	—	235	—	—	235
Foreign currency translation adjustments	—	—	—	—	270	270
Balance at October 31, 2018	47,192,429	\$ 472	\$ 331,030	\$ (258,202 )	\$ 2,370	\$ 75,670

	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 October 31, 2017	—	—	—	—	—	(640 )	—	(640 )
Purchase of treasury stock	—	80,751	—	—	(815 )	—	—	(815 )
Vesting of restricted stock	1,001	—	—	—	—	—	—	—
Exercise of stock options	487,106	—	5	1,472	—	—	—	1,477
Share-based compensation charges	—	—	—	205	—	—	—	205
Foreign currency translation adjustments	—	—	—	—	—	—	83	83
Balance at October 31, 2017	46,994,283	80,751	\$ 470	\$ 329,971	\$ (815 )	\$ (242,540 )	\$ 2,096	\$ 89,182

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

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

	Three Months Ended October 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(5,981 )	\$(640 )
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization of property, plant and equipment	519	521
Amortization of intangible assets	247	228
Share-based compensation charges	235	205
Accrual for share-based 401(k) employer match expense	196	177
Foreign exchange loss	302	198
Changes in operating assets and liabilities:		
Accounts receivable	312	713
Inventories	(309 )	(198 )
Prepaid expenses and other assets	449	207
Accounts payable – trade	(2,361 )	(819 )
Accrued liabilities, other current liabilities and other liabilities	187	2,003
Total adjustments	(223 )	3,235
Net cash (used in) provided by operating activities	(6,204 )	2,595
Cash flows from investing activities:		
Capital expenditures	(406 )	(461 )
Security deposits and other	(609 )	—
Net cash used in investing activities	(1,015 )	(461 )
Cash flows from financing activities:		
Installment loan and capital lease obligation payments	(59 )	(101 )
Proceeds from exercise of stock options	25	658
Net cash (used in) provided by financing activities	(34 )	557
Effect of exchange rate changes on cash and cash equivalents	(11 )	(9 )
(Decrease) increase in cash and cash equivalents	(7,264 )	2,682
Cash and cash equivalents - beginning of period	60,041	64,167
Cash and cash equivalents - end of period	\$52,777	\$66,849

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

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

**As of October 31, 2018**  
**(Unaudited)**  
**(Dollars in thousands, except share data)**

Note 1 – Basis of Presentation

The accompanying consolidated financial statements include the accounts of Enzo Biochem, Inc. and its wholly-owned subsidiaries, Enzo Life Sciences, Enzo Clinical Labs, Enzo Therapeutics and Enzo Realty LLC, collectively or with one or more of its subsidiaries referred to as the “Company” or “Companies”. The consolidated balance sheet as of October 31, 2018, the consolidated statements of operations and comprehensive income (loss) for the three months ended October 31, 2018 and 2017, the consolidated statements of cash flows for the three months ended October 31, 2018 and 2017 and the consolidated statement of stockholders’ equity for the three months ended October 31, 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 months ended October 31, 2018 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 consolidated operations and cash flows is presented in the table below:

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Adoption of the standard impacted the Company's reported results for the three months ended October 31, 2017 as follows:

	As Previously Reported	Adjustment for New Accounting Standard on Revenue Recognition	Reclassification of Residual	As Restated
<b>Consolidated Statements of Operations:</b>				
Total Revenues	\$27,676	\$(800)	—	\$26,876
Provision for uncollectible accounts receivable	814	(800)	\$(14)	—
Selling, general and administrative expenses	10,891	—	14	10,905
Net loss	(640)	—	—	\$(640)
<b>Consolidated Statements of Cash Flows:</b>				
Provision for uncollectible accounts receivable	814	(814)	—	—
Changes in operating assets and liabilities: Accounts receivable	(101)	814	—	713
Balance, July 31, 2018				
<b>Consolidated balance sheet:</b>				
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. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. As amended in July 2018, an additional and optional transition method to adopt the new leases standard was established. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases).

We believe 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 sales 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 41% and 40% of Clinical Services net revenue for the three months ended October 31, 2018 and 2017 respectively. 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 37% and 47% of Clinical Services net receivables for the three months ended October 31, 2018 and 2017 respectively.

### **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 months ended October 31, 2018 and 2017 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 months ended October 31, 2018 and 2017, the number of potential common shares (“in the money options”) and unvested restricted stock excluded from the calculation of diluted earnings per share was 135,000 and 931,000, respectively, because their effect would be antidilutive. For the three months ended October 31, 2018, the effect of approximately 1,330,000 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 months ended October 31, 2017, 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 67% and 73% of the Company's total net revenues for the three months ended October 31, 2018 and 2017, 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 October 31, 2018		Three months ended October 31, 2017	
<u>Revenue category</u>				
Third-party payer	\$7,907	55 %	\$10,860	56 %
Patient self-pay	1,974	14	2,859	14
Medicare	2,751	19	2,985	15
HMO's	1,665	12	2,830	15
Total	\$14,297	100 %	\$19,534	100 %

For the three months ended October 31, 2018 and 2017, 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 months ended October 31, 2018 and 2017, royalty income was zero and \$261, respectively.

Product revenue by geography is as follows:

	October 31, 2018	October 31, 2017
United States	\$ 3,879	\$ 3,736
Europe	1,342	1,632
Rest of world	1,742	1,713
Net product revenues	\$ 6,963	\$ 7,081

Note 4 - Supplemental disclosure for statement of cash flows

For the three months ended October 31, 2018 and 2017, income taxes paid by the Company were \$0 and \$15, respectively.

For the three months ended October 31, 2018 and 2017, interest paid by the Company was \$12 and \$25, respectively.

For the three months ended October 31, 2018 and 2017, the Company did not finance any machinery or transportation equipment under installment loans.

Note 5 – Inventories

Inventories consist of the following:

	October 31, 2018	July 31, 2018
Raw materials	\$ 797	\$ 754
Work in process	2,338	2,174
Finished products	4,453	4,350

\$7,588 \$7,278

-

Note 6 – Goodwill and intangible assets

At October 31, 2018 and July 31, 2018, the Company's carrying amount of goodwill, related to Clinical Services is \$7,452.

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	—	(247 )	(247 )
Foreign currency translation	(137 )	123	(14 )
October 31, 2018	\$27,210	\$ (25,585 )	\$ 1,625

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

	<b>October 31, 2018</b>			<b>July 31, 2018</b>		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents	\$11,027	\$ (10,983 )	\$44	\$11,027	\$ (10,980 )	\$47
Customer relationships	11,699	(10,118 )	1,581	11,836	(9,997 )	1,839
Total	\$27,210	\$ (25,585 )	\$1,625	\$27,347	\$ (25,461 )	\$1,886

At October 31, 2018, information with respect to intangibles assets acquired is as follows:

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

At October 31, 2018, the weighted average remaining useful life of intangible assets is approximately two years.

#### Note 7 – Accrued Liabilities

Accrued liabilities consist of the following:

	October 31, 2018	July 31, 2018
Payroll, benefits, and commissions	\$5,919	\$4,870
Legal fee expense	1,475	2,121
Professional fees	807	811
Other	2,647	2,252
	\$10,848	\$10,054

#### Note 8 – Stockholders' Equity

##### ***Controlled Equity Offering***

The Company has a Controlled Equity Offering<sup>SM</sup> Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”). Under the Sales Agreement, the Company may offer and sell, from time to time, through Cantor, shares of the Company’s common stock, par value \$0.01 per share (the “Common Stock”). The Company pays Cantor a commission of 3.0% of the aggregate gross proceeds received under the Sale 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 three months ended October 31, 2018 and 2017, 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 October 31,	
	<u>2018</u>	<u>2017</u>
Stock options	\$ 232	\$ 202
Restricted stock	3	3
	\$ 235	\$ 205

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 October 31,	
	<u>2018</u>	<u>2017</u>
Selling, general and administrative	235	205
	\$235	\$205

No excess tax benefits were recognized during the three month periods ended October 31, 2018 and 2017.

**Stock Option Plans**

The following table summarizes stock option activity during the three month period ended October 31, 2018:

	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	—	\$ —		
Exercised	(10,000 )	\$ 2.53		\$ 41
Cancelled or expired	(2,000 )	\$ 4.51		
Outstanding at end of period	1,870,116	\$ 4.97	2.6 years	\$ 412
Exercisable at end of period	1,139,156	\$ 4.29	1.6 years	\$ 142

As of October 31, 2018, the total future compensation cost related to non-vested options, not yet recognized in the statements of operations, was \$0.9 million and the weighted average period over which the remaining expense of these awards is expected to be recognized is twelve 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.



***Restricted Stock Awards***

A summary of the activity pursuant to the Company's unvested restricted stock awards for the three months ended October 31, 2018 is as follows:

	Awards	Weighted Average Award Price
Outstanding at July 31, 2018	2,613	\$ 1.74
Awarded	—	—
Vested	(175 )	\$ (5.62 )
Forfeited	—	—
Unvested at end of period	2,438	\$ 1.47

The fair value of a restricted stock award is determined based on the closing stock price on the award date. As of October 31, 2018, there was approximately \$0.1 million of unrecognized compensation cost related to unvested restricted stock-based compensation to be recognized over a weighted average remaining period of approximately twenty-seven months.

The fair value of the awards that vested during the three months ended October 31, 2018 and 2017 was \$1 and \$10, respectively.

The total number of shares available for grant as equity awards from the 2011 Incentive Plan is approximately 1,933,000 shares as of October 31, 2018.

***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, the Company awarded a total of 32,000 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 October 31, 2018, 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. At the grant date, the fair value of this award was \$141.

#### Note 9 – 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 October 31, 2018**

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	14,297	6,963	—	—	21,260
Operating costs and expenses:					
Cost of revenues	10,968	3,271	—	—	14,239
Research and development	—	507	\$ 221	—	728
Selling, general and administrative	6,060	2,924	—	\$1,986	10,970
Legal fee expense	36	7	—	1,258	1,301
Total operating costs and expenses	17,064	6,709	221	3,244	27,238
Operating income (loss)	(2,767 )	254	(221 )	(3,244)	(5,978 )
Other income (expense):					
Interest	(18 )	16	—	276	274
Other	40	4	—	3	47
Foreign exchange loss	—	(324 )	—	—	(324 )
Loss before income taxes	\$(2,745 )	\$(50 )	\$(221 )	\$(2,965)	\$(5,981 )
Depreciation and amortization included above	\$ 403	\$ 342	\$ —	\$ 21	\$ 766
Share-based compensation included in above:					
Selling, general and administrative	38	\$ 24	—	\$ 173	235
Total	\$ 38	\$ 24	\$ —	\$ 173	\$ 235
Capital expenditures	\$ 354	\$ 52	\$ —	\$ —	\$ 406

## Three months ended October 31, 2017

	Clinical Services	Products	Therapeutics	Other	Consolidated
Revenues	19,534	7,342	—	—	26,876
Operating costs and expenses:					
Cost of product revenues	12,042	3,389	—	—	15,431
Research and development	—	523	\$ 224	—	747
Selling, general and administrative	6,095	2,628	—	\$2,182	10,905
Legal fee expense	13	3	—	415	431
Total operating costs and expenses	18,150	6,543	224	2,597	27,514
Operating income (loss)	1,384	799	(224 )	(2,597)	(638 )
Other income (expense):					
Interest	(25 )	12	—	170	157
Other	14	7	—	15	36
Foreign exchange gain	—	(195 )	—	—	(195 )
Income (loss) before income taxes	\$ 1,373	\$ 623	\$ (224 )	\$ (2,412)	\$ (640 )
Depreciation and amortization included above	\$ 404	\$ 326	\$ —	\$ 19	\$ 749
Share-based compensation included in above:					
Selling, general and administrative	32	\$ 23	—	\$ 150	205
Total	\$ 32	\$ 23	\$ —	\$ 150	\$ 205
Capital expenditures	\$ 418	\$ 43	\$ —	\$ —	\$ 461

**Note 11 – Contingencies**

There are seven cases that are either pending 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 opening brief in the Consolidated Appeals pending in the Federal Circuit filed on November 28, 2017. 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. Briefing is now complete in the Consolidated Appeals. The Federal Circuit has scheduled an oral argument in the Consolidated Appeals for January 7, 2019. 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. 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. The schedule is as follows: (1) Entry of Appearance is due on 12/17/2018; (2) Certificate of Service is due on 12/17/2018; (3) Docketing Statement is due on 12/17/2018; and (4) Enzo’s opening brief is due on 2/1/2019. 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.

The Company and Enzo Life Sciences are engaged in litigation in the United States District Court for the Southern District of New York against Roche Diagnostic GmbH and its related company Roche Molecular Systems, Inc. (“Roche”), as declaratory judgment defendants. This case was commenced in May 2004. Roche seeks a declaratory judgment of non-breach of contract and patent invalidity against the Company and Enzo Life Sciences. Roche has also asserted tort claims against the Company and Enzo Life Sciences. The Company and Enzo Life Sciences have asserted breach of contract and patent infringement causes of action against Roche. There has been extensive discovery. In 2011, Roche moved for summary judgment of non-infringement regarding the Company’s patent claims. In 2012, the motion was granted in part and denied in part. In December 2012, Roche moved for summary judgment on the Company’s non-patent claims. Additional discovery was taken and the Company responded to the motions in May 2013. In December 2013, the Court granted in part and denied in part Roche’s summary judgment motion. In

October 2014, the Court ordered that damages discovery concerning the Company's remaining contract and patent claims and Roche's claims should be completed by the end of January 2015, and expert discovery should be completed following the Court's claim construction ruling concerning the Company's patent infringement claim against Roche. Roche dropped its tort claims during damages discovery. On October 2, 2017, the Court issued its claim construction ruling. On September 8, 2018, the Court issued an order (i) directing that motions for summary judgment should be filed on October 10, 2018 and a proposed pretrial order by February 22, 2019, and (ii) scheduling an April 8, 2019 trial. On October 10, 2018, the parties filed their motions for summary judgment and also filed motions to preclude. Those motions are now fully briefed. The Company and Enzo Life Sciences intend to vigorously press their remaining claims and contest the claims against them.

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**

As part of implementing our growth strategy, on November 27, 2018, we closed on the \$6 million purchase of a new facility with nearly 36,000 square feet adjacent to our current campus in Farmingdale, NY to be used for manufacturing and distributing our low cost, diagnostic platform products and related services. This facility extends Enzo's New York campus to nearly 101,000 square feet, complementing our existing sites in Michigan, Switzerland, France and Belgium.

In connection with the purchase, we entered into a fee mortgage security agreement with Citibank, N.A., the mortgagee in the amount of \$4.5 million. The mortgage is for a term of 10 years, bears a fixed interest rate of 5.09% per annum, and requires monthly principal and interest payments of \$30,106. The mortgage includes financial covenants requiring adherence to certain financial ratios. We have Town of Babylon Industrial Development Agency (IDA) commitments that will provide significant multi-year tax abatements and additional incentives with respect to our entire Farmingdale campus

We assumed an operating lease for the facility from the seller. The current tenant may occupy the facility until December 2019, unless it is given or gives notice to vacate prior to that date.

## **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. 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 October 31, 2018 compared to October 31, 2017****(in 000s)**Comparative Financial Data for the Three Months Ended October 31,

	2018	2017	Increase (Decrease)	%	
				Change	
Revenues	\$21,260	\$26,876	\$ (5,616 )	(21 )	
Operating costs and expenses:					
Cost of revenues	14,239	15,431	(1,192 )	(8 )	
Research and development	728	747	(19 )	(3 )	
Selling, general and administrative	10,970	10,905	65	1	
Legal fee expense	1,301	431	870	**	
Total operating costs and expenses	27,238	27,514	(276 )	(1 )	
Operating loss	(5,978 )	(638 )	(5,340 )	**	
Other income (expense):					
Interest	274	157	117	75	
Other	47	36	11	31	
Foreign currency loss	(324 )	(195 )	(129 )	66	
Loss before income taxes	\$(5,981 )	\$(640 )	\$ 5,341	**	

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

The “2019 period” and the “2018 period” refer to the three months ended October 31, 2018 and 2017, respectively.

Clinical services revenues for the 2019 period were \$14.3 million compared to \$19.5 million in the 2018 period, a decrease of \$5.2 million or 27% largely due to reduced insurance reimbursement payments and mix of testing, which were reimbursed at higher than average rates in the prior year. Total diagnostic testing volume, measured by the number of accessions, decreased 5% year over year, again due to lower high-value testing, partially offset by an increase in esoteric testing.

Product revenues for the 2019 period was \$7.0 million compared to \$7.1 million in the 2018 period, a decrease of \$0.1 million or 2% due to slightly lower product order volume. There was no royalty income in the 2019 period because the license agreement has expired. Royalty income in 2018 was \$0.3 million.

The cost of clinical services during the 2019 period was \$11.0 million as compared to \$12.1 million in the 2018 period, a decrease of \$1.1 million or 9% primarily due to test mix. The components of the decrease are \$1.2 million for outside reference lab testing costs, internalizing the use of our AMPIPROBE® technology platform, and \$0.1 million of testing supplies, partially offset by an increase in compensation related expenses of \$0.2 million. Gross profit margin was 23% in the 2019 period and 38% in the 2018 period, impacted by the mix of tests and decreased payer reimbursement rates.

The cost of product revenues was \$3.3 million in the 2019 period and \$3.4 million in the 2018 period, a decrease of \$0.1 million or 3% due to lower product sales. The gross profit margin on products was 53% in the 2019 period and 52% in the 2018 period due to mix of products sold.

Research and development expenses were \$0.7 million in the 2019 and 2018 periods. The expense for Life Sciences Products was \$0.5 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 \$11.0 million during the 2019 period versus \$10.9 million during the 2018 period, an increase of \$0.1 million or 1%. Clinical Services expense was unchanged, as the cost of increased headcount to market our new molecular diagnostic products for use by other reference labs was offset by lower sales commissions. The Products expense increased \$0.3 million due to increased headcount focused on sales, marketing and business development of our diagnostic platform technologies. The Other segment expense decreased \$0.2 million, due to a decrease in compensation related expenses.

Legal fee expense was \$1.3 million during the 2019 period compared to \$0.4 million in the 2018 period, an increase of \$0.9 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 increased \$0.1 million in the 2019 period from rising interest rates earned on cash and cash equivalents.

## **Liquidity and Capital Resources**

At October 31, 2018, the Company had cash and cash equivalents of \$52.8 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 \$57.3 million at October 31, 2018 compared to \$63.0 million at July 31, 2018. The decrease in working capital of \$5.7 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 \$6.2 million as compared to cash provided by operating activities of \$2.6 million during the 2018 period, a decrease of approximately \$8.8 million. The decrease is mainly due to net loss of \$5.3 million and net change in assets and liabilities of \$3.6 million.

Net cash used in investing activities in fiscal 2019 and 2018 was approximately \$1.0 million and \$0.5 million, respectively. The increase in the 2019 period is mainly due to security deposits.

Net cash used in financing activities in fiscal 2019 was less than \$0.1 million as compared to cash provided by financing activities of \$0.6 million in fiscal 2018. The change of \$0.6 million is mainly due to a decrease in proceeds from the exercise of stock options.

The Company believes that its current cash and cash equivalents level, and utilization of the Controlled Equity Offering program if necessary, 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. 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, 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**

Subsequent to the end of the period covered by this report, 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%. We assumed an operating lease for the facility from the seller that runs to December 2019. See Note 12. 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 October 31, 2018 and 2017, the contractual adjustment percentages, determined using current and historical reimbursement statistics, were 87.5% and 85.0%, respectively, of gross billings. 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 \$1.1 million and \$1.4 million for the three months ended October 31, 2018 and 2017, respectively, and a change in the net accounts receivable of approximately \$0.5 million as of October 31, 2018.

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 October 31, 2018, and July 31, 2018, approximately 74% 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 \$1.1 million or 32% of foreign receivables as of October 31, 2018 and July 31, 2018.

Net accounts receivable

<b>Billing category</b>	<b>As of October 31, 2018</b>		<b>As of July 31, 2018</b>	
Clinical Services				
Third party payers	\$4,792	51 %	\$4,692	48 %
Patient self-pay	2,268	23	2,010	20
Medicare	1,682	18	1,740	18
HMO's	731	8	1,329	14
Total Clinical Services	9,473	100%	9,771	100%
Total Products	3,363		3,376	
Total accounts receivable	\$12,836		\$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.

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.

<b>As of October 31, 2018</b>	<b>Total</b>	<b>%</b>	<b>Third Party Payers</b>	<b>%</b>	<b>Medicare</b>	<b>%</b>	<b>Self-Pay</b>	<b>%</b>	<b>HMO's</b>	<b>%</b>
1-30 days	\$ 24,365	53	\$ 15,486	55	\$ 4,136	50	\$ 1,695	27	\$ 3,048	93
31-60 days	5,764	13	3,473	12	891	11	1,278	20	122	4
61-90 days	4,173	9	2,779	10	653	8	707	11	34	1
91-120 days	2,716	6	1,605	6	485	6	604	9	22	1
121-150 days	2,341	5	1,303	5	504	6	529	8	5	—
Greater than 150 days	6,654	14	3,435	12	1,550	19	1,617	25	52	1
Totals	\$ 46,013	100%	\$ 28,081	100%	\$ 8,219	100%	\$ 6,430	100%	\$ 3,283	100%

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<b>As of July 31, 2018</b>	<b>Total</b>	<b>%</b>	<b>Third Party Payers</b>	<b>%</b>	<b>Medicare</b>	<b>%</b>	<b>Self-Pay</b>	<b>%</b>	<b>HMO's</b>	<b>%</b>
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.

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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.

### **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 October 31, 2018, 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 \$0.3 million, respectively, on an annual basis.

We also maintain intercompany balances and loans with subsidiaries in different local currencies. These amounts are at risk of foreign exchange losses if exchange rates fluctuate. Assuming a hypothetical increase of 10% in the value of the U.S. dollar versus foreign currencies, our pre-tax earnings (loss) would be unfavorably impacted by approximately \$1.4 million on an annual basis.

#### *Interest Rate Risk*

As of October 31, 2018, we have fixed interest rate financing on transportation and equipment leases.

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

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

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 October 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

##### **Plan to Remediate Material Weaknesses**

As of October 31, 2018, 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 October 31, 2018.

### Item 1A. Risk Factors

There have been no material changes from the risk factors disclosed in Part 1, Item 1A of the Company's Annual Report on Form 10-K for the fiscal year ended July 31, 2018.

### Item 6. Exhibits

<b>Exhibit No.</b>	<b>Exhibit</b>
31.1	<u>Certification of Elazar Rabbani, Ph.D. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2	<u>Certification of Barry Weiner pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1	<u>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.</u>
32.2	<u>Certification of Barry Weiner pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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: December 10, 2018 by: /s/ Barry  
Weiner  
President,  
Chief  
Financial  
Officer,  
Principal  
Accounting  
Officer,  
Treasurer  
and  
Director