

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 11, 2019**

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 March 11, 2019, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its second fiscal quarter ended January 31, 2019. 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 11, 2019](#)

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 11, 2019

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 SECOND FISCAL QUARTER AND FIRST HALF 2019 RESULTS AND
REPORTS PROGRESS ON ITS INVESTMENTS AND STRATEGIC GOALS**

NEW YORK, NY, March 11, 2019 -- Enzo Biochem, Inc. (NYSE:ENZ), an integrated diagnostics and therapeutics company, today reported results for the fiscal quarter and first half ended January 31, 2019 along with providing more detail on its investments in the development of novel diagnostic system and centralized clinical services.

Recent Developments

- The Company is rapidly implementing its strategic plan to build a comprehensive menu of reagents, automated systems, and related consumables on several independent platforms and systems. This effort started with research and development activity, which was initiated several years ago, adaptation and validation of products to automated systems and has extended into GMP manufacturing. These automated systems are in the process of clinical trial for submission to obtain LDT, CE Mark and FDA approvals where appropriate. Enzo's business development efforts are ongoing with potential partners that would accelerate market access and penetration to provide much need margin relief to small and midsize clinical and hospital laboratories.
 - To accelerate and accommodate the manufacturing and commercial needs of all of its components of automated platforms and systems, the Company closed on its acquisition of a 36,000-square-foot commercial facility in Farmingdale, NY, and architectural design and construction development is underway. In connection with the acquisition of the new facility, the Company has Town of Babylon Industrial Development Agency (IDA) commitments that will provide Enzo with significant multi-year tax abatements and additional incentives with respect to its entire Farmingdale campus. The investment will enhance the infrastructure of the Company's Long Island campus aimed at facilitating production and distribution of Enzo's expanded high value and lower cost, open diagnostic platforms
 - The Company extended its product and platform development strategy to address rapidly declining reimbursement and high cost of goods affecting all clinical and hospital outreach laboratories. Development work is on track to expand the Company's menu of high volume and high value tests to be used in connection with Enzo's proprietary and affordable open system platforms capable of high throughput to improve the financial results of clinical laboratories.
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- The systems are targeted to make available highly efficient and lower cost solutions for diagnostic testing, with a focus on molecular diagnostics, immunohistochemistry and ELISA platforms.
 - Progress continues in transforming Enzo Clinical Labs to an efficient centralized service provider to other laboratories as a new market for Enzo. The Company is adopting Enzo's platforms and products to be able to offer services for a high value menu of tests to other clinical laboratories (not only to patients and physicians) at prices that will provide marginal return to the customer laboratory. Enzo has invested in the clinical laboratory in its translational capabilities, validation capabilities and its performance of Enzo test platforms. Enzo has expanded on marketing and sales activities to address the market opportunities which includes a broad range of diagnostic testing including FISH, immunohistochemistry, and molecular diagnostics.
 - The clinical laboratory market dynamics of lower reimbursement and high operating costs imposes a challenging future to the clinical laboratory industry. These market conditions present Enzo with an opportunity to address the industry needs in the form of reference services at a lower cost and provide products and systems at a lower cost than competitors.
 - Enzo's progress towards achieving this strategic goal is the result of Enzo's vertically integrated operating structure to provide both for products and services, and its extensive intellectual property estate, the Company is better positioned in the industry than most to address these needs. The Company has stepped up its investment activities to capitalize on its unique capabilities to address these industry challenges by offering highly efficient and lower costs systems that address valuable components of diagnostic testing. Enzo also continue to invest to grow our core business to drive efficiencies and growth in revenue per test and to improve gross margins. The Company continues to aggressively grow its business around its strategic plan by making investments in all aspects of product development, validation, clinical trial and sales and marketing to reach new markets for Enzo's platforms and products and reference services. Over the last several quarters Enzo estimates that it has invested approximately ten percent of costs in these areas.
 - Continuous efforts are being made to improve efficiencies in operations while expanding marketing and sales to drive revenue growth, while taking costs out of core operations. During the quarter, the Company realigned client facing groups such as client services and other support functions to eliminate costs while maintaining high quality services. In addition, Enzo continues to recruit new senior sales professionals to further penetrate U.S. market, including the Northeast markets.
 - Enzo is nearing completion of GMP manufacturing operations to support future LDT, CE Mark and FDA diagnostic submissions. The Company anticipates regulatory submissions on a number of products and platforms. In addition, the Company continues to invest in capital projects that support business growth.
 - On February 5, 2019, the Company entered into a legal settlement agreement in a New York case resulting in a payment to the Company of \$21 million. The agreement does not affect other infringement proceedings underway against the defendant in federal district court in Wilmington, Delaware.
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Barry Weiner, President, Comments

“We continue to focus relentlessly on our strategic program to provide lower cost, highly efficient and effective platforms and reagents to offset today’s reimbursement challenges facing independent and institutional clinical diagnostic laboratories. Our financial results thus far this year, and for the second fiscal quarter we are reporting today, have been directly impacted by lower reimbursement from governmental and commercial payors and a notable shift away from high margin esoteric molecular diagnostics testing to lower cost routine core tests. On balance, volume of accessions have remained constant but price per accession has decreased impacting both revenues and profitability.

“Enzo’s position as the leading independent clinical laboratory serving the important metropolitan New York-New Jersey-Connecticut market, which we now have extended into the New England states and as far south as Pennsylvania, remains intact. Enzo’s growing advanced testing menu, and especially our comprehensive women’s health panel using AMPIPROBE® multiplex real-time PCR assays featuring detection of infectious disease tests for a total of 16 organisms from a single vaginal swab specimen, continues to put our expertise at the forefront of quality, cost effective, high performance diagnostic technology.

“The challenges from reduced diagnostic reimbursements, which have been instituted without regard to the serious harm it has done to independent and hospital clinical labs profit margins, is a development Enzo foresaw early on in embarking on our strategic program. Moreover, private healthcare insurers are implementing tightened standards for approving tests and determining medical necessity is further evidence of more critical adverse reimbursement policies. All this has made Enzo’s developmental program to provide testing platforms and reagents easily adaptable to existing open systems more valuable. Our program to establish Enzo has a nationwide reference laboratory providing overnight services utilizing our technology also is aimed at shoring up independent operating margins for those for whom investing in new platforms is uneconomic.

“Our efforts currently are directed at developing a well-rounded offering of wide-ranging tests for approval by both the FDA and New York State Department of Health. In the meantime, while Enzo continues to be financially strong and highly liquid, our operating results are reflective of the cross currents now affecting the diagnostic laboratory industry. Despite the revenue shortfall, we are diligently working to invest behind our strategic program while we also focus on expense reductions and even more heightened efficiencies. When completed, our advanced Farmingdale campus will be important in that regard and we plan to continue to invest in our strategic plan. We also are taking steps to aggressively expand marketing and sales to reach a wider customer base, to maintain the high service standards for which we are known, and to control those aspects of our business that are within our reach to achieve improved results. We are confident that our efforts to do so and achieve our goals on the development front will pay off.”

Second Quarter Operating Results

- Total revenues were \$19.3 million, compared to \$26.1 million in the prior year, a decrease of \$6.8 million. Clinical services revenues were \$12.0 million, compared to \$18.7 million in the prior year, a decrease of \$6.7 million, largely due to reduced insurance reimbursement payments that were reimbursed at higher rates in the prior year, increased competition and testing denials and changes to medical and procedural requirements for genetic testing by payors. In addition, the Company recorded over \$1.2 million of reserves offsetting revenues due to
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slow paying commercial payers and claims made by a commercial payor for overpayments Enzo received in prior periods. Total diagnostic testing volume, measured by the number of accessions, decreased 3% 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 \$7.3 million compared to \$7.4 million in the prior year. The decrease year over year was the result of the elimination of product royalties due to expiration of the agreement in April 2018 offset by higher product volume in the U.S. market.

- Clinical services revenues for the three months ended January 31, 2018, the prior year period, 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 January 31, 2019 and 2018, respectively.
- Consolidated gross margins were 24% compared with 40% in the prior year. Clinical services gross margins were 8% compared to 37% a year ago. Gross margins in the current year were negatively impacted by lower reimbursement revenue from Clinical Services, as noted above. Products gross margin was 49% compared to 46% in the prior year period.
- Operating expenses totaled \$28.2 million, compared to \$29.2 million a year ago, a decrease of \$1 million or 3%. Total legal expenses were \$1.1 million compared to \$1.7 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 \$8.4 million or \$0.18 per share compared to a GAAP net loss of \$0.9 million or \$0.02 per share and a non-GAAP net loss of \$2.0 million or \$0.04 per share a year ago. EBITDA and adjusted EBITDA was a loss of \$7.9 million compared to a loss of \$1.4 million a year ago.

Total cash, cash equivalents and restricted cash at January 31, 2019 were \$42.7 million compared to \$60.0 million at July 31, 2018. This amount does not include the net proceeds of the \$21 million settlement paid in February as a result of the legal settlement noted above. Cash used in operations was \$8.6 million during the second quarter of fiscal 2019 and cash used in investing activities, principally due to the purchase of our new facility and capital expenditures, was \$6.0 million. Working capital at January 31, 2019 was over \$47.0 million.

First Half Operating Results

Total revenues were \$40.6 million compared to \$53.0 million in the prior year, a decline of \$12.4 million or 23% lower than prior year. Gross profit totaled \$11.6 million, compared to \$22.0 million a year ago, with gross margins of 29% and 41%, respectively. SG&A of \$22.5 million decreased \$0.5 million. Legal expenses increased to \$2.4 million, from \$2.1 million a year ago. The GAAP and Non-GAAP net loss totaled \$14.4 million, or \$0.30 per share, compared to \$1.5 million and \$2.6 million or \$0.03 and \$0.06 per share, respectively. EBITDA and adjusted EBITDA was a loss of \$13.4 million compared to a loss of \$1.4 million a year ago.

Conference Call

The Company will conduct a conference call Tuesday, March 12, 2019 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 2037608.

Interested parties may also listen over the Internet at:<http://tinyurl.com/y6ojnfqw>

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 March 26, 2019. The replay of the conference call can be accessed by dialing (855)-859-2056. International callers can dial (404) 537-3406, and when prompted, used the same PIN number 2037608.

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 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 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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Contact:

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or

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

	Three months ended		Six months ended	
	January 31		January 31,	
<u>Selected operations data:</u>	(unaudited)		(unaudited)	
	2019	2018	2019	2018
Total revenues	\$ 19,327	\$ 26,152	\$ 40,587	\$ 53,028
Gross profit	\$ 4,579	\$ 10,545	\$ 11,600	\$ 21,990
Gross profit %	24%	40%	29%	41%
Loss before income taxes	(8,408)	(1,998)	(14,389)	(2,638)
Benefit for income taxes	-	1,097	-	1,097
Net loss	\$ (8,408)	\$ (901)	\$ (14,389)	\$ (1,541)
Basic and diluted net income (loss) per share	(\$0.18)	(\$0.02)	(\$0.30)	(\$0.03)
Weighted average shares outstanding - basic and diluted	47,199	46,941	47,197	46,806
	1/31/2019	7/31/2018		
	(unaudited)	(unaudited)		
Cash and cash equivalents (including restricted cash \$750)	\$42,728	\$60,041		
Working capital	\$47,044	\$63,014		
Stockholders' equity	\$67,497	\$81,121		
Total assets	\$89,120	\$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 and six months ended January 31, 2019 and 2018:

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

	Three months ended January 31		Six months ended January 31,	
	2019	2018	2019	2018
Reported GAAP net loss	\$ (8,408)	\$ (901)	\$(14,389)	\$ (1,541)
Adjusted for:				
Legal settlements, net	-	-	-	-
Legal fees associated with settlements	-	-	-	-
Benefit for income taxes	-	(1,097)	-	(1,097)
Non-GAAP net loss	<u>\$ (8,408)</u>	<u>\$ (1,998)</u>	<u>\$(14,389)</u>	<u>\$ (2,638)</u>
<i>Weighted Shares Outstanding</i>				
Basic and diluted	47,199	46,941	47,197	46,806
<i>Basic and diluted earnings per share</i>				
Basic and diluted net income (loss) per share GAAP	(\$0.18)	(\$0.02)	(\$0.30)	(\$0.03)
Basic and diluted net income (loss) per share non-GAAP	(\$0.18)	(\$0.04)	(\$0.30)	(\$0.06)

The following table presents a reconciliation of reported net income (loss) for the three and six months ended January 31, 2019 and 2018, 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,	
	2019	2018	2019	2018
GAAP net loss	\$ (8,408)	\$ (901)	\$ (14,389)	\$ (1,541)
Plus (minus):				
Depreciation and amortization	768	786	1,534	1,535
Interest income	(227)	(185)	(501)	(342)
Benefit for income taxes	-	(1,097)	-	(1,097)
EBITDA	<u>\$ (7,867)</u>	<u>\$ (1,397)</u>	<u>\$ (13,356)</u>	<u>\$ (1,445)</u>
Adjusted for:				
Legal settlements, net	-	-	-	-
Legal fees associated with settlements	-	-	-	-
Separation payments	-	-	-	-
Adjusted EBITDA	<u>\$ (7,867)</u>	<u>\$ (1,397)</u>	<u>\$ (13,356)</u>	<u>\$ (1,445)</u>