

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 10, 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 *fee* 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 December 10, 2018, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its first fiscal quarter ended October 31, 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.

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 10, 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: December 10, 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 FISCAL 2019 FIRST QUARTER RESULTS

Recent Reimbursement Cuts Emphasize Value of Enzo's Strategy

NEW YORK, NY, December 10, 2018 – Enzo Biochem, Inc. (NYSE:ENZ), an integrated diagnostics and therapeutics company, today reported operating results for the first fiscal quarter ended October 31, 2018, in addition to providing an update on the company's development of lower cost products, platforms and services for the diagnostics and therapeutics markets.

Recent Developments

- Optimizing diagnostic processes towards FDA clinical trials on Enzo's proprietary and affordable open system platform capable of high throughput to meet the needs of clinical laboratories of all sizes. Enzo's platform includes automation-compatible reagent systems and associated products for sample collection and processing to further drive costs down for diagnostic testing. Enzo's programs also include manufacturing and assembly of all components required for each step in the diagnostic process for integration into an open platform. Focusing on molecular diagnostics, immunohistochemistry and ELISA platforms which consist of a significant percentage of the cost of goods for clinical laboratories. The Company's programs encompass all steps from research and development to manufacturing, translation, clinical trials, to FDA approval.
 - To address the tightening reimbursement paradigm, Enzo is expanding its approach to centralize lab to lab reference services providing margin improvement, expanding its specialized testing menu to the Company's clientele, developing opportunities with institutional clients, and expanding its geographical reach. To support Enzo's strategic approach, it recently obtained a license from the State of Connecticut allowing Enzo to open a new free standing clinical laboratory in the state. The new facility expands Enzo's geographical reach, allowing it to expand its Lab-to-Lab reference services in the Northeast. It will also enable Enzo to open additional patient service centers in collaboration with commercial insurance providers to address this large patient population need. Enzo is already designated an in-network provider for three health insurance providers in New England.
 - Impact of diagnostic reimbursements pressures on clinical laboratories is now more widely evident throughout the industry, irrespective of laboratory testing volume. Enzo's early recognition of the industry challenges has driven the development of the Company's innovative, expanding line of cost effective, highly efficient platforms and reagents, as well as establishment of a nationally available reference laboratory incorporating these advances.
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- Reported on publication in recent Journal of Lipid Research of a preclinical study by scientific collaborators involving a company-developed proprietary Sphingosine Kinase 1 inhibitor drug candidate effective in reversing resistance to the breast cancer drug tamoxifen, potentially a first line treatment for estrogen receptor-positive breast cancer patients. With more than 50% of patients who initially respond to tamoxifen ultimately failing therapy due to development of resistance, these results suggest that SK1-I may have potential in the treatment of tamoxifen-resistant breast cancers. Enzo research results, as well as those of its collaborators, show that SK1-I may address significantly unmet medical needs in the treatment of multiple oncology indications and immune-related disorders, warranting further development anticipated in the coming year.
- Continuing to build one of the most comprehensive intellectual property estate in the industry with recently awarded patent for optimizing real time nucleic acid detection processes.
- Completed purchase of previously announced additional 36,000-square foot commercial facility in Farmingdale, NY, adjacent to the Company's current Long Island campus. A renovation underway will add needed infrastructure to produce and distribute Enzo's expanding low cost, open architecture diagnostic platform products and broaden related services, including automation-compatible reagent systems and associated products for sample collection and processing through to analysis. This new facility will also include GMP manufacturing capabilities.

Barry Weiner, President, Comments:

"In the few weeks since we last reported on fiscal 2018 results and commented on how we viewed the inevitable consequences of PAMA reimbursement reductions, estimated by some to be at least \$2 billion industry wide, we are seeing industry wide impact today. With these developments, Enzo's strategy to provide low-cost, efficient and high capacity diagnostic solutions has become even more important and critical for an industry being challenged to maintain high quality services, while being paid less for work performed. Our investment and focus on development of cost effective products should assist in the improvement of our financial performance in the future.

"Also, we believe that it will prove to be a beneficial solution for a large number of independent and hospital labs adversely affected by lower reimbursement rates. For some time, Enzo has recognized the inevitable negative impact of both Medicare reimbursement reductions, along with more stringent policies of private payors, and the inflexible high pricing of products associated with closed end diagnostic systems. Our unique operating structure, coupled with innovative product development make Enzo uniquely positioned to provide unique laboratory solutions for our industry.

"In this environment, our strategy to build upon our deep knowledge and experience to develop an extensive line of products and services that are inexpensive, highly efficient and utilizing open ended architecture is now also a commercially available alternative as a service.

"Enzo is moving quickly to capitalize on opportunities that lie ahead. We continue to expand our comprehensive menu of tests for the market. Our commercialization efforts are well underway, which we believe will address the economic challenges we see throughout the industry and to create future value for our shareholders. The industry challenges play to our strengths as a developer and provider of unique platforms and reagents. In addition, due to our expanded Farmingdale campus, our ability to

provide clinical laboratories anywhere in the U.S. with reference diagnostic services utilizing our tools will prove highly attractive and economical, as well as rewarding, for them and for Enzo.”

“In light of the significant reimbursement changes that have impacted Enzo and other clinical laboratories in this quarter, Enzo has taken a number of steps to adjust its operations to this new paradigm. These actions include tightening billing and client services practices, expanding our reference laboratory services menu of tests, and hiring sales professionals in new geographical regions. Most importantly, our vertically integrated structure allows Enzo to move quickly to position our broader lab to lab reference service. “

First Quarter Operating Results

- Total revenues were \$21.3 million, compared to \$26.9 million in the prior year, a decrease of \$5.6 million. Clinical services revenues were \$14.3 million, compared to \$19.5 million in the prior year, a decrease of \$5.2 million, largely due to reduced insurance reimbursement payments and mix of testing, which were reimbursed at higher than average rates, in the prior year. Total diagnostic testing volume, measured by the number of accessions, decreased 5% year over year, again due to lower high-value testing, partially offset by an increase in esoteric testing, including Enzo’s Ampiprobe woman’s health panel which has increased in volume each quarter since its launch last fiscal year. Product and royalty revenue was \$7.0 million compared to \$7.3 million in the prior year. The decline year over year was the result of elimination of product royalties due to expiration of the agreement in April 2018.
- Clinical services revenues for the three months ended October 31, 2017 have been restated to reflect adoption of new revenue recognition rules on a full retrospective basis. Under the new rules, Enzo reports uncollectible balances associated with patient responsibility as a reduction in net revenues; historically these amounts were separately classified in operating expenses as a provision for uncollectable accounts receivable, and amount to \$0.6 million and \$0.8 million in the three months ended October 31, 2018 and 2017, respectively.
- Consolidated gross margins were 33% compared with 42.6% in the prior year. Clinical services gross margins were 23.3% compared to 38.4% a year ago. Gross margins in the current year were negatively impacted by lower reimbursement revenue from Clinical Services, as noted above. Clinical products gross margin was 53% compared to 52% in the prior year period.
- Operating expenses totaled \$13.0 million, up 8% compared to \$12.0 million a year ago. The increase reflected legal fee expenses in anticipation of a patent infringement and contract related trial, where Enzo is plaintiff, slated to occur next calendar year. Total legal expenses were \$1.3 million compared to \$0.4 million in the prior year. Selling and general administrative expenses (SG&A) as well as research and development (R&D) expenses were slightly higher year over year in support of the Company’s growth strategies.
- The GAAP and Non-GAAP net loss was \$6.0 million compared to \$0.6 million a year ago. The GAAP and non-GAAP net loss per share was \$0.13, compared to \$0.01 a year ago. EBITDA was a loss of \$5.5 million compared to \$0.1 million a year ago.

Total cash and cash equivalents at October 31, 2018 were \$52.8 million compared to \$60.0 million at July 31, 2018. Cash used in operations was \$6.2 million during the first quarter of fiscal 2019 and cash used for investing activities, principally capital expenditures, was \$1.0 million. Working capital at October 31, 2018 was over \$57.3 million.

Conference Call

The Company will conduct a conference call Tuesday, December 11, 2018 at 8:30 AM ET. The call can be accessed by dialing (888) 459-5609. International callers can dial (973) 321-1024. Please reference PIN number 3927608.

Interested parties may also listen over the Internet at: <https://tinyurl.com/ybstv2tp>

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 December 25, 2018. The replay of the conference call can be accessed by dialing (855)-859-2056. (International callers can dial (404) 537-3406) and, when prompted, use the same PIN number 3927608.

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, 2018. 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)

<i>Selected operations data:</i>	Three months ended	
	October 31	
	(unaudited)	
	2018	2017
Total revenues	\$ 21,260	\$ 26,876
Gross profit	\$ 7,021	\$ 11,445
Gross profit %	33.0%	42.6%
Loss before income taxes	(5,981)	(640)
Benefit for income taxes	—	—
Net loss	\$ (5,981)	\$ (640)
Basic and diluted net income (loss) per share	(\$0.13)	(\$0.01)
Weighted average shares outstanding - basic and diluted	47,186	46,914

<i>Selected balance sheet data:</i>	10/31/2018	7/31/2018
	(unaudited)	(unaudited)
Cash and cash equivalents	\$52,777	\$60,041
Working capital	\$57,315	\$63,014
Stockholders' equity	\$75,670	\$81,121
Total assets	\$94,183	\$101,660

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, 2018 and 2017:

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

	October 31	
	2018	2017
Reported GAAP net loss	\$ (5,981)	\$ (640)
Adjusted for:		
Legal settlements, net	—	—
Legal fees associated with settlements	—	—
Separation payments	—	—
Non-GAAP net loss	<u>\$ (5,981)</u>	<u>\$ (640)</u>
<i>Weighted Shares Outstanding</i>		
Basic and diluted	47,186	46,914
<i>Basic and diluted earnings per share</i>		
Basic and diluted net income (loss) per share GAAP	(\$0.13)	(\$0.01)
Basic and diluted net income (loss) per share non-GAAP	(\$0.13)	(\$0.01)

The following table presents a reconciliation of reported net income (loss) for the three months ended October 31, 2018 and 2017, respectively to EBITDA and Adjusted EBITDA:

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

	October 31	
	2018	2017
GAAP net loss	\$ (5,981)	\$ (640)
Plus (minus):		
Depreciation and amortization	766	749
Interest income	(274)	(157)
Benefit for income taxes	—	—
EBITDA	\$ (5,489)	\$ (48)
Adjusted for:		
Legal settlements, net	—	—
Legal fees associated with settlements	—	—
Separation payments	—	—
Adjusted EBITDA	\$ (5,489)	\$ (48)