

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): **March 9, 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 March 9, 2016, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its second fiscal quarter ended January 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 March 9, 2016.

SIGNATURES

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: March 9, 2016

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



news
release

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

FOR IMMEDIATE RELEASE

ENZO BIOCHEM REPORTS INCREASED FISCAL SECOND QUARTER RESULTS

Molecular Diagnostics Spurs Double-Digit Clinical Lab Revenue Gains, Contributes to Consolidated Net Income of \$6.8 Million

NEW YORK, NY, March 9, 2016 – Enzo Biochem, Inc. (NYSE:ENZ) today reported results for the second fiscal quarter and fiscal first half ended January 31, 2016, led by strong gains at Enzo Clinical Labs reflecting increased molecular diagnostic testing demand.

Among the quarter's highlights:

- Revenues of \$24.6 million grew 6% year over year, including a 19% increase at Enzo Clinical Labs
- Net income of \$6.8 million, or \$0.15 per fully diluted share, compared to a net loss of (\$4.1) million or \$(0.09) in the year-earlier period,
- Gross margins improved to 44%, a 100 basis point improvement year over year.
- Both the Clinical Labs and Life Sciences continue profitability trends and are cash flow positive as reported in previous quarters. Operating expenses are being well controlled.
- Strong balance sheet as cash and cash equivalents increased nearly \$19 million for the fiscal year to over \$37 million.
- Enzo Life Sciences began to shift its efforts toward manufacturing and global marketing of Company's proprietary molecular products.
- Development of new Ampiprobe™-related assays on target for regulatory review.

Comment from Barry Weiner, President:

"Enzo generated strong net income and cash flow during the recently completed quarter, particularly at Clinical Labs, where our emphasis on high value molecular diagnostics created strong demand as well as attracted new customers. In addition to those products already approved, we are actively developing, and expect to soon file for approval, major new assays that will further enhance the flexibility and application of our Ampiprobe™ and Flowscript™ technologies. Following recent New York State Health Department approval of our Ampiprobe HCV™, our Ampiprobe™ technology is expected to highly efficient and important cost saving diagnostic tool for labs. With its use, savings could amount to 30% to 50% on certain diagnostic tests, offsetting steadily declining reimbursements and rising product costs that are sharply cutting into profitability at Clinical Labs.

"At Life Sciences, while revenues were lower, increased focus on higher margin products resulted in steady profit margins, at a time when the unit is increasing its marketing program for our proprietary molecular diagnostic products and services by building an expanded, well-trained global sales team. The market for life science products industry-wide has been affected by reduced availability of government funds for academic and other research projects. However, the strategic integration of Life Science's development and marketing capabilities with our Clinical Lab's diagnostic and product testing strength is now increasingly paying off.

The Company expects over the coming year to introduce various analytes in its developing women's health panel, in addition to a fertility assay and a cardiac marker. The Company has completed and submitted a validation package to the New York State Department of Health for its latest AmpProbe™ based assay to identify the presence of the most common species of Candida. The Company continues to process a number of products through its robust pipeline with additional launches for its enhanced immunohistochemistry line scheduled for later this month. Our efforts on the legal front likewise are yielding positive results, as recent settlements generated substantial cash flow which strengthened our balance sheet considerably. To date, of 11 cases originally brought by Enzo in the United States District Court for the District of Delaware alleging patent infringements against various companies, eight remain pending. In addition, a patent infringement case is awaiting a trial date in the Southern District of NY Federal Court.

2Q16 Results

Total revenues advanced 6% year over year, to \$24.6 million, supported by double digit growth at Clinical Labs, more than offsetting lower revenues from Life Science products and royalties. Gross margin advanced 8%, to \$10.8 million, and as a percentage of revenues increased 100 basis points to 44%. Operating income of \$7.5 million compared with a year ago loss of (\$3.9) million, an improvement of \$11.4 million, and increased 61% sequentially.

Included in results were legal settlements, net of \$11.7 million, while legal fee expenses were lower year over year to \$2.4 million, or 14%. One-time expenses, in part associated with the recent dissident-aborted proxy contest, were largely reflected in SG&A which increased to \$11.3 million or 17%, while R&D expenses, which Enzo continues to use highly efficiently, increased to \$0.9 million or 3%. Provision for uncollectable receivables declined to \$0.5 million. Net income was \$6.8 million, or \$0.15 per fully diluted share, compared with a year ago net loss of (\$4.1) million, or (\$0.09) per share. EBITDA (earnings before interest, taxes, depreciation and amortization), a non GAAP measure, amounted to \$8.0 million, compared to an EBITDA loss of (\$3.2) million a year ago. On an adjusted basis, which excludes legal settlements, contested proxy expenses and other non-recurring expenses, Non-GAAP earnings per share was a loss of (\$0.07) compared to a loss of (\$0.09) in the prior year period and Non-GAAP adjusted EBITDA was a loss of (\$2.1) million compared to a loss of (\$3.2) million a year ago.

At January 31, 2016, Cash and cash equivalents amounted to \$37.0 million, more than double the \$18.1 million at the fiscal 2015 year-end.

Segment Results

Enzo Clinical Labs posted strong gains for the quarter, in line with growing molecular diagnostic service activity. The results reflect both an expanding number of MDx tests and an increasing roster of clients attracted by this broadening capability. Revenues amounted to \$17.5 million, a 19% increase from the same period a year ago. Gross margins, as a percentage of revenues, increased to 40%, from 37% a year ago, due both to increased efficiencies and increased MDX testing at higher reimbursement. During the current year quarter, the Clinical Labs recorded a legal settlement charge of \$1.5 million as a result of achieving certain financial thresholds associated with the OIG settlement agreement that was finalized in the prior fiscal year. As a result the Clinical Labs reported an operating loss of (\$0.7) million for the quarter. Excluding the legal settlement charge, the second quarter 2016 operating profit would have amounted to \$0.8 million, compared to a year ago operating loss of (\$0.3) million.

Enzo Life Sciences product revenues amounted to \$6.6 million, a decline of \$1.1 million, or 15%. Royalty and licensing fee income continued to contract, amounting to \$0.4 million, compared with \$0.6 million last year. The product revenue shortfall reflects continued industry-wide weak demand from academia and research laboratories with reduced government funding, along with unfavorable foreign currency adjustments. Still, the segment remained profitable, with positive cash flow. Its continued emphasis on higher margin products enabled Life Sciences to maintain gross profit margins as a percentage of revenues at 54%, comparable to the year-earlier period. Excluding legal settlements, net, of \$13.2 million in the quarter, operating profit amounted to \$0.4 million, compared with \$1.3 million a year ago and an adjusted (for legal settlements, net) operating profit of \$0.8 million in the preceding quarter. Enzo Life Sciences continues to shift its emphasis towards higher value molecular based products and is increasing both manufacturing capacity and marketing capabilities to align itself with this strategy.

First Half 2016 Results

Total revenues rose to \$49.7 million, from \$47.9 million a year ago, with Clinical Laboratories revenues increasing to \$34.6 million, or 13%. Overall cost of goods sold declined 3%, underscoring the Company's increased redirection of sourcing products internally, while gross margin advanced 5%, to \$22.1 million. As a percentage of revenues, gross profit remained steady at 44%. Selling, general and administrative expenses were \$21.5 million, an increase of 8% and the provision for uncollectible accounts receivable rose slightly by 2%, while legal expenses declined 24%, to \$4.0 million. Operating income amounted to \$12.1 million, compared to a year ago operating loss of (\$7.0) million, an improvement of over \$19 million. Included in first half 2016 operating income is legal settlements, net totaling \$18.5 million. Net income amounted to \$11.3 million, or \$0.24 per fully diluted share, compared to a year ago net loss of (\$7.8) million, or (\$0.17) per fully diluted share. EBITDA totaled \$13.5 million, compared to a year ago negative EBITDA of (\$5.8) million.

On an adjusted basis, Non-GAAP earnings per share for the six month period was a loss of (\$0.12) compared to a loss of (\$0.17) in the prior year and Non-GAAP adjusted EBITDA was a loss of (\$3.3) million compared to (\$5.8) million a year ago.

Conference Call

The Company will conduct a conference call Thursday, March 10, 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 59699572. Interested parties may also listen over the Internet

<http://event.on24.com/r.htm?e=1143378&s=1&k=C00C63DAEA69FBCB79719C8154314F9E>. 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 Thursday, March 24, 2016. The replay of the conference call can be accessed by dialing 1-800-585-8367, and when prompted, use PIN number 59699572. 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) 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 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 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.

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

Selected operations data:	Three months ended January 31, (unaudited)		Six months ended January 31, (unaudited)	
	2016	2015	2016	2015
Revenues:				
Clinical laboratory services	\$ 17,523	\$ 14,725	\$ 34,613	\$ 30,547
Product revenues	6,578	7,723	14,265	15,725
Royalty and license fee income	459	644	859	1,644
Total revenues	\$ 24,560	\$ 23,092	\$ 49,737	\$ 47,916
Gross profit	\$ 10,819	\$ 10,028	\$ 22,053	\$ 21,027
Gross profit %	44%	43%	44%	44%
Income (loss) before income taxes	7,039	(4,206)	11,560	(7,812)
(Provision) benefit for income taxes	(207)	115	(294)	(8)
Net income (loss)	\$ 6,832	\$ (4,091)	\$ 11,266	\$ (7,820)
Basic net income (loss) per share	\$ 0.15	(\$ 0.09)	\$ 0.24	(\$ 0.17)
Diluted net income (loss) per share	\$ 0.15	(\$ 0.09)	\$ 0.24	(\$ 0.17)
Weighted average shares outstanding - basic	46,077	45,000	46,070	44,782
Weighted average shares outstanding - diluted	46,518	45,000	46,353	44,782

Selected balance sheet data:	January 31, 2016 (unaudited)	July 31, 2015
Cash and cash equivalents	\$ 37,016	\$ 18,109
Working capital	\$ 34,650	\$ 22,528
Stockholders' equity	\$ 54,447	\$ 42,606
Total assets	\$ 80,906	\$ 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 and six months ended January 31, 2016 and 2015, respectively:

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

	Three months ended January 31,		Six months ended January 31,	
	2016	2015	2016	2015
Reported GAAP net income (loss)	\$ 6,832	\$ (4,091)	\$ 11,266	\$ (7,820)
Adjusted for:				
Legal settlements, net	(11,650)	—	(18,450)	—
Legal fees associated with settlements	—	—	—	—
Costs related to contested proxy	1,483	—	1,483	—
Separation payments	51	—	132	—
Non-GAAP net income (loss)	<u>\$ (3,284)</u>	<u>\$ (4,091)</u>	<u>\$ (5,569)</u>	<u>\$ (7,820)</u>
<i>Weighted Shares Outstanding</i>				
Basic	46,077	45,000	46,070	44,782
Diluted	46,518	45,000	46,353	44,782
<i>Basic and diluted earnings per share</i>				
Basic and diluted net income (loss) per share				
GAAP	\$ 0.15	(\$ 0.09)	\$ 0.24	(\$ 0.17)
Basic and diluted net income (loss) per share non-				
GAAP	(\$ 0.07)	(\$ 0.09)	(\$ 0.12)	(\$ 0.17)

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

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

	Three months ended January 31,		Six months ended January 31,	
	2016	2015	2016	2015
GAAP net income (loss)	\$ 6,832	\$ (4,091)	\$ 11,266	\$ (7,820)
Plus:				
Depreciation and amortization	952	935	1,902	1,873
Interest expense	42	49	82	118
Provision (benefit) for income taxes	207	(115)	294	8
EBITDA	<u>\$ 8,033</u>	<u>\$ (3,222)</u>	<u>\$ 13,544</u>	<u>\$ (5,821)</u>
Adjusted for:				
Legal settlements, net	(11,650)	—	(18,450)	—
Legal fees associated with settlements	—	—	—	—
Costs related to contested proxy	1,483	—	1,483	—
Separation payments	51	—	132	—
Adjusted EBITDA	<u>\$ (2,083)</u>	<u>\$ (3,222)</u>	<u>\$ (3,291)</u>	<u>\$ (5,821)</u>