

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **December 9, 2020**

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-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition

On December 9, 2020, Enzo Biochem, Inc. (the “Company”) issued a press release announcing its operating results for its first fiscal quarter ended October 31, 2020. 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 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.

Item 9.01. Financial Statements and Exhibits.**(d) Exhibits.**

99.1 [Press Release of Enzo Biochem, Inc., dated December 9, 2020](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ENZO BIOCHEM, INC.

Date: December 14, 2020

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



ENZO BIOCHEM REPORTS FIRST QUARTER FISCAL 2021
FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- *Company reports \$28.7 million in revenue, exceeding revenue guidance by \$1.7 million and representing a 47% increase over sequential quarter and continued recovery and opportunity from impact of COVID-19 pandemic on business operations.*
- *Profitable quarter reflects positive EBITDA in excess of \$1 million and EPS of \$0.01.*
- *Company achieves significant progress in applying its assets to new market opportunities including point-of-care and direct-to-consumer offerings, and progress in ongoing strategic alignment.*
- *Industry leaders Ian Walters, MD and Mary Tagliaferri, MD join ENZO Board of Directors*

*Conference call and live webcast scheduled for today,
Wednesday, December 9, 2020 at 4:30 pm (ET)*

New York, NY, Dec. 9, 2020 (GLOBE NEWSWIRE) – Enzo Biochem, Inc. (NYSE:ENZ), a leading biosciences and diagnostics company, today reported financial results for the first quarter ended October 31, 2020 and provided a business update on recent corporate and operational developments.

“During this quarter we exceeded guidance and achieved profitability based on strong results that reflect our strategy to both streamline our operations and expand our product and platform capabilities as an integrated solutions provider of products and services in molecular diagnostics, immunoassays, cytology, and immunohistochemistry,” said Elazar Rabbani, PhD., Chairman and Chief Executive Officer of Enzo. “The rapid application of our proprietary GenFlex™ platform in response to the COVID-19 pandemic is the most recent reflection of the strength and flexibility of our molecular diagnostic capabilities. We have also worked aggressively to expand our operations to focus on more advanced, higher margin market opportunities that reflect the core strengths of Enzo and our team. Our portable microplate reader brings new potential capabilities in point-of-care testing to researchers and healthcare providers while our GoTestMeNow.com online portal represents a major step forward in bringing access to diagnostic testing directly to people who need it conveniently and quickly.”

“During this very strong quarter for our company we also added two outstanding industry leaders to our Board of Directors. Drs. Mary Tagliaferri and Ian Walters significantly expand the operational and commercial expertise of our Company’s board, particularly concerning companion diagnostics and other therapeutic opportunities. We continue to execute on our strategy to position Enzo as a leading vertically integrated end-to-end diagnostic company capitalizing on our multi-platform technologies and products now and in a post-COVID-19 environment,” said Barry Weiner, President of Enzo.

Operational Highlights:

- The Company posted another successful quarter of progress in implementing its strategic plan as a fully integrated end-to-end diagnostic product and service provider while navigating through a range of operational issues during the COVID-19 pandemic. Our first responder staff’s response and commitment has been noteworthy in our achieving these goals.
 - Enzo rapidly expanded capacity in reagent and consumable supply manufacturing while broadening its menu of tests on its GenFlex™ molecular diagnostic platform.
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- The Company continued its strategic operational expansion program including plans to double its facility footprint in Farmingdale, NY.
- Enzo completed the launch of the company's new portable microplate reader for use with its ELISA and assay kits to simplify laboratory workflow and expand POC capabilities in molecular diagnostics.
- In response to the continuing demand for improved access to molecular testing, Enzo introduced the GoTestMeNow™ online portal where consumers can directly order COVID-19 laboratory tests that are physician-approved, with plans to expand its use to other testing needs in 2021.
- Customer interest for Enzo's diagnostic platforms was strong following award of Emergency Use Authorization from the FDA highlighting the Company's integrated in-house capabilities and ability to develop high throughput sensitive detection platforms. These platforms support rapid scalability of testing for COVID-19 in a model that can be applied to future testing needs in multiple areas including upper respiratory panels, STDs and expanded women's health panels.

Corporate & Organizational Highlights:

- Enzo added industry veterans Mary Tagliaferri, MD and Ian B. Walters, MD to the Company Board of Directors.
- The Company planned and executed a range of operational and technological strategies to further its cost efficiencies.
- The Company is in the process of evaluating various business opportunities concerning Enzo's assets and capabilities for investment, partnerships, and commercial relationships.

Financial Highlights:

- Following a slow-down of operations at the beginning of the COVID-19 pandemic as a result of a sharp industry-wide fall-off in medical visits and the closure of many customer facilities, Enzo monthly revenues have registered steady gains since April. Quarterly revenues advanced 47% sequentially and 42% year-over-year during the period.
- The Company's current annual revenue run-rate is approximately \$115 million, representing more than 50% topline growth on an annualized basis.
- Gross margins in the Enzo Clinical Labs division reached 39% in the first quarter.
- 1Q21 net income was \$0.3 million compared to a net loss of \$7.6 million in the previous year's period, representing a \$7.9 million improvement over the corresponding period a year ago and a \$3.6 million improvement over the prior quarter.

First Quarter 2021 Financial Results

- Total first quarter revenue was \$28.7 million, compared to \$20.2 million in the first quarter last year, an increase of 42%, reflecting continuing expansion of operations and revenue following the slow-down associated with the impact of COVID-19 on the diagnostic testing sector. Consolidated gross margin was 42% compared to 28% a year ago.
- Enzo Clinical Lab revenue increased 66% to \$21.2 million from \$12.8 million in the first quarter 2020 and more than 55% sequentially. The year over year improvement was driven by volume growth to 300,000 accessions in the period versus approximately 200,000 in the previous year's first quarter. Net revenue per accession increased to more than \$69 per accession vs. \$62 in the previous year's period. Clinical services gross margin amounted to 39% up from 14% in the first quarter 2020, primarily due to testing mix as well as from ongoing cost-saving initiatives.
- Enzo Life Sciences revenue of \$7.4 million increased 27% from \$5.8 million in the previous quarter reflecting the beginning of a recovery from the impact of COVID-19 pandemic globally. Gross margin was 49%, compared to 52% in the previous year's quarter and 46% in the fourth quarter due to product mix and the impact of the COVID-19 pandemic.

- Research and development expenses decreased 29% to \$0.8 million (3% of total revenues) from \$1.1 million, (5% of total revenues), in the year ago period. Selling, general and administrative expenses of \$10.0 million (down to 35% of total revenue) declined from \$11.1 million (55% of total revenue) in year ago period, 10% lower.
- GAAP net income was \$0.3 million or \$0.01 per share versus a net loss of \$3.3 million or (\$0.07) per share last quarter and a loss of \$7.7 million, or (\$0.16) per share, in the year-ago quarter. Adjusted EBITDA in the quarter was \$1.0 million compared to an adjusted EBITDA loss of \$5.7 million in the previous year's first quarter. The year-over-year improvement was driven mainly by an increase in gross margin (from COVID-19 testing and lower reagent costs) and lower SG&A expenses from headcount efficiencies, as well as reduced intangibles amortization and travel.
- Cash and cash equivalents totaled \$46 million at the end of the first quarter, slightly lower than the \$48 at the end of the fiscal year due to increases in accounts receivable, inventory, and capital expenditures. Working capital improved to \$37 million from \$36 million at the end of the fiscal year. As of October 31, 2020, the Company had 47.9 million shares outstanding.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, December 9, 2020, 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
Conference ID:	13713236
Webcast:	http://public.viavid.com/index.php?id=142445

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, Inc.

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 475 issued patents worldwide along with extensive enabling technologies and platforms.

Forward-Looking Statements

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, revenue, 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 press release.

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

<i>Selected operations data:</i>	Three months ended October 31 (unaudited)	
	2019	2019
Total revenues	\$ 28,655	\$ 20,207
Gross profit	\$ 11,897	\$ 5,686
Gross profit %	42%	28%
Income (loss) before income taxes	299	(7,648)
Benefit for income taxes	-	-
Net income (loss)	\$ 299	\$ (7,648)
Basic net income (loss) per share	\$ 0.01	\$ (0.16)
Diluted net income (loss) per share	\$ 0.01	\$ (0.16)
Weighted average shares outstanding - basic	47,895	47,557
Weighted average shares outstanding - diluted	47,905	47,557
	10/31/2020	7/31/2020
	(unaudited)	(unaudited)
<i>Selected balance sheet data:</i>		
Cash and cash equivalents (including restricted cash of \$750)	\$ 46,664	\$ 48,615
Working capital	\$ 36,694	\$ 35,964
Stockholders' equity	\$ 59,018	\$ 58,381
Total assets	\$ 113,503	\$ 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 months ended October 31, 2020 and 2019:

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

	Three months ended October 31	
	2020	2019
Reported GAAP net income (loss)	\$ 299	\$ (7,648)
Adjusted for:		
Legal expenses related to contingencies	-	800
Contested proxy expenses	-	645
Non-GAAP net income (loss)	<u>\$ 299</u>	<u>\$ (6,203)</u>
<i>Weighted Shares Outstanding:</i>		
Basic	47,895	47,557
Diluted	47,905	47,557
<i>Basic and diluted earnings per share:</i>		
Basic net income (loss) per share GAAP	\$ 0.01	\$ (0.16)
Diluted net income (loss) per share GAAP	\$ 0.01	\$ (0.16)
Basic net income (loss) per share non-GAAP	\$ 0.01	\$ (0.13)
Diluted net income (loss) per share non-GAAP	\$ 0.01	\$ (0.13)

The following table presents a reconciliation of reported net income (loss) for the three months ended October 31, 2020 and 2019, respectively to EBITDA and Adjusted EBITDA:

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

	Three months ended October 31	
	2020	2019
GAAP net income (loss)	\$ 299	\$ (7,648)
Plus (minus):		
Depreciation and amortization	660	725
Interest expense (income)	51	(237)
EBITDA	\$ 1,010	\$ (7,160)
Adjusted for:		
Legal expenses related to contingencies	-	800
Contested proxy expenses	-	645
Adjusted EBITDA	\$ 1,010	\$ (5,715)