

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 8-K

CURRENT REPORT Pursuant  
to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **December 7, 2015**

**Enzo Biochem, Inc.**

(Exact Name of Registrant as Specified in Its Charter)

**New York**

(State or Other Jurisdiction of Incorporation)

**001-09974**

(Commission File Number)

**13-2866202**

(IRS Employer Identification No.)

**527 Madison Avenue  
New York, New York**

(Address of Principal Executive Offices)

**10022**

(Zip Code)

**(212) 583-0100**

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions *see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 2.02. Results of Operations and Financial Condition.**

On December 7, 2015, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its first fiscal quarter ended October 31, 2015. A copy of the press release is furnished as Exhibit 99.1 attached hereto and is incorporated by reference in its entirety into this item 2.02 of this Current Report on Form 8-K.

In its press release, the Company discloses items not prepared in accordance with accounting principles generally accepted in the United States (“GAAP”), or non-GAAP financial measures (as defined in Regulation G promulgated by the U.S. Securities and Exchange Commission) that exclude certain significant charges or credits that are important to an understanding of the Company’s ongoing operations. The Company believes that its inclusion of non-GAAP financial measures provides useful supplementary information to and facilitates analysis by investors in evaluating the Company’s performance and trends. The determination of significant charges or credits may not be comparable to similar measures used by other companies and may vary from period to period. The Company uses both GAAP financial measures and the disclosed non-GAAP financial measures internally to evaluate and manage the Company’s operations and to better understand its business. These non-GAAP financial measures are in addition to, not a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP.

Non-GAAP net income, non-GAAP earnings per share, and adjusted EBITDA are supplemental measures of our performance that are not required by, or presented in accordance with, GAAP. We define non-GAAP net income as consolidated net income / (loss) for such period adjusted for the following net of tax (i) litigation charges and settlements, (ii) business restructuring or other restructurings of a similar nature, and (iii) other unusual charges or expenses. We define adjusted EBITDA as an amount equal to consolidated net income / (loss) for such period adjusted for the following (i) interest expense, (ii) interest income, (iii) provision for income taxes, (iv) depreciation and amortization expenses, (v) litigation charges and settlements, (vi) business restructuring charges or other restructurings of a similar nature, and (vii) other unusual charges or expenses.

**Item 7.01. Regulation FD Disclosure.**

The information provided in Item 2.02 of this Current Report on Form 8-K is incorporated herein by reference in its entirety.

The information discussed under Item 2.02 and Item 7.01 above, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

*The information in this report (including the exhibits) is furnished pursuant to Item 2.02 and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.*

**Item 9.01. Financial Statements and Exhibits.****(d) Exhibits.**

99.1 Press Release of Enzo Biochem, Inc., dated December 7, 2015.

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**SIGNATURES**

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

ENZO BIOCHEM, INC.

Date: December 7, 2015

By: /s/ Barry W. Weiner  
Barry W. Weiner  
President

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**news  
release**

Enzo Biochem, Inc.  
527 Madison Avenue  
New York, NY 10022

FOR IMMEDIATE RELEASE

**ENZO BIOCHEM REPORTS STRONG FIRST QUARTER**  
**Execution on Corporate Strategy seen in Company's Results**

NEW YORK, NY, December 7, 2015 – Enzo Biochem Inc. (NYSE:ENZ) today reported another period of strong results for the first fiscal quarter ended October 31, 2015.

**First Quarter Highlights**

- Strong financial performance at Enzo Clinical Labs and new legal settlements contributes to year-over year revenues and net income gains.
- Total Revenue was \$25.2 million with Clinical Lab Revenue of \$17.1 million up 8% over prior year. Gross margins at the Lab climbed to 40%, an increase of 400 basis points. Consolidated margins were 45% compared to 44% in the prior year period.
- Enzo Life Sciences product-only results were profitable despite continuing weak European R&D market and currency translation expenses, plus costs associated with preparatory marketing expenses related to Ampiprobe™ rollout.
- GAAP net income was \$4.4 million, or \$0.10 per share. On an adjusted basis, Non-GAAP net loss per share was (\$0.05), compared to (\$0.08). EBITDA was \$5.5 million and on an adjusted basis Non-GAAP EBITDA improved by \$1.4 million.
- Cash and cash equivalents was over \$30.6 million, an increase of \$12.5 million, or 69%, from fiscal 2015 year-end, underscoring mounting benefits from continuing to monetize the Company's intellectual property portfolio.
- Ampiprobe-HCV™ assay approval shortly after quarter's end is first in a series of tests under development to capitalize on high productivity, low-cost benefits for clinical testing market from Enzo's proprietary Ampiprobe™ technology

**Comments by Barry Weiner, President:**

"Fiscal 2016 has gotten off to an excellent start, with solid performance in our operating divisions. We are especially pleased with the New York State Department of Health's approval last month of our Ampiprobe-HCV™ assay. Ampiprobe-HCV™ is the forerunner of a battery of new products under development in the molecular diagnostics space, which we are looking to roll out over the course of the next two calendar years. In addition, our intellectual property portfolio continues to provide us with increasing financial strength and flexibility that will help drive our progress and growth."

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“The integration and coordination of our products and services segments is having the strategic results we have expected. The steadily improving gross margins we are seeing in our services business is a direct result of our focus on higher value testing, and we have been able to internally develop all of the capabilities, from discovery through platform development to manufacturing of finished products to validation and distribution of both products and services, in an efficient manner. We have deliberately constructed our product pipeline to be able to take advantage of the numerous proprietary platforms we have developed over the years in order to maximize the return on our research investment, and we are seeing the benefit of this approach reflected in our results.

“We remain confident that we will continue to execute on our mission to produce products and services that are economical, provide medically relevant information at specifications at or above the market leaders, and are easily adaptable into our customers’ workflow. It is with this plan that we believe we can address the challenges facing the molecular diagnostics industry today—namely an increased demand for tests that is coupled with high costs of goods and declining reimbursement from payors. The value inherent in Enzo emanates from internally developed content, ranging from innovation to product, as well as our vertically integrated structure, all of which should allow us to provide products and services at significant savings to the market.”

#### **First Quarter Results**

Revenues advanced to \$25.2 million, from \$24.8 million in the corresponding year-ago period, paced by an 8% year over year increase in clinical laboratory services. Selling, general and administrative expenses remained steady both on a dollar basis and, at 41%, as a percentage of revenues, as the Company continues to closely monitor costs. Reflecting increased services revenues, the allowance for uncollectible receivables increased slightly, to \$0.7 million, from \$0.5 million, or as a percentage of revenues 4% and 3%, in the current and year ago respective quarters. Legal expenses declined to \$1.6 million, from \$2.5 million, a year ago, or to 6% of revenues, versus 10% last year.

Net income for the quarter equaled \$4.4 million, or \$0.10 per share fully diluted, compared to a loss of (\$3.7) million, or (\$0.08) per share, a year ago. Adjusted Non-GAAP earnings (loss) per share was (\$0.05) compared to (\$0.08) per share last year. EBITDA (earnings before interest, taxes, depreciation and amortization), a non GAAP number, equaled \$5.5 million, compared to the year ago EBITDA loss of (\$2.6) million, representing an \$8.1 million turnaround.

Finances strengthened materially, with cash and cash equivalents of \$30.6 million and working capital at \$27 million.

#### **First Quarter Segment Results**

**Enzo Clinical Labs** revenues were \$17.1 million, an increase of \$1.3 million or 8%, over prior year, due to the continued focus on its menu of high margin molecular-based assays. Utilizing a greater number of in-house developed assays, along with other efficiencies, gross margins improved to 40% from 36% a year ago. Operating expenses overall declined by \$0.3 million, to \$6.0 million, and operating profit advanced to \$0.8 million, from just above break-even last year.

**Enzo Life Sciences** product revenues were \$7.7 million versus \$8.0 million last year, a decline of \$0.3 million, or 4%. Virtually the entire decline was due to foreign currency headwinds; on a constant currency basis, product sales were even. Product gross margins eased slightly, to \$4.1 million, or 53% of revenues, from 54% last year, again due to foreign currency impacts. SG&A totaled approximately \$3.1 million, equal to approximately 40% of product revenues in both periods. Operating income for Life Sciences was \$7.6 million, which included legal settlements.

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## **Overview**

Enzo's corporate strategy has come increasingly to the fore, based on the Company being an integrated diagnostics entity, one uniquely structured to capitalize upon ongoing reimbursement pressures being experienced in the molecular diagnostics market. The recent approval of the Ampiprobe-HCV assay™ represents just the first of a number of molecular tests that Enzo plans to introduce based on that nucleic acid amplification and detection platform. Currently in the Ampiprobe™ development pipeline are products for the identification of women's health infectious diseases as well as additional assays for quantification of viral loads for other diseases.

Through Enzo's research and production capabilities, and state-of-the-art clinical laboratory, the Company is commercializing high-value diagnostic assays designed to deliver cost-effective, high-performance, easily adaptable products and services that will help assure the economic vitality of clinical labs on a global basis, while positioning Enzo as a key source of products and services .

## **Conference Call**

The Company will conduct a conference call Tuesday , December 8, 2015 at 8:30 AM ET. The call can be accessed by dialing 1-888-459-5609. International callers can dial 1-973-321-1024. Please reference PIN number 93174150. Interested parties may also listen over the Internet: <http://event.on24.com/r.htm?e=1102529&s=1&k=C908C968956D1FF7DE7BF6C5809D4F05>. To listen to the live call on the Internet, please go to the web site at least fifteen minutes early to register, download and install any necessary audio software. For those who cannot listen to the live broadcast, a replay will be available approximately two hours after the end of the live call, through midnight (ET) on Tuesday, December 22, 2015. The replay of the conference call can be accessed by dialing 1-800-585-8367, and when prompted, use PIN number 93174150. International callers can dial 1-404-537-3406, using the same PIN number.

## **NON-GAAP Financial Measures**

To comply with Regulation G promulgated pursuant to the Sarbanes-Oxley Act, Enzo Biochem attached to this news release and will post to the Company's investor relations web site ([www.enzo.com](http://www.enzo.com)) any reconciliation of differences between non-GAAP financial information that may be required in connection with issuing the Company's quarterly financial results.

The Company uses EBITDA, as a measure of performance to demonstrate earnings exclusive of interest, taxes, depreciation and amortization. Adjustments to EBITDA are for items of a non-recurring nature and are reconciled on the table provided. The Company manages its business based on its operating cash flows. The Company, in its daily management of its business affairs and analysis of its monthly, quarterly and annual performance, makes its decisions based on cash flows, not on the amortization of assets obtained through historical activities. The Company, in managing its current and future affairs, cannot affect the amortization of the intangible assets to any material degree, and therefore uses EBITDA as its primary management guide. Since an outside investor may base its evaluation of the Company's performance based on the Company's net income (loss) not its cash flows, there is a limitation to the EBITDA measurement. EBITDA is not, and should not be considered, an alternative to net income (loss), income (loss) from operations, or any other measure for determining operating performance or liquidity, as determined under accounting principles generally accepted in the United States (GAAP). The most directly comparable GAAP reference in the Company's case is the removal of interest, taxes, depreciation and amortization.

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We refer you to the tables attached to this press release which includes reconciliation tables of GAAP to Non-GAAP net income (loss) and EBITDA to Adjusted EBITDA.

#### **About Enzo Biochem**

Enzo Biochem is a pioneer in molecular diagnostics, leading the convergence of clinical laboratories, life sciences and therapeutics through the development of unique diagnostic platform technologies that provide numerous advantages over previous standards. A global company, Enzo Biochem utilizes cross-functional teams to develop and deploy products systems and services that meet the ever-changing and rapidly growing needs of health care both today and into the future. Underpinning Enzo Biochem's products and technologies is a broad and deep intellectual property portfolio, with patent coverage across a number of key enabling technologies.

*Except for historical information, the matters discussed in this news release may be considered "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include declarations regarding the intent, belief or current expectations of the Company and its management, including those related to cash flow, gross margins, revenues, and expenses are dependent on a number of factors outside of the control of the company including, inter alia, the markets for the Company's products and services, costs of goods and services, other expenses, government regulations, litigations, and general business conditions. See Risk Factors in the Company's Form 10-K for the fiscal year ended July 31, 2015. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this press release.*

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#### **Contact:**

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**ENZO BIOCHEM, INC.**  
(in thousands, except per share data)

**Three months ended  
October 31,  
(unaudited)**

***Selected operations data:***

	<u>2015</u>	<u>2014</u>
Revenues:		
Clinical laboratory services	\$ 17,090	\$ 15,822
Product revenues	7,687	8,002
Royalty and license fee income	400	1,000
Total revenues	<u>\$ 25,177</u>	<u>\$ 24,824</u>
Gross profit	<u>\$ 11,234</u>	<u>\$ 10,999</u>
Gross profit %	<u>45%</u>	<u>44%</u>
Income (loss) before income taxes	4,521	(3,606)
Provision for income taxes	(87)	(123)
Net income (loss)	<u>\$ 4,434</u>	<u>\$ (3,729)</u>
Basic net income (loss) per share	<u>\$ 0.10</u>	<u>(\$ 0.08)</u>
Diluted net income (loss) per share	<u>\$ 0.10</u>	<u>\$ 0.08</u>
Weighted average shares outstanding - basic	<u>46,068</u>	<u>44,564</u>
Weighted average shares outstanding - diluted	<u>46,193</u>	<u>44,564</u>

***Selected balance sheet data:***

	<u>10/31/2015 (unaudited)</u>	<u>July 31, 2015</u>
Cash and cash equivalents	\$ 30,642	\$ 18,109
Working capital	\$ 26,978	\$ 22,528
Stockholders' equity	\$ 47,213	\$ 42,606
Total assets	\$ 74,396	\$ 68,394



The following table presents a reconciliation of reported net income (loss) and basic and diluted earnings per share to non-GAAP net income (loss) and basic and diluted earnings per share for the three months ended October 31, 2015 and 2014, respectively.

**ENZO BIOCHEM, INC.**  
 Non-GAAP, Reconciliation Table  
 (Unaudited, in thousands, except per share data)

	Three months ended October 31,	
	2015	2014
Reported GAAP net income (loss)	\$ 4,434	\$ (3,729)
Adjusted for:		
Legal settlements, net	(6,800)	—
Legal fees associated with settlements	—	—
Separation payments and accelerated stock compensation	81	—
Exit costs associated with contract terminations	—	—
Non-GAAP net income (loss)	\$ (2,285)	\$ (3,729)
 <i>Weighted Shares Outstanding</i>		
Basic	46,068	44,564
Diluted	46,193	44,564
 <i>Basic and diluted earnings per share</i>		
Basic and diluted earnings per share GAAP	\$0.10	(\$0.08)
Basic and diluted earnings per share non-GAAP	(\$0.05)	(\$0.08)

The following table presents a reconciliation of reported net income (loss) for the three months ended October 31, 2015 and 2014, respectively to EBITDA and Adjusted EBITDA:

**ENZO BIOCHEM, INC.**  
Adjusted EBITDA, Reconciliation Table  
(Unaudited, in thousands, except per share data)

	Three months ended October 31,	
	2015	2014
GAAP net income (loss)	\$ 4,434	\$ (3,729)
Plus:		
Depreciation and amortization	950	938
Interest expense	40	69
Provision for income taxes	87	123
EBITDA	\$ 5,511	\$ (2,599)
Adjusted for:		
Legal settlements, net	(6,800)	—
Legal fees associated with settlements	—	—
Separation payments and accelerated stock compensation	81	—
Exit costs associated with contract terminations	—	—
Adjusted EBITDA	\$ (1,208)	\$ (2,599)