

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 10, 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock \$0.01 par	ENZ	New York Stock Exchange

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 10, 2019, Enzo Biochem, Inc. (the "Company") issued a press release announcing its operating results for its third fiscal quarter ended April 30, 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 June 10, 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: June 10, 2019

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



news
release

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FOR IMMEDIATE RELEASE

ENZO BIOCHEM REPORTS FISCAL THIRD QUARTER AND NINE MONTHS OPERATING RESULTS

Company Outlines Three Prong Short-Term Value Creation and Growth Strategy

Intellectual Property Settlements Generate Approximately \$30 Million in Cash in the Third Quarter

NEW YORK, NY, June 10, 2019 -- Enzo Biochem, Inc. (NYSE:ENZ), a n integrated life sciences company focused on commercializing innovative diagnostic and therapeutics products, today reported results for the fiscal quarter and nine months ended April 30, 2019. The Company updated the market on the progress of its short-term growth and profitability initiatives designed to unlock value.

Financial Results

- Third quarter net income was \$22.3 million, or \$0.47 per share including \$28.9 million in net legal settlements, on revenues of \$19.7 million. This compared to a year ago net loss of \$3.0 million, or \$0.06 per share when there were no similar settlements. On a sequential basis, revenue increased nearly 2%, and Non-GAAP net loss improved by approximately \$1.7 million, or 21%.
- Fiscal third quarter 2019 results reflect the combined impact of continuing reduced insurance reimbursement payments at rates lower than a year ago and reduced genetic test volume, while total diagnostic testing volume, measured by the number of accessions, was up 1% year over year and 3% sequentially to the second fiscal quarter due to increases in esoteric testing. Cash and cash equivalents at the end of the quarter was \$64 million and working capital was \$71 million.

Strategic Short-Term Initiatives

The Company reiterated the three core pillars of its value creation strategy which are all expected to have a positive impact by the end of calendar 2019.

Forming Strategic Relationships for Diagnostic Growth

Enzo is in active discussions with several leading global life sciences and medical device companies, as well as manufacturers of automated systems to develop strategic relationships in three key platforms pioneered by Enzo's proprietary products and intellectual property: molecular diagnostics, immunohistochemistry and the Company's Elisa platform. The discussions involve developing long-term relationships in automation and manufacturing, distribution and marketing and product sales.

Enzo's goal is to announce at least one of these relationships by the end of calendar 2019.

Building a New Model for the Diagnostic Marketplace

As a lower cost and vertically integrated manufacturer and service provider of molecular testing in the US, Enzo is rolling out a new business model for its labs to labs business whereby Enzo will serve as the "central capability" for smaller labs, capitalizing on its scale in high value and lower cost operations, proprietary intellectual property and products, decades of innovation and commitment to medical solutions.

Response of labs has been positive and Enzo anticipates announcing the formal roll out of this program by the end of calendar 2019.

Return to Operating Profitability and Growth in the Lab Segment

Enzo is focused on returning its lab segment to profitability and growth in three significant ways. Enzo is working aggressively to control operational costs in its lab segment, which has been negatively impacted by a declining reimbursement environment, through, amongst others, consolidating supply chain functions, as well as reorganization and alignment of customer support teams to create greater efficiencies without sacrificing service levels. The Company is also developing a series of compelling growth initiatives that capitalize on our strong intellectual property and integrated approach to manufacturing, which can be offered as either product or services. Finally, Enzo will continue to pursue, through licensing, business development and litigation, revenue opportunities derived from strong intellectual property development and innovation throughout the Company. While Enzo cannot predict the outcome of ongoing patent infringement litigation, the Company believes that its history of settlements and business relationships will continue to help fund our business and growth initiatives.

We expect to see meaningful sequential quarterly cost reduction improvement throughout fiscal 2020, and assuming no further changes in reimbursement programs, with a return to operating profitability at the labs in early calendar 2020.

Elazar Rabbani, Chairman and Chief Executive Officer, Comments:

“Enzo is poised to leverage and capitalize on our deep-rooted, proprietary technology, product development and intellectual property portfolio in very real, short-term strategic initiatives designed to unlock the value we know exists across our business. The Board and the management team are aligned in our belief that we can be an agent of change and transformation in our industry, delivering tangible benefits for our customers, partners, colleagues and shareholders. We know there is tremendous value in our Company not reflected in today’s market and believe that the programs highlighted in today’s announcement underscore our commitment in our business and its prospects.

We are outlining our three-prong value creation strategy: developing strategic relationships, building a new market for the diagnostic marketplace and further reducing operating costs.

We are focused on growth, in both the short and long-term. We are gratified by the interest we are receiving from a number of industry leaders in the life sciences and medical device industries to engage in discussions with us. These companies recognize our vision for the future of the diagnostic marketplace and our commitment to platforms and services.

This growth strategy embraces development of our high volume and lower cost tests used in connection with our proprietary and affordable open system platforms capable of high throughput to improve financial margins at clinical laboratories. We believe we are uniquely positioned to drive change.

At the same time, we have launched an intensive cost cutting and heightened efficiency program that will achieve greater integration of our Company’s financial and operating performances. We anticipate sequential quarterly improvement and a return to operating profitability in our lab in early calendar 2020.

The Company continues to operate on solid financial footing – with, at April 30, 2019, over \$64 million in cash and cash equivalents and working capital of almost \$71 million, allowing us to comfortably fund the realistic goals we have set out for Enzo.”

Third Quarter Operating Results

- Total revenues were \$19.7 million, compared to \$25.2 million in the prior year, a decrease of \$5.5 million or 22%, while improving nearly 2% sequentially from the second fiscal quarter of 2019. Clinical services revenues were \$11.7 million, compared to \$17.7 million in the prior year, a decrease of \$6.0 million, largely due to the aforementioned reduced insurance reimbursement payments, insurance company claims rejections and changes to medical and procedural requirements for genetic testing by payors. Enzo’s AMPIPROBE® woman’s health panel has increased in volume each quarter since its launch last fiscal year. Product revenue was \$7.9 million compared to \$7.4 million in the prior year. Product gross profit was \$4.5 million and gross margins were 57%, a 15% increase over the prior year period.
 - Clinical services revenues for the three and nine months ended April 30, 2018, 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
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provision for uncollectable accounts receivable, and amounted to \$0.8 million and \$0.4 million in the three months ended April 30, 2019 and 2018, respectively, and \$2.0 million in both nine month periods.

- Consolidated gross margins were 27% compared with 42% in the prior year, and up from 24% from the second fiscal quarter of 2019. Clinical services gross margins were 7% compared to 38% a year ago and 1% lower sequentially to last quarter. Gross margins in the current year period were negatively impacted by lower reimbursement revenue from Clinical Services. Products gross margin was 57% compared to 53% in the prior year period and 50% in the preceding quarter.
- Operating expenses totaled \$11.9 million, compared to \$13.5 million a year ago, a decrease of \$1.6 million or 12%. Total legal expenses were \$0.3 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 essentially flat year over year.
- During the quarter, the Company recorded legal settlements and licensing payments, net of \$28.9 million related to a patent infringement and contract case in New York and an unrelated patent infringement case in Delaware.
- GAAP net income was \$22.3 million or \$0.47 per share compared to a GAAP net loss of \$3.0 million or \$0.06 per share in the prior year. The non-GAAP net loss was \$6.7 million or \$0.14 per share compared to a non-GAAP net loss of \$3.0 million or \$0.06 per share a year ago. EBITDA in the quarter was \$22.8 million and adjusted EBITDA was a loss of \$6.1 million.

Nine-month Operating Results

Total revenues were \$60.2 million compared to \$78.3 million in the prior year, a decline of \$18.1 million or 23% lower than prior year. Gross profit totaled \$16.9 million, compared to \$32.7 million a year ago, with gross margins of 28% and 42%, respectively. SG&A of \$33.3 million increased a modest \$0.3 million over the prior year. Legal expenses were \$2.7 million, down from \$3.8 million a year ago. The GAAP net income and Non-GAAP net loss totaled \$7.9 million, or \$0.17 per share and \$21 million or \$0.45 per share, respectively. EBITDA for the nine months ended April 30, 2019 was \$9.5 million and Adjusted EBITDA was a loss of \$19.4 million.

Conference Call

The Company will conduct a conference call Tuesday, June 11, 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 June 25, 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 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 April 30 (unaudited)		Nine months ended April 30, (unaudited)	
	2019	2018	2019	2018
Total revenues	\$ 19,662	\$ 25,230	\$ 60,249	\$ 78,258
Gross profit	\$ 5,302	\$ 10,673	\$ 16,902	\$ 32,663
Gross profit %	27%	42%	28%	42%
Income (loss) before income taxes	22,265	(3,016)	7,876	(5,654)
Benefit for income taxes	-	-	-	1,097
Net income (loss)	\$ 22,265	\$ (3,016)	\$ 7,876	(4,557)
Basic net income (loss) per share	\$0.47	(\$0.06)	\$0.17	(\$0.10)
Diluted net income (loss) per share	\$0.47	(\$0.06)	\$0.17	(\$0.10)
Weighted average shares outstanding - basic	47,452	47,073	47,259	46,895
Weighted average shares outstanding - diluted	47,555	47,073	47,364	46,895
	4/30/2019 (unaudited)	7/31/2018 (unaudited)		
Cash and cash equivalents (including restricted cash \$750)	\$64,802	\$60,041		
Working capital	\$70,451	\$63,014		
Stockholders' equity	\$90,999	\$81,121		
Total assets	\$111,000	\$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 nine months ended April 30, 2019 and 2018:

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

	Three months ended		Nine months ended	
	April 30		April 30,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
Reported GAAP net income (loss)	\$ 22,265	\$ (3,016)	\$ 7,876	\$ (4,557)
Adjusted for:				
Legal settlements, net	(28,925)	-	(28,925)	-
Benefit for income taxes	-	-	-	(1,097)
Non-GAAP net loss	<u>\$ (6,660)</u>	<u>\$ (3,016)</u>	<u>\$ (21,049)</u>	<u>\$ (5,654)</u>
<i>Weighted Shares Outstanding</i>				
Basic	47,452	47,073	47,259	46,895
Diluted	47,555	47,073	47,364	46,895
<i>Basic and diluted earnings per share</i>				
Basic and diluted net income (loss) per share GAAP	\$0.47	(\$0.06)	\$0.17	(\$0.10)
Basic and diluted net income (loss) per share non-GAAP	(\$0.14)	(\$0.06)	(\$0.45)	(\$0.12)

The following table presents a reconciliation of reported net income (loss) for the three and nine months ended April 30, 2019 and 2018, respectively 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,	
	<u>2019</u>	<u>2018</u>	<u>2019</u>	<u>2018</u>
GAAP net income (loss)	\$ 22,265	\$ (3,016)	\$ 7,876	\$ (4,557)
Plus (minus):				
Depreciation and amortization	838	815	2,372	2,350
Interest income	(258)	(227)	(759)	(569)
Benefit for income taxes	-	-	-	(1,097)
EBITDA	<u>\$ 22,845</u>	<u>\$ (2,428)</u>	<u>\$ 9,489</u>	<u>\$ (3,873)</u>
Adjusted for:				
Legal settlements, net	<u>(28,925)</u>	<u>-</u>	<u>(28,925)</u>	<u>-</u>
Adjusted EBITDA	<u>\$ (6,080)</u>	<u>\$ (2,428)</u>	<u>\$ (19,436)</u>	<u>\$ (3,873)</u>