

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 15, 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 March 15, 2021, Enzo Biochem, Inc. (the "Company") issued a press release announcing its operating results for its second fiscal quarter ended January 31, 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On March 15, 2021, Enzo Biochem, Inc. (the "Company") issued a press release announcing that Dr. Elazar Rabbani, Founder and CEO, will step down as CEO and transition to a scientific role with the Company once a qualified successor is identified and hired by the Board. Dr. Rabbani will remain as a Director of the Company. 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 5.02 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 March 15, 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.

ENZO BIOCHEM, INC.

Date: March 16, 2021

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

Enzo Biochem Reports Second Quarter Fiscal 2021 Results; Company Provides Leadership and Corporate Updates

- Total second quarter revenue of \$31.5 million increased 62% year-over-year on continued recovery and expansion from impact of COVID-19 pandemic
- Second quarter clinical laboratory revenue of \$24.0 million increased 92% on significant volume and pricing growth due to improved product mix
- Consolidated quarterly gross margin of 50% improved 2000 basis points year-over-year
- Achieved adjusted EBITDA at \$4.3 million for the quarter with increases in sequential and YOY profitability
- EPS of \$0.05 for the quarter vs. EPS loss of (\$0.16) in Q2 2020
- Dr. Elazar Rabbani, Founder and CEO, to step down as CEO and transition to a scientific role with the Company once a qualified successor is identified and hired by the Board
- Executive search firm Korn Ferry engaged to identify CEO candidates
- Gary M. Huff, former LabCorp Diagnostics CEO, named Strategic Consultant to Board
- Enzo retains Cain Brothers to help identify, evaluate, and execute strategic initiatives

**Conference call and live webcast scheduled for today,
Monday, March 15, 2021 at 4:30 pm (ET)**

NEW YORK, March 15, 2021 (GLOBE NEWSWIRE) -- Enzo Biochem, Inc (NYSE: ENZ), a leading biosciences and diagnostics company, today reported financial results for the second quarter ended January 31, 2021 and provided a business update on recent corporate and operational developments.

“The Company’s strong financial performance in the second quarter is another reflection of the strength of our new business model for integrated diagnostic product and services. The high gross margins achieved this quarter further validate the strength of Enzo’s strategy,” said Elazar Rabbani, Ph.D., Enzo’s Chairman and CEO. “These results are especially indicative of the advancements we have made in development of proprietary products, notably our versatile GENFLEX™ molecular diagnostic platform, as well as our integrated end-to-end business strategy that ranges from research through final diagnostic products and services.”

Enzo’s financial improvement from an operating loss of \$16.2 million in 1H 2020 to an operating profit of \$2.2 million in 1H 2021, an \$18.4 million improvement, supported by management’s strategic shift to addressing the COVID-19 pandemic on its proprietary GENFLEX™ platform as well as cost efficiencies identified and executed by the Company. These operational measures were achieved despite staff limitations, supply chain interruptions, and other unprecedented circumstances caused by the pandemic.

“Our open system approach allows for the highest levels of flexibility and adaptability in the post COVID-19 environment,” said Barry Weiner, Enzo’s President. “Our GENFLEX™ platform enables laboratories to use third-party or their own reagents on this open platform with ease and flexibility. Through this platform, we can provide substantially lower costs for molecular testing and address reimbursement pressure in one of the fastest growing segments of the clinical testing market.”

“We remain committed to our growth strategy and expect that the higher margins achieved by the vertically integrated model of COVID-19 testing can be extended to a range of other molecular tests as well as key platforms such as immunohistochemistry (IHC) and cytology, both of which can face challenges as a result of widespread use of closed system platforms,” continued Mr. Weiner. “We are currently validating test menus and panel extensions to drive utility in the high-volume molecular testing space through deployment of Enzo’s internal sales and marketing operations as well as with industry partners.”

After years of dedicated service, Dr. Elazar Rabbani, Founder and CEO, will remain a Director of the Company and will step down as CEO and transition to a scientific role with the Company once a qualified successor is identified and hired by the Board. To fully capitalize on the potential of Enzo’s business model, the Company and the Board of Directors have retained the global search firm Korn Ferry to conduct the CEO search.

In addition, the Company also announced that Gary Huff, the former CEO of LabCorp Diagnostics, will serve as a strategic consultant to the Board. Mr. Huff is an industry veteran who held multiple positions of increasing responsibility at LabCorp and demonstrated a strong history of leadership and business acumen. He was formerly CEO of Baylor Genetics Laboratories where he provided leadership and guidance on the continuous development of their product pipeline.

To assist with strategic initiatives, the Company has also retained Cain Brothers, a healthcare investment banking firm, to help identify, evaluate and execute strategic and commercial opportunities.

Second Quarter 2021 and Recent Business Highlights

- Announced results of an analysis showing that tests processed on the Company’s proprietary GENFLEX™ molecular diagnostic platform are successfully able to detect the presence of currently known variants of COVID-19. While the Company’s PCR testing does not distinguish between different variants, positive samples can be further analyzed for variant identification. Rapid antigen tests currently available in the marketplace do not have this capability.
- Received an expansion of its Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) authorizing the use of pooled samples containing up to five individual swab specimens with the Company’s AMPIPROBE® SARS-Cov-2 Test System utilizing tests on three different platforms including Enzo’s proprietary GENFLEX™ automated high-throughput platform.
- Received a U.S. Patent for polyclonal antibodies against osteoporosis drug target sclerostin. This patent 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.

Second Quarter 2021 Financial Results

- Total second quarter revenue was \$31.5 million, an increase of 62% from \$19.4 million in the second quarter last year. The gains reflected continued increased activity, particularly related to COVID-19. Consolidated gross margin was 50.3%, a 2,030 basis points improvement, vs 30.0% in the year ago period.
- Enzo Clinical Lab revenues totaled \$24.0 million, an increase of 92% from \$12.5 million in the second quarter last year. This performance was primarily driven by services accession count exceeding 330,000 in the quarter compared to approximately 200,000 a year ago, an increase of nearly 65% year-over-year. Clinical services margin advanced to 51.2%, from 18.1% in the year-ago comparable period and 38.8% in the preceding quarter, largely due to testing mix and ongoing cost-saving initiatives.

- Enzo Life Sciences revenue was \$7.5 million, an increase of 9% compared with \$6.9 million in the year ago period. The average product order value increased 18% during the period, due mainly to servicing higher value markets. Gross margin was 47.4%, lower than the 51.5% gross margin in the year ago period, but was flat when accounting for intercompany sales.
- Research and development expenses declined 24% to \$0.8 million, or 2.6% of total revenues, from \$1.1 million, or 5.5% of total revenues, in the year ago period. Selling, general and administrative expenses of \$11.0 million rose slightly from \$10.7 million in year ago period, although SG&A margin declined by more than 2000 basis points due to better fixed cost leverage as a result of vertical integration and cost efficiency measures.
- GAAP net income totaled \$2.3 million, or \$0.05 per share, compared with a loss of (\$7.7) million, or (\$0.16), in the year-ago quarter, an improvement of almost \$10 million. Adjusted EBITDA in the quarter totaled \$4.3 million, versus an adjusted EBITDA loss of \$5.4 million in the second 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 from headcount efficiencies, lower intangibles amortization, and reduced travel.
- Cash and cash equivalents totaled \$44.5 million as of January 31, 2021, slightly lower than the \$47.9 million at the end of fiscal year 2020, due to investments in inventory, higher accounts receivable and capital expenditures, and lower accounts payable. Working capital amounted to \$40.0 million, compared to \$36.0 million as of July 31, 2020. As of January 31, 2021, the Company had 48.2 million shares outstanding.

First Half 2021 Financial Results

- Total revenues of \$60.1 million during the six-month period ended January 31, 2021, an increase of 51.8% compared to revenues of \$39.6 million for the same period in 2020. Based on the first two quarters, Company's current annual revenue run-rate exceeds \$120 million, representing nearly 60% topline growth on an annualized basis.
- Enzo Clinical Lab revenue of \$45.2 million during the six-month period ended January 31, 2021, increased 78.6% compared to revenues of \$25.3 million for the same period in 2020.
- Enzo Life Sciences revenue of \$14.9 million during the six-month period ended January 31, 2021, increased 4.1% compared to revenues of \$14.3 million for the same period in 2020.
- Consolidated gross margin was 46.1%, as compared to 29.0% in the year-ago period. This was due to substantially higher gross margin in services primarily due to favorable mix from increased COVID-19 testing as well as from ongoing cost-saving initiatives.
- Research and development expenses, net, were \$1.6 million for the six months ended January 31, 2021, or 2.6% of total revenue, compared to \$2.1 million, or 5.4% of total revenue, for the same period in 2020. The decrease is mostly attributable to headcount efficiencies. Selling, general and administrative expenses for the six months ended January 31, 2021 were \$21.0 million, or 35.0% of total revenue, compared to \$21.8 million, or 55.1% of total revenue for the same period in 2020. The decrease is primarily due to cost efficiency measures implemented by management.
- Net income for the six months ended January 31, 2021 was \$2.6 million, or \$0.05 per share, basic and diluted, compared to a net loss of \$15.3 million, or (\$0.32) per share, basic and diluted, for the six months ended January 31, 2020.

Conference Call and Webcast Information

The Company will host a conference call on Monday, March 15, 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: 13716329
 Webcast: <http://public.viavid.com/index.php?id=143489>

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)

<u>Selected operations data:</u>	Three months ended		Six months ended	
	January 31 (unaudited)		January 31 (unaudited)	
	2021	2020	2021	2020
Total revenues	\$ 31,466	\$ 19,384	\$ 60,121	\$ 39,591
Gross profit	\$ 15,821	\$ 5,809	\$ 27,718	\$ 11,495
Gross profit %	50.3%	30.0%	46.1%	29.0%
Income (loss) before income taxes	2,302	(7,687)	2,601	(15,335)
Net income (loss)	\$ 2,302	\$ (7,687)	\$ 2,601	\$ (15,335)
Basic net income (loss) per share	\$ 0.05	(\$ 0.16)	\$ 0.05	(\$ 0.32)
Diluted net income (loss) per share	\$ 0.05	(\$ 0.16)	\$ 0.05	(\$ 0.32)
Weighted average shares outstanding - basic	48,006	47,557	47,951	47,557
Weighted average shares outstanding - diluted	48,053	47,557	47,973	47,557
			1/31/2021 (unaudited)	7/31/2020 (unaudited)
<u>Selected balance sheet data:</u>				
Cash and cash equivalents including restricted cash of \$750			\$ 45,286	\$ 48,615
Working capital			\$ 39,934	\$ 35,964
Stockholders' equity			\$ 61,789	\$ 58,381

Total assets		\$	112,031	\$	112,538
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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, 2021 and 2020:

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

	Three months ended January 31		Six months ended January 31	
	2021	2020	2021	2020
Reported GAAP net income (loss)	\$ 2,302	\$ (7,687)	\$ 2,601	\$ (15,335)
Adjustments	1,973	1,847	1,973	2,493
Non-GAAP net income (loss)	<u>\$ 4,275</u>	<u>\$ (5,840)</u>	<u>\$ 4,574</u>	<u>\$ (12,842)</u>

Weighted Shares Outstanding:

Basic and diluted	48,006	47,557	47,951	47,557
Basic and diluted	48,053	47,557	47,973	47,557

Basic and diluted earnings per share:

Basic net income (loss) per share GAAP	\$ 0.05	\$ (0.16)	\$ 0.05	\$ (0.32)
Diluted net income (loss) per share GAAP	\$ 0.05	\$ (0.16)	\$ 0.05	\$ (0.32)
Basic net income (loss) per share non-GAAP	\$ 0.09	\$ (0.12)	\$ 0.10	\$ (0.27)
Diluted net income (loss) per share non-GAAP	\$ 0.09	\$ (0.12)	\$ 0.10	\$ (0.27)

The following table presents a reconciliation of reported net income (loss) for the three and six months ended January 31, 2021 and 2020, 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	
	2021	2020	2021	2020
GAAP net income (loss)	\$ 2,302	\$ (7,687)	\$ 2,601	\$ (15,335)
Plus (minus):				
Depreciation and amortization	635	709	1,295	1,434
Interest expense (income)	49	(171)	100	(408)
EBITDA	<u>\$ 2,986</u>	<u>\$ (7,149)</u>	<u>\$ 3,996</u>	<u>\$ (14,309)</u>
Adjusted EBITDA	<u>\$ 4,334</u>	<u>\$ (5,381)</u>	<u>\$ 5,508</u>	<u>\$ (12,086)</u>

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