

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): **June 11, 2018**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 450 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-1 of this chapter).

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. []

Item 2.02. Results of Operations and Financial Condition.

On June 11, 2018, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its third fiscal quarter ended April 30, 2018. 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.

Adjusted net income, Adjusted 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 Adjusted 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 June 11, 2018](#)

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: June 11, 2018

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 THIRD QUARTER RESULTS

Operations to Launch High Quality Products and Services to Hospital and Independent Laboratories Headline Quarterly Activities

NEW YORK, NY, June 11, 2018 -- Enzo Biochem Inc. (NYSE:ENZ), an integrated diagnostic company, today reported results for the third fiscal quarter and nine months ended April 30, 2018, in addition to noting significant progression of its strategic plan aimed at providing cost-effective, high performing and easily adaptable products and services to hospital and independent laboratories.

Recent Developments

Implementation of Enzo's disruptive strategy to alleviate cost pressures for clinical laboratories by developing cost efficient high performing technologies and products for use in commonly available automated systems accelerated in a number of critical areas during the quarter, capitalizing on Enzo's integrated businesses:

- Overall testing volume gains in services revenue grew nearly 2% despite weather and specific items impacting services revenue, demonstrating resiliency in the turbulent marketplace for clinical laboratories. Services revenue of Enzo's newly launched women's health panel on the AmpProbe® platform was strong in the quarter.
- Recruitment of incremental sales force to drive revenue growth is well underway with addition of new professional team members, including new sales leadership.
- Enzo recently named an in-network laboratory provider to a large New England commercial payor covering more than 3 million lives. Applications for in-network status continue to be filed with several payors that will expand Enzo's reach of testing services to millions of covered lives across the U.S.
- Acceleration of product and services marketing efforts with additional staff hires and work around branding of technology platforms, new print and digital articles and marketing materials, and attendance at targeted trade shows and conferences.
- Enzo validated three clinically relevant cost-effective cancer biomarker detection tests as part of its expanded anatomical Pathology platform. In addition, Enzo added assays for detecting chromosomal abnormalities for cancer stagings to Enzo's development pipeline for introduction later this year and a UMM marker (Ureaplasma species, Mycoplasma hominis and Mycoplasma genitalium) is being validated that will expand the Company's 13-analyte women's health panel on the AmpProbe® platform.

- Growing number of important business development meetings and activities around potential partnerships and collaborations with hospital networks, diagnostic manufacturers and other laboratories in process, with specific emphasis on use of Enzo diagnostic reagents in existing automated systems that are commonly available.
- During fiscal 2018, Enzo has been granted 14 new patents, including key patents covering potential cancer therapeutic.
- Expect near term announcement on Enzo's facility expansion program to support growth.

Third Quarter Financial Highlights

- Total revenues in the quarter amounted to \$25.6 million or 5% lower than prior year due to a decrease in service revenue.
- Services revenue was affected in the third quarter by the loss of a medical practice that internalized genetic testing ordering of approximately \$1.9 million, storm related weather in the Northeast which impacted operations approximately \$1.0 million (five days), and an accounts receivable reserve adjustment of \$0.5 million due to a commercial payor payment practice. Despite these items, core service testing volume increased nearly 2% or \$2.0 million with growth in genetic and esoteric testing. Included in this amount were strong revenue related to the recently launched Ampiprobe® platform in the quarter. As a result, services revenue totaled \$18.1 million compared to \$19.6 million in the prior year.
- Product revenue was slightly ahead of prior year at \$7.4 million as reported sales increased in Europe and stabilized in the U.S.
- Gross margins in the quarter were 43% compared with 45% in the prior year period.
- Total operating expenses were \$13.9 million compared to \$12.4 million, an increase of \$1.5 million or 12%. Legal expense accounted for \$1.1 million of the increase along with marketing and sales related expenses of \$0.3 million in advance of launching new sales initiatives.
- The GAAP and Non-GAAP net loss was \$3.0 million or \$0.06 per share compared to breakeven results or \$0.00 per share in the prior year period.
- Total cash and cash equivalents at April 30, 2018 were \$62.6 million compared to \$64.2 million at July 31, 2017. Operating segments continue to be cash flow positive. Cash used in operations for the nine months ended April 30, 2018 was \$0.5 million compared to a use of \$1.9 million for the nine months ended April 30, 2017.

Barry Weiner, Enzo Biochem President, comments:

"Healthcare overall is in a transformative state, a situation Enzo has long recognized with innovative platforms and assays designed to bring hospitals and independent labs meaningful cost savings, improved service to physician customers, assure the comfort and needs of patients, and overall help to importantly build value.

"Our quarterly services revenue and gross margin was adversely impacted by a customer shift to internalizing genetic ordering, adverse weather, and payment practices at a commercial insurance payor. Nevertheless, Enzo showed its business model can replace this service revenue by expanding our coverage area,

increasing services to hospital networks and successfully launching tests such as AmpProbe[®] at lower cost, thereby improving gross margins.

“Enzo is making significant progress preparing to roll out our disruptive diagnostic technology to hospital and independent laboratories. Our operating and commercial activities have accelerated and we expect the pace to continue throughout calendar 2018. The insurance reimbursement market is shifting rapidly, making Enzo’s strategic plan to develop and market cost-efficient proprietary products and services that are high performing, critical to the laboratory industry. The Company saw increased service revenue from its AmpProbe[®] line with attractive gross margins in just the first quarter since launch. Our focus is clear: expanding Enzo’s proprietary technology platforms in high-valued molecular diagnostics, immunoassays and genomics segments that will provide laboratories margin relief as insurance reimbursement and cost challenges become more prevalent. This ongoing effort involves training an expanded sales team, investing in related marketing and promotion programs, in addition to continuing our pipeline development.

“We have a highly liquid and strong balance sheet with which to implement our strategic plan and bring it to fruition.”

Business Strategy

As an integrated diagnostic company, Enzo is driving the development of cost efficient, high performing and easily adaptable disruptive diagnostic technologies to the hospital and independent clinical laboratory industry. Enzo’s current market position is the culmination of extensive strategic planning and years of work developing reagents and assays in clinical markets. Key to our strategy is Enzo’s unique operating structure and integration of Enzo Life Sciences products and Enzo Clinical Laboratories services that provides us with a unique advantage. Enzo Life Sciences has broad capabilities for developing critical assays that have demonstrated unusually high sensitivity. In our facilities in New York and Michigan we also have the capability to manufacture them as they are approved.

In turn, Enzo Clinical Labs with its state-of-the-art diagnostic capabilities is working seamlessly with Life Sciences to assure the quality and effectiveness of our products through testing services on commonly available automated systems.

The result of this unique integration is that we are able to bring to market platforms and technologies that are fully vetted in a real world diagnostic facility. Moreover, these solutions cover multiple diagnostic segments including molecular diagnostics, anatomical pathology, immunoassays, and genetics. Affordable price structure is related to our ability to access installed automated systems. At a time when reimbursement pressures and cost challenge persist, Enzo’s solutions provide much needed margin relief for clinical laboratories.

Third Quarter Results

Total revenues in the quarter amounted to \$25.6 million or 5% lower than prior year due to a decrease in services revenue. As noted above, services revenue was impacted in the third quarter by the loss of a large medical practice that internalized genetic testing ordering of approximately \$1.9 million, storm related weather in the Northeast that impacted operations approximately \$1.0 million, and an

accounts receivable reserve adjustment of \$0.5 million due to a commercial payor payment practice. Despite these items, core service testing volume increased nearly 2%, or \$2.0 million, with growth in genetic and esoteric testing. Product revenue was slightly ahead of prior year at \$7.4 million as reported sales increased in Europe and stabilized in the U.S. The current quarter's products revenue was impacted favorably by foreign currency movements of approximately \$0.2 million.

Gross margins in the quarter were 43% compared with 45% in the prior year period. Total operating expenses were \$13.9 million compared to \$12.4 million, an increase of \$1.5 million or 12%. Legal expenses were \$1.7 million and accounted for \$1.1 million of the increase in operating expenses along with marketing and sales related expenses of \$0.3 million in advance of launching New Sales initiatives. The increase in legal expenses was principally related to the New York litigation with Roche, where Enzo is the plaintiff.

The GAAP and Non-GAAP net loss was \$3.0 million or \$0.06 per share compared to breakeven results or \$0.00 per share in the prior year period.

EBITDA (earnings before interest, taxes, depreciation and amortization) and Adjusted EBITDA was a loss of \$2.4 million, compared to EBITDA of \$0.7 million in the prior year period.

Segment Results

Services revenues were \$18.1 million verse \$19.6 million in the prior year period as a result of the aforementioned specific items offset by growth in testing volume. Gross margins declined to 39.4%, from 42.1% a year ago. Operating income amounted to \$0.5 million, compared to \$1.5 million, a year ago. Noteworthy was steady growth in tests using the newly installed AmpProbe™ platform with significantly above average profit margins compared to historical laboratory testing.

Products revenue increased to \$7.4 million from \$7.3 million a year ago. With costs well maintained, and sales of higher margin products, resulting from the unit's recent product mix realignment, Life Science product profit margins advanced to 52%, from 51% a year earlier. Operating income approximated \$0.4 million for the April 2018 quarter and \$0.6 million in the year ago period.

Nine Month Results

Total products and services revenues year to date amounted to \$80.3 million, up 1% from \$79.6 million a year ago. Gross margins were 43.2%, vs. 44.9% a year ago, and SG&A as a percentage of revenue was 41% vs. 42%. Legal expenses amounted to \$3.8 million, up from \$1.3 million a year ago principally due to litigation expenses in New York with Roche, where Enzo is the plaintiff. The GAAP and Non-GAAP net loss was \$4.6 million or \$0.10 per share and \$5.7 million or \$0.12 per share, respectively, compared to GAAP and Non-GAAP net loss of \$2.6 million or \$0.06 in the prior year period. EBITDA and Adjusted EBITDA was a loss of \$3.9 million compared to a loss of \$0.2 million in the prior year period.

Conference Call

The Company will conduct a conference call Tuesday, June 12, 2018 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 8178498.

Interested parties may also listen over the Internet at: <https://tinyurl.com/ybasc9sh>

To listen to the live call, individuals should go to the website at least 15 minutes early to register, download and install any necessary audio software. Any pop up blocker installed on your PC should be disabled while accessing the webcast. A rebroadcast of the call will be available starting approximately two hours after the conference call ends, through 12 AM (E.T.) Tuesday June 26, 2018. The replay of the conference call can be accessed by dialing 1-855-859-2056 (International callers can dial 1-404-537-3406) and, when prompted, use the same PIN number 8178498.

Adjusted 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 GAAP and Adjusted 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 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 Adjusted 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, 2017. 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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or

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

	Three months ended April 30, (unaudited)		Nine months ended April 30, (unaudited)	
	2018	2017	2018	2017
<i>Selected operations data:</i>				
Revenues:				
Clinical laboratory services	\$ 18,137	\$ 19,584	\$ 58,001	\$ 56,979
Product revenues	7,415	7,312	21,618	21,721
Royalty and license fee income	78	193	639	933
Total revenues	<u>\$ 25,630</u>	<u>\$ 27,089</u>	<u>\$ 80,258</u>	<u>\$ 79,633</u>
Gross profit	<u>\$ 11,073</u>	<u>\$ 12,173</u>	<u>\$ 34,663</u>	<u>\$ 35,940</u>
Gross profit %	<u>43%</u>	<u>45%</u>	<u>43%</u>	<u>45%</u>
Income (loss) before income taxes	(3,016)	(71)	(5,654)	(2,598)
Benefit for income taxes (1)	-	-	1,097	-
Net income (loss)	<u>\$ (3,016)</u>	<u>\$ (71)</u>	<u>\$ (4,557)</u>	<u>\$ (2,598)</u>
Basic and diluted net income (loss) per share	<u>(\$0.06)</u>	<u>(\$0.00)</u>	<u>(\$0.10)</u>	<u>(\$0.06)</u>
Weighted average shares outstanding - basic and diluted	<u>47,073</u>	<u>46,367</u>	<u>46,895</u>	<u>46,310</u>

(1) The statement of operations for the nine months ended April 30, 2018 includes a one-time tax benefit related to the passing of the Tax Cut and Jobs Act, which was signed into law in December 2017.

	4/30/2018 (unaudited)	7/31/2017 (unaudited)
<i>Selected balance sheet data:</i>		
Cash and cash equivalents	\$62,556	\$64,167
Working capital	\$67,748	\$71,274
Stockholders' equity	\$86,379	\$88,872
Total assets	\$105,451	\$107,665

The following table presents a reconciliation of reported net income (loss) and basic and diluted net income (loss) per share to Adjusted net income (loss) and basic and diluted net income (loss) per share for the three and nine months ended April 30, 2018 and 2017:

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

	Three months ended		Nine months ended	
	April 30,		April 30,	
	2018	2017	2018	2017
Reported GAAP net income (loss)	\$ (3,016)	\$ (71)	\$ (4,557)	\$ (2,598)
Adjusted for:				
Benefit for income taxes	-	-	(1,097)	-
Adjusted net income (loss)	<u>\$ (3,016)</u>	<u>\$ (71)</u>	<u>\$ (5,654)</u>	<u>\$ (2,598)</u>
<i>Weighted Shares Outstanding:</i>				
Basic and diluted	47,073	46,367	46,895	46,310
<i>Basic and diluted earnings per share:</i>				
Basic and diluted net income (loss) per share - GAAP	(\$0.06)	(\$0.00)	(\$0.10)	(\$0.06)
Basic and diluted net income (loss) per share - Adjusted	(\$0.06)	(\$0.00)	(\$0.12)	(\$0.06)

(1) The statement of operations for the 2018 nine month period includes a one-time tax benefit related to the passing of the Tax Cut and Jobs Act, which was signed into law in December 2017. The Company has excluded the one-time impact of this law in the calculation of Adjusted net income as it is non-recurring.

The following table presents a reconciliation of reported net income (loss) for the three and nine months ended April 30, 2018 and 2017 to EBITDA and Adjusted EBITDA:

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

	Three months ended		Nine months ended	
	April 30,		April 30,	
	2018	2017	2018	2017
GAAP net income (loss)	\$ (3,016)	\$ (71)	\$ (4,557)	\$ (2,598)
Plus (minus):				
Depreciation and amortization	815	849	2,350	2,692
Interest income	(227)	(115)	(569)	(240)
Benefit for income taxes	-	-	(1,097)	-
EBITDA and Adjusted EBITDA	<u>\$ (2,428)</u>	<u>\$ 663</u>	<u>\$ (3,873)</u>	<u>\$ (146)</u>