

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 9, 2021**

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	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 June 9, 2021, Enzo Biochem, Inc. (the "Company") issued a press release announcing its operating results for its third fiscal quarter ended April 30, 2021. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

99.1 [Press Release of Enzo Biochem, Inc., dated June 9, 2021](#)

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.

Date: June 11, 2021

By: /s/ David Bench
David Bench
Chief Financial Officer



Enzo Biochem Reports Third Quarter Fiscal 2021 Results

- Total third quarter revenue of \$32.8 million, a record quarterly high, increased 94% year-over-year
- Consolidated quarterly gross margin was 49% versus 26% in the previous year period, confirming Enzo's vertically integrated approach can continue to drive healthy margins in a post pandemic environment
- Third consecutive quarter of positive earnings and EPS for the Company
- Adjusted quarterly EBITDA of \$2.7 million and year to date adjusted EBITDA of \$8.2 million
- EPS amounted to \$0.04 per share, compared to a year ago loss of \$(0.21)
- Company proceeding with previously announced strategic initiatives

**Conference call and live webcast scheduled for today,
Wednesday, June 9, 2021 at 4:30 PM (ET).**

NEW YORK, June 08, 2021 (GLOBE NEWSWIRE) -- Enzo Biochem, Inc. (NYSE:ENZ), a leading biosciences and diagnostics company, today reported operating results for the third quarter ended April 30, 2021 and provided a business update on recent corporate and operational developments.

Enzo announced a set of strategic objectives in 2019 to strengthen its financial and operational performance within the rapidly changing diagnostic testing market. As a vertically integrated end-to-end diagnostic company leveraging control of its own supply chain in conjunction with its proprietary platforms, the Company was able to expand control over operational performance to achieve new levels of success. Enzo validated this approach during COVID-19 and will continue executing this underlying strategy moving into a post pandemic business environment.

"Our performance during the last quarter was particularly impressive as our team delivered another solid quarter of \$32.8 million in revenue with significant profitability during an extraordinary period of transformation for the lab testing market," said Elazar Rabbani, Ph.D., Chairman. "Our company's strength amidst many challenges in a difficult health environment is indicative of the strength of our determined strategy that enables Enzo to operate on a truly unique integrated basis. It provides us with consummate capabilities to achieve research advancements, operating efficiencies, and remarkable product innovation and delivery – a combination few companies can claim. We are especially proud of our dedicated team of people who have remained steadfast in advancing our mission in this environment and fueling our continued success."

"I am especially proud of the strategic foresight and execution of our management team as they positioned the Company to opportunistically address the turbulent times of COVID-19. Now, as COVID-19 testing volumes will normalize, Enzo's fully integrated diagnostic approach will evolve to address broader market needs and continue to generate value for our shareholders. As a result of this collective effort, we are proud to announce that Enzo's financial situation has improved considerably from an operating loss of \$9.7 million in Q3 2020 to an operating profit of \$2.0 million in Q3 2021," Dr. Rabbani continued.

As industry experts have indicated, Enzo management fully expects COVID-19 volumes to decline in the quarters ahead. The percentage of Americans who are vaccinated has increased dramatically. During the Company's last quarter, vaccination rollout across the United States gained significant momentum from just 32 million vaccines administered in January to 240 million at the end of April and 300 million administered by the first week of June. In the face of this rapidly changing diagnostics environment, Enzo remains well positioned for continued success.

Enzo's go-forward commercial strategy is clear. The Company is leveraging its higher margin testing model demonstrated during COVID-19 to other markets such as women's health, sexually transmitted diseases and other testing needs based on the applications and versatility of the GENFLEX® molecular platform. The platform is being used internally at the Company's facilities and is in the early stage of commercialization into laboratories, academic institutions, and other commercial entities throughout the country.

Enzo is currently validating test menus and panel extensions to drive utility in the high-volume molecular testing space through deployment of the Company's internal sales and marketing operations as well as with industry partners. These include chlamydia, gonorrhea, trichomonas, human papillomavirus vaccine (HPV) and Enzo's full women's health panel. The Company will follow this molecular diagnostic test rollout with cost-effective, flexible solutions involving other technologies and platforms including cytology, immunology, immunohistochemistry, and other key clinical areas.

"Our open system approach allows for the highest levels of flexibility and adaptability in the post COVID-19 environment, and we have actively engaged our partners, vendors and customers in maximizing the potential of our unique operational structure," said Barry Weiner, Enzo's President. "While vaccinations are increasing, demand for testing services will remain in place in the many months and years ahead. Our objective as the health markets transition is to remain flexible and agile to maximize opportunities related to COVID while expanding our focus to address many new and important testing needs."

As announced in the previous quarter, the Company's strategic initiatives and succession planning are proceeding. The Company, management and board are working in unison to translate Enzo's capabilities to benefit all shareholders and enhance shareholder value.

Enzo's focus remains on achieving further efficiencies and enhanced integration while investigating additional commercial opportunities. The Company is determined to promote top line growth while targeting profitability from operations in the immediate future.

Third Quarter 2021 and Recent Business Highlights

- Received Food and Drug Administration ("FDA") clearance for its AMPICOLLECT™ Sample Collection kit (manufactured under GMP) for distribution under Emergency Use Authorization. The AMPICOLLECT™ Sample Collection kit is now available for sample collection for COVID-19 testing protocols in the United States.

- Enzo's Loop RNA probe was featured in an independent publication of work derived from Enzo's scientific collaborators in conjunction with Enzo scientists that details improvements regarding in situ hybridization reflecting higher sensitivity and lower background noise when compared to leading commercially available technologies. Enzo's probes uniquely identify a single genetic sequence within a cell and without destroying the cell structure. This allows for better medical interpretation, accelerated drug development and improved research capabilities. This innovative technology may reduce the risk of false positives and false negatives for early stage detection of HPV and potentially other RNA based infections.
- Enzo is integrating its campuses to include GMP manufacturing, CLIA clinical laboratory, research and development, and sales and marketing capabilities, all within four adjacent buildings at our Farmingdale facilities. This integration includes the forthcoming closure of our Ann Arbor, Michigan manufacturing facilities this summer.
- Received a U.S. Patent for polyclonal antibodies against osteoporosis drug target sclerostin. U.S. Patent No. 10,899,827 entitled "Antibodies Specific for Sulfation Sites of Sclerostin" is a member of a broader U.S. and international patent family that also includes issued patents and pending patent applications for therapies including monoclonal antibodies and small synthetic peptides used to inhibit sclerostin in the treatment of bone disorders such as osteoporosis.

Third Quarter 2021 Financial Results

- Total third quarter revenues amounted to \$32.8 million, a 94% improvement over \$16.9 million a year ago and a \$1.3 million improvement sequentially when the peak months of the pandemic reduced demand for non-COVID diagnostic testing services and curtailed physician visits, and caused a dramatic slowdown in economic and business activity. By contrast, the recent quarter reflects increased activity, including growing demand for testing services and a steady improvement in sales of products and services.
- Consolidated gross margin amounted to 49%, compared to 26% a year ago. Operating income totaled \$2.1 million compared to a year-ago operating loss of \$9.7 million, an \$11.8 million YOY improvement.
- Reflecting heightened activity, particularly in testing, Enzo Clinical Lab revenues totaled \$25.0 million, an increase of 139% from \$10.5 million in the third quarter last year. Gross margin in the ECL division was 49.1%, compared with 12.9% a year ago, largely due to improved product mix and continued cost-saving initiatives coming to fruition.
- Enzo Life Sciences revenue was \$7.8 million, an increase of 22% compared with \$6.4 million in the year ago period. Product orders have averaged over \$1,000 for the last three quarters. Gross margin was 48.4%, or 53% prior to intercompany eliminations, compared to 47.9% gross margin in the year ago period, slightly higher than the previous quarterly margins.
- Research and development expenses declined 28% to \$0.8 million, or 2.5% of total revenues, from \$1.1 million, or 6.8% of total revenues, in the year ago period. Selling, general and administrative expenses of \$12.1 million rose from \$11.1 million in year ago period, although SG&A margin significantly declined due to better fixed cost leverage as a result of vertical integration and cost efficiency measures.
- GAAP net income totaled \$2.0 million, or \$0.04 per share, compared with a loss of (\$9.9) million, or (\$0.21), in the year-ago quarter, an improvement of almost \$12 million. Adjusted EBITDA in the quarter totaled \$2.7 million, versus an adjusted EBITDA loss of (\$7.0) million in the third quarter of 2020. The year-over-year increase was driven mainly by improvement in gross margin (from COVID-19 testing and lower reagent and reference lab costs) and lower SG&A expenses as a percent of revenues from headcount efficiencies, lower intangibles amortization, and reduced travel.
- Cash, cash equivalents and marketable securities amounted to \$45.1 million as of April 30, 2021. Cash and marketable securities were slightly lower as compared to July 31, 2020 due to investments in inventory, higher A/R and capital expenditures and lower accounts payable. Working capital amounted to \$42.1 million as of April 30, 2021, compared to \$36.0 million on July 31, 2020. As of April 30, 2021, the Company had 48.5 million shares outstanding.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, June 9, 2021, at 4:30 pm, Eastern Standard Time, to review the operational, corporate, and financial highlights. To participate in the conference call, please dial the following numbers prior to the start of the call or click the webcast link below to participate over the internet:

Domestic: 877-407-0792
 International: 201-689-8263
 ConferenceID: 13719822
 Webcast: <http://public.viavid.com/index.php?id=144968>

A replay of the call will be available via webcast for on-demand listening shortly after completion of the call on the Investor Relations section of the Company's website, <https://www.enzo.com>, and will remain available for approximately 90 days. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

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 investor relations section of the Company's website (<https://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.

Forward-Looking Statements

Except for historical information, the matters discussed in this 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, 2020. 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 release.

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

<i>Selected operations data:</i>	Three months ended		Nine months ended	
	April 30,		April 30,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Total revenues	\$ 32,797	\$ 16,903	\$ 92,918	\$ 56,494
Gross profit	\$ 16,046	\$ 4,425	\$ 43,764	\$ 15,920
Gross profit %	48.9%	26.2%	47.1%	28.2%
Income (loss) before income taxes	2,006	(9,860)	4,607	(25,195)
Net income (loss)	\$ 2,006	\$ (9,860)	\$ 4,607	\$ (25,195)
Basic net income (loss) per share	\$ 0.04	\$ (0.21)	\$ 0.10	\$ (0.53)
Diluted net income (loss) per share	\$ 0.04	\$ (0.21)	\$ 0.10	\$ (0.53)
Weighted average shares outstanding - basic	48,391	47,780	48,097	47,668
Weighted average shares outstanding - diluted	48,788	47,780	48,201	47,668

<i>Selected balance sheet data:</i>	4/30/2021	7/31/2020
	(unaudited)	(unaudited)
Cash and cash equivalents including restricted cash of \$750 and marketable securities	\$ 45,021	\$ 48,615
Working capital	\$ 42,127	\$ 35,964
Stockholders' equity	\$ 64,967	\$ 58,381
Total assets	\$ 113,623	\$ 112,538

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, 2021 and 2020:

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

	Three months ended April 30,		Nine months ended April 30,	
	2021	2020	2021	2020
Reported GAAP net income (loss)	\$ 2,006	\$ (9,860)	\$ 4,607	\$ (25,195)
Adjusted for:				
Contested proxy expenses	-	1,547	1,973	4,042
Separation expenses	-	235	-	235
Non-GAAP net income (loss)	\$ 2,006	\$ (8,078)	\$ 6,580	\$ (20,918)
<i>Weighted Shares Outstanding:</i>				
Basic and diluted	48,391	47,780	48,097	47,668
Basic and diluted	48,788	47,780	48,201	47,668
<i>Basic and diluted earnings per share:</i>				
Basic net income (loss) per share GAAP	\$ 0.04	\$ (0.21)	\$ 0.10	\$ (0.53)
Diluted net income (loss) per share GAAP	\$ 0.04	\$ (0.21)	\$ 0.10	\$ (0.53)
Basic net income (loss) per share non-GAAP	\$ 0.04	\$ (0.17)	\$ 0.14	\$ (0.44)
Diluted net income (loss) per share non-GAAP	\$ 0.04	\$ (0.17)	\$ 0.14	\$ (0.44)

The following table presents a reconciliation of reported GAAP net income (loss) for the three and nine months ended April 30, 2021 and 2020, respectively to EBITDA and Adjusted EBITDA:

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

	Three months ended April 30,		Nine months ended April 30,	
	2021	2020	2021	2020
GAAP net income (loss)	\$ 2,006	\$ (9,860)	\$ 4,607	\$ (25,195)
Plus (minus):				
Depreciation and amortization	673	723	1,968	2,166
Interest expense (income)	(60)	(88)	40	(495)
EBITDA	\$ 2,619	\$ (9,225)	\$ 6,615	\$ (23,524)
Adjusted for:				
Foreign exchange loss (gain)	33	358	(428)	88
Contested proxy expenses	-	1,547	1,973	4,042
Separation expenses	-	235	-	235
Adjusted EBITDA	\$ 2,652	\$ (7,085)	\$ 8,160	\$ (19,159)