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): **October 15, 2019**

Enzo Biochem, Inc.
(Exact Name of Registrant as Specified in Its Charter)

New York
(State or Other Jurisdiction of Incorporation)

001-09974	**13-2866202**
(Commission File Number)	(IRS Employer Identification No.)
527 Madison Avenue **New York, New York**	**10022**
(Address of Principal Executive Offices)	(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	Name of Each Exchange on Which Registered
Common Stock, $.01 par value	ENZ	The New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 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 October 15, 2019, Enzo Biochem, Inc. (the "Company") issued a press release announcing its operating results for its fourth fiscal quarter ended July 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 October 15, 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: October 15, 2019

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

news release

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

ENZO BIOCHEM REPORTS FISCAL FOURTH QUARTER AND FULL YEAR FINANCIAL RESULTS

Company's Vertically Integrated Life Sciences and Labs Business Generates Breakthrough Diagnostic Testing Approvals and Services in Rapidly Expanding Markets

Company Progressing on Three-Pronged Value Creation and Growth Strategy; Engages Lazard to Assist in Strategic Relationship Exploration and New Venture Creation

NEW YORK, NY, October 15, 2019 -- Enzo Biochem, Inc. (NYSE:ENZ), an integrated diagnostics, clinical lab, and life sciences company focusing on delivering and applying advanced technology capabilities to produce affordable, reliable products and services that enable its customers to meet their clinical needs, today reported results for the fiscal fourth quarter and year ended July 31, 2019.

The Company reports progress in the three core pillars of its value creation strategy: strategic relationships for growth, creating a new paradigm for the laboratory diagnostic marketplace and returning to operating profitability and growth in the lab segment of the business. In furtherance of these objectives, Enzo has retained Lazard to assist in the previously announced initiative to form strategic relationships or new venture creation across the Company's four core platforms: molecular, immunohistochemistry, cytology and immunology.

Highlights for the Quarter and Full Year

- Enzo's vertically integrated research and development program, harnessing the collective benefits of its laboratory and diagnostic operations, continued to deliver substantial technological advances. By leveraging its broad intellectual property portfolio and manufacturing expertise, Enzo is able to create novel products and platforms with the potential to be transformative to diagnostic products and services.

- In September, Enzo Clinical Labs, Inc., received New York State Department of Health approval for its AMPIPROBE® HBV viral load monitoring assay for Hepatitis B virus (HBV) based on performance versus an FDA-approved competitive product. Enzo's growing portfolio in the viral load monitoring market includes previous New York State Department of Health approval for a viral load monitoring assay for Hepatitis C virus (HCV) and a viral load monitoring assay under development for human immunodeficiency virus (HIV). The Company's expanding menu allows Enzo to provide one of the most comprehensive panels for sexually transmitted infections (STI) testing, a rapidly growing healthcare segment where reported common STIs in the US have increased for the 5th consecutive year.

- Approval of the HBV assay follows the July announcement of New York State Department of Health approval for Gonorrhea and Chlamydia tests for extragenital specimens, and the announcement that Enzo was creating a direct to consumer testing business for STIs. Furthermore, the Company is developing an additional test for HPV testing in multiple sample types.

- The Company was issued 74 patents worldwide during fiscal year 2019. Notably, the Company was issued U.S. Patent No. 10,323,272 entitled "Nucleic acid probes for in situ hybridization" on June 18, 2019, which is directed to a new probe technology that allows for significantly more cost effective, simple and scalable processes across the multi-billion dollar diagnostic testing, drug development and academic research marketplaces. The probes can be used to detect clinically relevant genomic targets with high sensitivity in cell samples and biopsy tissue. Compared to competitive probes, Enzo's novel probe will lower cost, decrease complexity, save time and avoid disruptions of sample integrity.

- In fiscal year 2019, Enzo's Life Sciences and laboratory divisions invested approximately $10 million in strategic growth initiatives such as developing a Good Manufacturing Practice (GMP) Lab, expanding strategic salesforce and marketing practices, and ramping up R&D and Lab Developed Test initiatives. This investment is already resulting in cost reductions for the laboratory and diagnostics operations. Currently, approximately $4M of the Company's revenue is associated with strategic growth initiatives.

- Over the past 5 years, Enzo has systematically introduced its technology onto its clinical production floor through LDTs validated by the New York State Department of Health. Over this period, Enzo has run over 100,000 of these Enzo LDTs, resulting in savings of over $5M by substituting third-party vendor tests with Enzo's own internally developed tests. Enzo expects the annual savings from these tests to increase in the next fiscal year to $3M and to $5M in the following year.

Elazar Rabbani, PhD., Chairman and Chief Executive Officer, Comment:

"Enzo's structure and business strategy represent the culmination of years of extensive planning and productive work. The Company has the ability to offer low cost, high performance products and services in molecular diagnostics. While reimbursement pressures facing diagnostic labs

remain a headwind in the short term, our unique offering positions us well to capitalize on these secular trends over the long term. Our pioneering work in genomic analysis coupled with our extensive patent estate and enabling platforms have positioned the Company to continue to play an important role in the rapidly growing molecular medicine marketplaces.

“Enzo technology solutions and platforms and unique operational structure are designed to reduce overall healthcare costs for both government and private insurers. Our proprietary technology platforms reduce our current and prospective customers’ needs for multiple, specialized instruments, and offer a variety of high throughput capabilities together with a demonstrated high level of accuracy and reproducibility. Our genetic test panels are focused on large and growing markets primarily in the areas of personalized medicine, women’s health, infectious diseases and genetic disorders.

“Our Company continues to make significant progress toward unlocking shareholder value, guided by the three core pillars of our strategy – strategic relationships, creating a new paradigm for the laboratory and diagnostic marketplaces, and returning to operating profitability and lab segment growth. One of our chief goals, as we’ve stated previously, is to achieve clinical laboratory profitability despite a very challenging reimbursement environment. We feel confident we are on track towards accomplishing this objective.”

“Testing activity and volume is up sequentially this quarter, as overall lab revenues grew 11% in the fourth quarter vs. the third quarter of fiscal 2019. Our expanding panel of STI testing, enhanced by a recent diagnostic test approval, is one of the most extensive available, including the highly comprehensive women’s health diagnostic panel.

“Our diagnostic products, developed and manufactured at Enzo Life Sciences, and formatted and validated at Enzo Clinical Labs, are perfect examples of the integrated nature of our Company’s businesses and the value and leverage we generate from these synergies. It would be extremely difficult and costly to replicate as two separate units and more importantly, this combination demonstrates the real time benefits that labs around the country can achieve as the result of our work. In an adverse laboratory-wide climate of shrinking margins and declining profitability, our proprietary platforms that offer high sensitivity, compatibility with existing systems and low cost/higher margins, are tailor-made for both product sales and the lab-to-lab growth opportunities that we are actively pursuing.

“This active, commercial installation in our Lab is attracting increasing attention among major as well as smaller players who are showing meaningful enthusiasm for our platforms and products. Discussions with leading life sciences and medical device companies as well as manufacturers of automated systems of our molecular diagnostics, immunohistochemistry and ELISA platform are progressing well. We expect to update the market by the end of the calendar year on these discussions.”

Fourth Quarter Operating Results

- Total revenues amounted to $21.0 million, compared to $22.8 million in the year ago period, a decline of 8% reflecting new, sharply lower industry-wide Protecting Access to Medicare Act reimbursement rates; sequential total testing volume increased 4%. Sequentially, clinical laboratory services revenues increased 11% from the prior quarter's $11.8 million, while product revenues for the quarter were up 3% over the prior year period as a result of the successful implementation of new marketing and sales initiatives. Lab revenues declined to $13.1 million, from $15.1 million in the year ago period, due to the reduced insurance reimbursement payments and changes to medical and procedural requirements for genetic testing by payors. Overall, gross profit improved sequentially by 21%, to $6.3 million, with clinical lab gross profit more than doubling to $1.8 million, from $0.8 million, and product gross margin increasing 2% to $4.6 million.
- As noted previously, clinical services revenues for the fourth quarter and full year ended July 31, 2019, reflect adoption of new revenue recognition accounting 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 uncollectible accounts receivable, and amounted to $3.1 million and $3.7 million, respectively in the fiscal years ended July 31, 2019 and 2018, and $1.0 million and $1.7 million for the respective fourth quarter periods.
- Consolidated gross margins for the quarter of 30.3% compared with 35.2% a year ago, and up 300 basis points sequentially. Clinical services gross margins were 13.8% compared to 25.4% a year ago and sequentially improved from in the third quarter. The improvement reflected both higher testing volume and enhanced efficiency. Product gross margin for the quarter increased to 58%, from 54%, and sequentially was up 200 basis points.
- Operating expenses declined 12%, or $1.6 million to $12.0 million year over year, and sequentially remained flat, adjusted for net legal settlements. Legal fee expenses declined by $1.0 million compared to the fourth quarter last year, to $0.3 million, and sequentially were flat in both periods.
- GAAP net loss was ($5.4) million, or ($0.11) per share, an improvement of 7% compared with a year ago quarter net loss of ($5.8) million, or ($0.12) per share. The non-GAAP net loss was ($5.4) million, compared to ($5.8 million) a year ago and ($6.7) million in the preceding quarter. On a per share basis, the non-GAAP loss equaled ($0.11), compared with ($0.12) a year ago and ($0.14) in 3Q19 on an adjusted basis. EBITDA loss in the quarter and a year ago approximated ($5.0) million and ($5.3) million respectively and decreased sequentially from ($6.1) million on an adjusted basis.

Full Year Operating Results

Total revenues were $81.2 million compared to $101.0 million, a year ago, a decline of 20%, and as noted earlier reflected newly instituted reduced reimbursement payments, insurance company claims rejections and changes to medical and procedural requirements for genetic testing by

payors. Gross profit was $23.2 million, compared to $40.7 million the prior year, with gross margins at 28.6% and 40.3%, respectively. Legal fees declined by 41%, to $3.0 million, and tailed off sharply towards year end, while SG&A declined to $44.2 million from $44.5 million. GAAP net income amounted to $2.5 million, or $0.05 per diluted share, compared to a net loss of ($10.3) million, or ($0.22) per share, a year earlier. Non-GAAP net loss amounted to ($26.4) million, net of legal settlements, compared to a non-GAAP fiscal 2018 net loss of approximately ($11.4) million. EBITDA was $4.5 million, compared to year ago EBITDA loss of ($9.1) million.

At year-end, cash, cash equivalent and restricted cash totaled $60.9 million, and working capital amounted to $65.4 million.

Conference Call

The Company will hold a conference call on Tuesday, October 15, 2019, at 4:30 PM E.T. To listen to the conference call dial 1-888-459-5609. International callers can dial 1-973-321-1024. When prompted, use PIN number 4196818.

Interested parties may also listen over the Internet at: https://tinyurl.com/yxb9r46c

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 October 29, 2019. 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 4196818.

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 406 issued patents worldwide and over 75 pending patent applications, along with extensive enabling technologies and platforms.

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, 2019. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that could materially affect actual results. The Company disclaims any obligations to update any forward-looking statement as a result of developments occurring after the date of this press release.

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

Selected operations data:	Three months ended July 31, (unaudited)		Twelve months ended July 31, (unaudited)	
	2019	**2018**	**2019**	**2018**
Total revenues	$ 20,921	$ 22,755	$ 81,170	$ 101,013
Gross profit	$ 6,346	$ 7,999	$ 23,248	$ 40,628
Gross profit %	30%	35%	29%	40%
Income (loss) before income taxes	(5,387)	(5,764)	2,489	(11,418)
Benefit for income taxes	-	-	-	1,097
Net income (loss)	$ (5,387)	$ (5,764)	$ 2,489	(10,321)
Basic net income (loss) per share	($0.11)	($0.12)	$0.05	($0.22)
Diluted net income (loss) per share	($0.11)	($0.12)	$0.05	($0.22)
Weighted average shares outstanding - basic	47,557	47,173	47,351	46,972
Weighted average shares outstanding - diluted	47,557	47,173	47,476	46,972

Selected balance sheet data:	**7/31/2019 (unaudited)**	**7/31/2018 (unaudited)**
Cash and cash equivalents (including restricted cash $750)	$60,896	$60,041
Working capital	$65,444	$63,014
Stockholders' equity	$86,028	$81,121
Total assets	$106,640	$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 twelve months ended July 31, 2019 and 2018:

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

	Three months ended July 31,		Twelve months ended July 31,	
	2019	2018	2019	2018
Reported GAAP net income (loss)	$ (5,387)	$ (5,764)	$ 2,489	$ (10,321)
Adjusted for:				
Legal settlements, net	-	-	(28,925)	-
Benefit for income taxes	-	-	-	(1,097)
Non-GAAP net loss	$ (5,387)	$ (5,764)	$ (26,436)	$ (11,418)
Weighted Shares Outstanding				
Basic	47,557	47,173	47,351	46,972
Diluted	47,557	47,173	47,476	46,972
Basic and diluted earnings per share				
Basic and diluted net income (loss) per share GAAP	($0.11)	($0.12)	$0.05	($0.22)
Basic and diluted net income (loss) per share non-GAAP	($0.11)	($0.12)	($0.56)	($0.24)

The following table presents a reconciliation of reported net income (loss) for the three and twelve months ended July 31, 2019 and 2018, respectively to EBITDA and Adjusted EBITDA:

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

	Three months ended July 31,		Twelve months ended July 31,	
	2019	2018	2019	2018
GAAP net income (loss)	$ (5,387)	$ (5,764)	$ 2,489	$ (10,321)
Plus (minus):				
Depreciation and amortization	664	784	3,036	3,149
Interest income	(296)	(283)	(1,056)	(853)
Benefit for income taxes	-	-	-	(1,097)
EBITDA	$ (5,019)	$ (5,263)	$ 4,469	$ (9,122)
Adjusted for:				
Legal settlements, net	-	-	(28,925)	-
Adjusted EBITDA	$ (5,019)	$ (5,263)	$ (24,456)	$ (9,122)