

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): **October 13, 2016**

**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 October 13, 2016, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its fourth fiscal quarter and year ended July 31, 2016. 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 October 13, 2016.

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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: October 13, 2016

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

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**news  
release**

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

FOR IMMEDIATE RELEASE

**ENZO BIOCHEM REPORTS STRONG 2016 OPERATING RESULTS**

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NEW YORK, NY, October 13, 2016 – Enzo Biochem Inc. (NYSE:ENZ) today reported strong results for the fourth quarter and fiscal year ended July 31, 2016, paced by revenue growth, margin expansion and litigation successes.

**Highlights**

- Fourth quarter fiscal 2016 revenue was \$26.6 million and full year fiscal 2016 revenue was \$102.8 million; increases of 4% and 5%, over the respective prior year periods. Enzo Clinical Labs revenue grew 5% in the fourth quarter of 2016 and generated double digit year over year revenue growth of 12%.
  - Clinical Labs and Life Sciences operating segments continue to be profitable and generate positive cash flow from operations.
  - Gross profit margins increased both quarterly and full year in both Life Sciences and Clinical Labs. In the fourth quarter of fiscal 2016, consolidated gross margin was 45% compared to 44% in the prior year period.
  - Net income for the fourth fiscal quarter was \$36.1 million or \$0.77 on a diluted share basis compared to \$8.4 million or \$0.18 on a diluted share basis in the prior year period. Full year net income was \$45.3 million or \$0.97 on a diluted basis compared to a loss of \$2.3 million or \$0.05 on a diluted share basis in the prior year.
  - New product approvals, along with a strong product development pipeline, underscore Enzo's growth opportunities as a supplier of advanced lower cost molecular diagnostics for reimbursement constrained independent clinical labs.
  - Enzo Clinical Labs is growing market share in the women's health market and expanding beyond the current regional New York area. During the year, three assays were approved by New York State.
  - At July 31, 2016, cash and cash equivalents were \$67.8 million; working capital was \$70.8 million. Cash flow provided by operations in the fourth quarter and year ended July 31, 2016 was \$36.1 million and \$53.1 million, respectively, driven by legal settlements and licenses and operating performance of business segments.
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**Comments by Barry Weiner, Enzo President:**

"Fiscal 2016 was a highly successful year for Enzo Biochem. We solidified our growth opportunities on every front, setting a strong foundation for the future. Life Sciences' product development emphasis on high profit margin products is paying off with several key approvals awarded in 2016. Enzo Labs came off a strong year with solid forward momentum from its expanding line of innovative molecular diagnostics, especially in the women's health category, and a growing client roster. The unique combination of our Life Sciences development and marketing team with our Clinical Labs' hands-on testing capabilities, and our deep patent estate, has resulted in a formidable development program, to prepare our broad pipeline of products for regulatory approval.

"This past year, New York State's Health Department conditionally approved three new, highly efficient assays. We also have reported to the scientific community new analysis pointing to the effectiveness of our AmpProbe® platform technology. Included among the approved tests was our Candidiasis™ assay based on AmpProbe® and, last month, that of the stand-alone PLAQPRO™ Lp-PLA<sub>2</sub> activity assay for identifying arterial inflammation, a possible potential indicator of coronary risk. Notably, both received approval for laboratory use just months after submission, and both are testaments to our growing expertise and recognition as a leading diagnostics supplier-producer in the women's health field.

"On the operating side, we have also made significant progress. Costs are well under control, profit margins are enjoying an upward trend, and operating income at both Clinical Labs and Life Sciences remains positive. By bringing to resolution several court cases, legal expenses have trended lower, though this might change as possible trials could take place in calendar 2017. Meanwhile, with total patent infringement settlements and licenses in the past twenty-four months of over \$100 million, our financial condition is robust and highly liquid. This is enabling us to pursue our growth strategies in the diagnostics market where, with Enzo's highly efficient, economic and effective products, we are increasingly making our mark."

**Fourth Quarter Results**

Total revenues increased to \$26.6 million, a \$0.9 million or 4% improvement over a year ago. Gross profit was up 7%, to \$12.1 million, equal to gross margin of 45%, compared to 44% a year ago. Research and development expenses held steady, as a percentage of revenues declined 100 basis points to 3%, while selling, general and administrative ("SG&A") costs likewise improved 100 basis points, to 42%, all of which underscores the Company's effective management controls. The provision for uncollectible expenses remained flat at 3% of revenues, as a result of the Company's effective credit procedures. Legal fees for the quarter declined by more than half, to \$0.7 million, from \$1.6 million a year ago.

Including \$38.8 million legal settlements and licensing agreements, and a \$0.4 million foreign currency loss, net income amounted to \$36.1 million, or \$0.77 per fully diluted share. In the year ago quarter, with net legal settlements at \$11.3 million, net income totaled \$8.4 million, or \$0.18 per fully diluted share. Adjusted for the 2016 legal settlements and licensing agreements, the non-GAAP quarterly net loss amounted to \$1.9 million or \$0.04 on a fully diluted share basis, compared to a year ago non-GAAP net loss of \$2.6 million, a 27% improvement. Non-GAAP adjusted EBITDA (earnings before interest, taxes, depreciation and amortization) was a negative \$0.7 million, compared to a year ago negative \$1.5 million, a 53% improvement.

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## **Fiscal 2016 Results**

With Clinical Labs revenues increasing by double digits, consolidated revenues rose to \$102.8 million, up 5% from fiscal 2015's \$97.6 million. Gross profit for the year increased 6%, to \$45.6 million, equaling gross margin of 44% in both years. R&D expenses were up modestly by 5% year over year, but flat at 3% as a percentage of revenues; SG&A increased 6%, but again held firm at 42% of revenues for both years; and legal expenses declined \$2.4 million, or 27%, to \$6.4 million.

Net income amounted to \$45.3 million, or \$0.97 per fully diluted share, including \$57.3 million in net legal settlements and license agreement for the year. This compared to a year ago net loss of \$2.3 million, or (\$0.05) per share fully diluted, with net legal settlements and license agreements at \$11.5 million in the prior year period. On a non-GAAP basis, adjusted for legal settlements and license agreements, extraordinary proxy and other expenses and related tax effects, the net loss was \$9.2 million, or (\$0.20) per share fully diluted, vs. a year earlier loss on a similar adjusted basis of \$13.5 million, or (\$0.30) per fully diluted share, a \$4.3 million improvement. Non-GAAP adjusted EBITDA was a negative \$5.0 million and \$9.4 million, respectively, for the past two years, a \$4.4 million improvement. Excluding direct legal litigation costs, adjusted EBITDA would be positive in the full year 2016 results.

As of July 31, 2016, cash and cash equivalents amounted to \$67.8 million and total assets of were approximately \$112.0 million.

## **Segment Results**

**Enzo Clinical Labs** continued its strong growth, the result of the increased role of molecular diagnostics in its services mix, particularly those targeted to women's health, as well as adding new clients and effective management of the Labs' cost base. Fourth quarter revenues grew 5%, to \$18.1 million. Gross profit improved 7%, to \$12.1 million, and the gross margin percentage increased to 40%, from 39%. Operating income amounted to \$0.8 million, compared to \$0.5 million, up 60%.

Full year Lab revenues grew 12%, to \$70.9 million. Gross profit consequently increased 18%, to \$28.1 million, with the gross margin up 200 bps, to 40%, from 38%. The provision for uncollected receivables improved to 3.3%, from 3.8%, the result of improved collection procedures. Operating income more than doubled, to \$1.2 million, from \$0.5 million.

**Enzo Life Sciences** benefited from both higher margin product revenue and tight cost controls, although continuing to be challenged by a highly competitive environment and continued lower research funding, especially in academia. Product revenues were \$8.1 million for the fourth quarters of both fiscal 2016 and 2015, with cost of revenues declining 6% in 2016, to \$3.7 million. Gross profit on product revenues increased 5%, to \$4.4 million, from \$4.2 million, and gross margin advanced to 55%, from 52%. Excluding legal settlements, net, operating income improved to \$1.0 million, compared to \$0.6 million a year ago, up 66%.

Full year product revenues in 2016 amounted to \$30.3 million, compared to \$31.7 million in 2015. Products gross margin percentage increased by 200 basis points to 53% from 52%. Operating income amounted to \$3.1 million, excluding \$58.8 million from patent litigation settlements, compared to \$4.4 million, excluding \$11.5 million in settlements a year ago. Royalty and fee income declined to \$1.5 million from \$2.5 million a year earlier.

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## **Product Development**

In line with Enzo's objective to develop, manufacture and sell high- throughput, high value reliable and affordable molecular diagnostic products and services that use our proprietary technologies to allow customers to meet their clinical needs, and to offer independent labs a counterweight to reduced reimbursement, Enzo has underway an aggressive product development program. This past year, the Company obtained conditional approval for several tests and assays from the New York State Department of Health, allowing the Company to provide these tests across the majority of the United States.

These approvals included our Ampiprobe<sup>®</sup> technology platform that encompasses high sensitivity, real time nucleic acid amplification assays that is expected to provide low cost molecular diagnostics to benefit independent laboratories. At the same time, the Ampiprobe<sup>®</sup> HCV Assay was approved for the quantitative detection of hepatitis C virus, which is expected to be the first in a line of expanded applications using the Ampiprobe<sup>®</sup> platform. Last year, Enzo scientists presented data at the prestigious American Society for Clinical Pathology annual meeting showing new thresholds of sensitivity for the Company's Ampiprobe<sup>®</sup> - based HCV Assay. This demonstrated that the limit of detection was greater in sensitivity than leading commercially available HCV viral load assays.

Also approved was the Candidiasis<sup>™</sup> Assay, the Company's second test aimed at the rapidly expanding women's health market, and Enzo Clinical Labs' PLAQPRO<sup>™</sup> Lp-PLA<sub>2</sub> Assay, for evaluating lipoprotein-associated phospholipase A2 activity, a marker associated with the potential for coronary heart disease. Currently under development are tests for Hepatitis B virus, HIV viral diseases, and cancers, as well as a full spectrum of tests designed to identify a number of infectious diseases related to women's health, one of the fastest growing segments of the molecular diagnostic market.

## **Conference Call**

The Company will conduct a conference call Friday, October 14, 2016 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 85947927. Interested parties may also listen over the Internet at <http://tinyurl.com/hlgvp9k>. 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 Friday, October 28, 2016. The replay of the conference call can be accessed by dialing 1-800-585-8367, and when prompted, use PIN number 85947927. 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

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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 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 loss, loss from operations, or any other measure for determining operating performance of 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.

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 intellectual property 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 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, 2016. 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.

*Contact:*

For: Enzo Biochem, Inc.  
Steve Anreder, 212-532-3232  
[steven.anreder@anreder.com](mailto:steven.anreder@anreder.com)

or

Michael Wachs, CEOcast, Inc., 212-732-4300  
[mwachs@ceocast.com](mailto:mwachs@ceocast.com)

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

<b><u>Selected operations data:</u></b>	<b>Three months ended July 31 (unaudited)</b>		<b>Fiscal year ended July 31 (unaudited)</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Revenues:				
Clinical laboratory services	\$ 18,140	\$ 17,210	\$ 70,915	\$ 63,414
Product revenues	8,071	8,059	30,337	31,690
Royalty and license fee income	392	428	1,521	2,495
<b>Total revenues</b>	<b>\$ 26,603</b>	<b>\$ 25,697</b>	<b>\$ 102,773</b>	<b>\$ 97,599</b>
Gross profit	\$ 12,085	\$ 11,317	\$ 45,583	\$ 42,827
Gross profit %	45%	44%	44%	44%
Income (loss) before income taxes (1)	37,068	8,523	46,515	(2,292)
(Provision) benefit for income taxes	(933)	(81)	(1,229)	7
Net income (loss)	\$ 36,135	\$ 8,442	\$ 45,286	\$ (2,285)
Basic net income (loss) per share	\$ 0.78	\$ 0.18	\$ 0.98	(\$ 0.05)
Diluted net income (loss) per share	\$ 0.77	\$ 0.18	\$ 0.97	(\$ 0.05)
Weighted average shares outstanding - basic	46,267	46,061	46,153	45,355
Weighted average shares outstanding - diluted	46,717	46,091	46,602	45,355

(1) - includes legal settlements of \$38.8 million, \$11.3 million, \$57.3 million and \$11.5 million for the three months ended July 31, 2016 and 2015 and for the fiscal year ended July 31, 2016 and 2015, respectively.

<b><u>Selected balance sheet data:</u></b>	<b>July 31, 2016</b>	<b>July 31, 2015</b>
Cash and cash equivalents	\$ 67,777	\$ 18,109
Working capital	\$ 70,829	\$ 22,528
Stockholders' equity	\$ 89,554	\$ 42,606
Total assets	\$ 111,821	\$ 68,394

The following table presents a reconciliation of reported net income (loss) and basic and diluted net income (loss) per share to non-GAAP net income (loss) and basic and diluted net income (loss) per share for the three months and fiscal year ended July 31, 2016 and 2015, respectively:

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

	Three months ended		Fiscal year ended	
	July 31		July 31	
	2016	2015	2016	2015
Reported GAAP net income (loss)	\$ 36,135	\$ 8,442	\$ 45,286	\$ (2,285)
Adjusted for:				
Legal settlements, net	(38,800)	(11,288)	(57,250)	(11,458)
Legal fees associated with settlements	—	217	—	217
Costs related to contested proxy	—	16	1,483	76
Separation payments	—	—	207	—
Tax effect on adjusted items	721	—	1,064	—
Non-GAAP net loss	<u>\$ (1,944)</u>	<u>\$ (2,613)</u>	<u>\$ (9,210)</u>	<u>\$ (13,450)</u>

*Weighted Shares Outstanding*

Basic	46,267	46,061	46,153	45,355
Diluted	46,717	46,091	46,602	45,355

*Basic and diluted earnings per share*

Basic net income (loss) per share GAAP	\$ 0.78	\$ 0.18	\$ 0.98	(\$ 0.05)
Diluted net income (loss) per share GAAP	\$ 0.77	\$ 0.18	\$ 0.97	(\$ 0.05)

Basic net income (loss) per share non-GAAP	(\$ 0.04)	(\$ 0.06)	(\$ 0.20)	(\$ 0.30)
Diluted net income (loss) per share non-GAAP	(\$ 0.04)	(\$ 0.06)	(\$ 0.20)	(\$ 0.30)

The following table presents a reconciliation of reported net income (loss) for the three months and fiscal year ended July 31, 2016 and 2015, respectively to EBITDA and Adjusted EBITDA:

**ENZO BIOCHEM, INC.**  
EBITDA & Adjusted EBITDA, Reconciliation Table  
(Unaudited, in thousands)

	Three months ended		Fiscal year ended	
	July 31		July 31	
	2016	2015	2016	2015
GAAP net income (loss)	\$ 36,135	\$ 8,442	\$ 45,286	\$ (2,285)
Plus:				
Depreciation and amortization	978	992	3,840	3,789
Interest expense	14	69	136	245
Provision (benefit) for income taxes	933	81	1,229	(7)
EBITDA	<u>\$ 38,060</u>	<u>\$ 9,584</u>	<u>\$ 50,491</u>	<u>\$ 1,742</u>
Adjusted for:				
Legal settlements, net	(38,800)	(11,288)	(57,250)	(11,458)
Legal fees associated with settlements	—	217	—	217
Costs related to contested proxy	—	16	1,483	76
Separation payments	—	—	207	—
Adjusted EBITDA	<u>\$ (740)</u>	<u>\$ (1,471)</u>	<u>\$ (5,069)</u>	<u>\$ (9,423)</u>