

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 8, 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 December 8, 2016, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its first fiscal quarter ended October 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 December 8, 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: December 8, 2016

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 IMPROVED FIRST QUARTER RESULTS**

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**Clinical Labs Continues Strong Performance with 9% Revenue and Gross Margins Gains on**

**Increasing Demand for Molecular Diagnostics Services and Tests**

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NEW YORK, NY, December 8, 2016 – Enzo Biochem, Inc. (NYSE: ENZ) today reported strong operating results for the first fiscal quarter ended October 31, 2016, with significant operating profit achieved at Enzo Clinical Labs.

**Quarterly Highlights**

- Consolidated revenues grew 4% and Clinical Labs revenue grew 9% over the prior year period as a result of demand for high margin molecular diagnostic services.
- Gross margin at Clinical Labs increased 100 basis points to 41% and consolidated gross margins increased to 46%.
- Non-GAAP net loss and Non-GAAP EBITDA registered steady quarterly progress, improving 35% and 53%, respectively, year-over-year. Both Clinical Labs and Life Science units remained profitable, in addition to generating positive cash flow.
- Balance sheet remains strong with cash and cash equivalents and working capital exceeding \$67 million and \$69 million, respectively. Remaining bank debt was eliminated following quarter's end.
- Also post-quarter, federal court in Delaware set firm trial target dates for next year on three patent infringement cases.

**Barry Weiner, President, Comments**

"The year has gotten off to a good start, and we expect to see the year progress nicely as we continue to complete development and file for approval of additional proprietary low cost, high performance molecular diagnostic products designed to capitalize on reimbursement pressures facing diagnostic labs. Our strategic focus is paying off, notably at the Clinical Labs, where our molecular diagnostics services are increasing and our extensive and growing women's health diagnostic services is experiencing increased usage. As we add to our product line-up in this field, we are providing cost savings that can ensue from our growing line of high performing competitive cost products. We are increasing marketing efforts to we expand into the national market."

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"Meanwhile, we are operating at a highly efficient level, as underscored by steady improvement in gross margins as the Company moves to sustained profitability. We are holding expenses flat overall, while increasing our sales and marketing and development efforts. Life Sciences continues to see delayed orders and currency fluctuations that impact quarterly product revenues, however, it remains focused on developing medically relevant products that are of the highest quality and easily adaptable to market needs. For example, we recently introduced our PolyView Plus line of pathology-based detection systems which has been shown in a peer-reviewed publication to provide improved results to the marketplace. Furthermore, our product pipeline continues to be robust. We will shortly introduce extensions to our human papillomavirus (HPV) product line, providing our customers additional optionality. We also continue to progress on development of a comprehensive suite of women's health infectious disease tests based on our AmpProbe platforms, as well as a biomarker assay for the rapidly growing infertility market. The common thread connecting all of these products is that they are easily adaptable to open laboratory systems, providing our customers with the flexibility to offer such tests while reducing their cost of goods."

"On the legal front, the recent announcement by the federal court in Delaware setting trial dates should help progress the remaining patent infringement cases."

"We are highly encouraged and confident regarding the outlook for our business, and our exceptionally strong and debt free financial position assures us of the ability to move forward toward operational profitability and further growth."

### **October 2016 First Fiscal Quarter Results**

Consolidated revenues increased 4%, to \$26.3 million from \$25.2 million. Gross profit increased to \$12.1 million, or 8%, and gross margin advanced 100 basis points, to 46%. Selling, general and administrative (SG&A) expenses were \$11.5 million, an increase of \$1.2 million, or 12%, due largely to commissions, bonuses and salaries, along with increased administrative expenses related to the greater molecular diagnostics volume. The provision for uncollectible receivables, reflecting improved collection efforts, continues to decline, falling 5% for the quarter. Legal expenses were sharply lower at \$0.4 million compared to \$1.6 million, a decline of 77% from a year ago.

The Company reported an operating loss of \$1.3 million compared to a year ago operating income of \$4.6 million. The prior year period included a licensing and legal settlement of \$6.8 million. Net loss amounted to \$1.5 million or \$0.03 per diluted share, compared to a year ago net income of \$4.4 million or \$0.10 per diluted share. Adjusted for licensing and legal settlements, the non-GAAP net loss was \$1.5 million or \$0.03 per diluted share compared to a loss of \$2.3 million or \$0.05 per diluted share in the prior year, an improvement of \$0.8 million, or 35%. EBITDA (earnings before interest, taxes, depreciation and amortization) amounted to a loss of \$0.6 million, compared with a positive \$5.5 million a year ago (which included the licensing and legal settlement of \$6.8 million, as noted above). Non-GAAP EBITDA was a loss of \$0.6 million compared to a loss of \$1.2 million, an improvement of 53% year over year.

On October 31, 2016, cash and cash equivalents totaled \$67.2 million, and working capital was \$69.7 million. Consolidated cash flows used in operation was only \$334,000 in the current year quarter. With the retirement in December 2016 of our outstanding bank loan, the Company, apart from lease obligations, currently has no outstanding debt.

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## **Segment Analysis**

**Enzo Clinical Labs** continued to benefit from growing demand and new accounts for molecular diagnostics, especially in the women's health marketplace. Service revenues were \$18.6 million, an increase of \$1.5 million, or 9%, from the year ago period. Gross profit improved 13%, to \$7.7 million, and gross margin increased to 41%, from 40%, helped by an increasing menu of approved, laboratory-developed tests (LDTs) tests. Despite higher SG&A related to sales growth, operating income increased to approximately \$1 million, compared to \$0.8 million a year ago, a 31% increase.

**Enzo Life Sciences** reported revenue of \$7.7 million compared to \$8.1 million from the year ago period. The segment continues to rationalize its product offerings to higher valued items, while focusing on product development and sales and marketing efforts. Gross profit remained flat, at \$4.1 million, and gross margin advanced 200 basis points, to 57%. SG&A declined to \$2.9 million, or 4%. Operating income amounted to \$0.8 million. The year ago period operating income totaled \$7.6 million, including the aforementioned \$6.8 million legal settlement, net.

## **Legal Developments**

The federal court in Delaware in late November issued orders regarding certain pending patent infringement cases brought by Enzo against various defendants. For the cases involving Gen-Probe/Hologic, Becton Dickinson, and Roche, the court has set summary judgment briefing deadlines, a summary judgment argument hearing, and trial dates in October, November and December 2017. "We are encouraged to have our day in court regarding our claims of infringement, and look forward to presenting our cases, a similar number of which have already been resolved by settlements," said Mr. Weiner.

## **Conference Call**

The Company will conduct a conference call Friday, December 9, 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 30122052. Interested parties may also listen over the Internet at <http://tinyurl.com/h5vvp4>. 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, December 23, 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

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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 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 which 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, litigation, 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.

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

<b><i>Selected operations data:</i></b>	<b>Three months ended October 31 (unaudited)</b>	
	<b>2016</b>	<b>2015</b>
Revenues:		
Clinical laboratory services	\$ 18,558	\$ 17,090
Product revenues	7,426	7,687
Royalty and license fee income	300	400
<b>Total revenues</b>	<b>\$ 26,284</b>	<b>\$ 25,177</b>
<b>Gross profit</b>	<b>\$ 12,079</b>	<b>\$ 11,234</b>
<b>Gross profit %</b>	<b>46%</b>	<b>45%</b>
Income (loss) before income taxes (1)	(1,454)	4,521
Provision for income taxes	(20)	(87)
<b>Net income (loss)</b>	<b>\$ (1,474)</b>	<b>\$ 4,434</b>
Basic net income (loss) per share	(\$ 0.03)	\$ 0.10
Diluted net income (loss) per share	(\$ 0.03)	\$ 0.10
Weighted average shares outstanding - basic	46,272	46,068
Weighted average shares outstanding - diluted	46,272	46,193

(1) - includes legal settlements of \$6.8 million for the three months ended October 31, 2015

<b><i>Selected balance sheet data:</i></b>	<b>10/31/2016 (unaudited)</b>	<b>7/31/2016 (unaudited)</b>
Cash and cash equivalents	\$ 67,214	\$ 67,777
Working capital	\$ 69,661	\$ 70,829
Stockholders' equity	\$ 88,491	\$ 89,554
<b>Total assets</b>	<b>\$ 110,471</b>	<b>\$ 111,821</b>



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 ended October 31, 2016 and 2015, respectively:

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

	Three months ended October 31	
	2016	2015
Reported GAAP net income (loss)	\$ (1,474)	\$ 4,434
Adjusted for:		
Legal settlements, net	—	(6,800)
Legal fees associated with settlements	—	—
Separation payments	—	81
Tax effect on adjusted items	—	—
Non-GAAP net loss	<u>\$ (1,474)</u>	<u>\$ (2,285)</u>
<i>Weighted Shares Outstanding</i>		
Basic	46,272	46,068
Diluted	46,272	46,193
<i>Basic and diluted earnings per share</i>		
Basic net income (loss) per share GAAP	(\$ 0.03)	\$ 0.10
Diluted net income (loss) per share GAAP	(\$ 0.03)	\$ 0.10
Basic net income (loss) per share non-GAAP	(\$ 0.03)	(\$ 0.05)
Diluted net income (loss) per share non-GAAP	(\$ 0.03)	(\$ 0.05)

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

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

	Three months ended October 31	
	2016	2015
GAAP net income (loss)	\$ (1,474)	\$ 4,434
Plus:		
Depreciation and amortization	927	950
Interest expense	(46)	40
Provision for income taxes	20	87
EBITDA	<u>\$ (573)</u>	<u>\$ 5,511</u>
Adjusted for:		
Legal settlements, net	—	(6,800)
Legal fees associated with settlements	—	—
Separation payments	—	81
Adjusted EBITDA	<u>\$ (573)</u>	<u>\$ (1,208)</u>

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