

October 12, 2021



Enzo Biochem Reports Fourth Quarter and Fiscal Year 2021 Financial Results and Provides Business Update

- *FY 2021 revenues of \$117.7 million vs. \$76.0 million, an increase of 55% YoY*
- *4Q 2021 revenues of \$24.8 million vs. \$19.5 million a year ago, an increase of 27%*
- *FY 2021 EPS of \$0.16 per share compared to a year ago loss of \$(0.60)*
- *4Q 2021 EPS of \$0.07 per share vs. (\$0.07) in the year-ago quarter*
- *Expanded FDA Emergency Use Authorization (EUA) for Enzo's SARS-CoV-2 testing platform, including use of Enzo extraction method that reduces time to obtain results and allows more test runs on a single instrument*
- *Consolidated manufacturing footprint with the closure of Ann Arbor and upgrade of Farmingdale, NY campus to enhance operating efficiencies*
- *GoTestMeNow direct-to-consumer testing service to launch access to testing for sexually transmitted infections this fall*

***Conference call and live webcast scheduled for today,
Tuesday, October 12, 2021 at 8:30 am (ET)***

NEW YORK, Oct. 12, 2021 (GLOBE NEWSWIRE) -- Enzo Biochem, Inc. (NYSE:ENZ), a leading biosciences and diagnostics company, today reported operating results for the fiscal year and fourth quarter ended July 31, 2021 and provided a business update on recent corporate and operational developments.

Operational Highlights:

- Enzo has expanded its position as an innovative leader through its rapid response to the COVID-19 pandemic and continued implementation of cost effective, adaptive technologies to address key challenges in the clinical diagnostics industry.
- The Company remained fully committed to implementing efficiency measures, building infrastructure, and transforming from a bifurcated life sciences company to an integrated end-to-end diagnostics company. Business strategy has remained focused on execution of several core objectives, including:
 - Strategic alignment with partners including governments, associations and other industry leaders to accelerate commercialization
 - Product and service expansion including a broader test menu on the GENFLEX® platform and new applications in the GoTestMeNow.com DTC testing service

- New strategies in financial and operational efficiency
- In July, Enzo received an expansion of its EUA for the Company's testing system for SARS-CoV-2, including genetic variants. Laboratories can now access Enzo's faster extraction process to reduce time to results by more than 25% and run more tests on a single instrument.
- In June, Enzo formed a new collaboration with CLX Health to provide rapid access to PCR tests required for international travel. Using this online service, travelers can schedule PCR tests immediately and receive results in advance of travel by using CLX Health's TrustAssure™ Global Testing Platform, which includes COVID-19 testing partners in more than 81 countries.
- In April, the Company received FDA EUA clearance for its AMPICOLLECT™ Sample Collection kit for sample collection for COVID-19 testing protocols in the United States.
- In March, the Company showed results that indicate its GENFLEX® platform successfully meets new FDA guidance calling for COVID-19 test developers to assess the impact of viral mutations on testing results.
- In January, Enzo received an expansion of its EUA from the FDA authorizing use of pooled samples containing up to five individual swab specimens with the Company's AMPIPROBE® SARS-CoV-2 Test System. The process can use tests on three different platforms including Enzo's proprietary GENFLEX® automated high-throughput platform.
- In November 2020, Enzo announced the appointment of Ian B. Walters, MD, and Mary Tagliaferri, MD, to the Board of Directors. Dr. Tagliaferri is a highly respected industry leader with experience in a range of operational areas, including business development, clinical R&D, and regulatory and medical affairs. Dr. Walters brings over two decades of diverse experience in drug development and business strategy, including both founding and executive level positions at several life sciences companies.
- In October 2020, Enzo Launched GoTestMeNow™, an online platform that enables consumers to directly order physician-authorized laboratory testing including COVID-19 molecular and antibody tests with plans to expand into other indications this fiscal year.
- In October 2020, the Company also launched a portable microplate reader for use with immunoassays and, ultimately, molecular diagnostics at point-of-care medicine.

Financial Highlights:

- FY 2021 revenues of \$117.7 million vs. \$76.0 million. an increase of 55% YoY
 - FY 21 services revenue of \$87 million vs. \$48 million, an increase of 81% YoY
 - FY 21 product revenue of \$31 million vs. \$27 million, an increase of 16% YoY
- Cost saving initiatives and improved efficiency measures generated approximately \$10 million in savings for FY 2021
- Received confirmation from the Small Business Administration in June that the entire

\$7 million loan received by Enzo under the Paycheck Protection Program (PPP) has been forgiven

“Fiscal 2021 was a validating and extraordinary year for Enzo as our team once again demonstrated unprecedented levels of innovation amid the most transformative time of our 45-year history. We have successfully modified our clinical services and products to profitably operate in the new COVID-19 pandemic with multiple variants where we anticipate testing to ebb and flow for the next 12-18 months,” said Barry Weiner, President of Enzo.

“With the launch of the GoTestMeNow™ platform, our first-ever direct-to-consumer offering, Enzo is now providing physician-authorized laboratory tests directly to patients for COVID-19 and, beginning this fall, for sexually transmitted infections. We are working diligently to broaden our menu of molecular testing on our proprietary GENFLEX® platform. We anticipate additional molecular tests to become available in 2022 as we build broader awareness of the Company’s diagnostic platform capabilities.

“The Company’s vertically integrated end-to-end diagnostic business model is distinctive in the industry. It enables Enzo to more rapidly and flexibly meet market and operational challenges associated with the COVID-19 pandemic and other shifts in the marketplace.

“In 2021 Enzo had record revenues of \$117.7 million, up 55% year-over-year, with consolidated gross margins of 45.5% and net income of \$7.9 million, or \$0.16 fully diluted per share. The Company, in line with its cost-cutting efforts, also reported reductions in cost of sales and operating expenses.

“Enzo is also planning for continued focus on opportunities driven by the continuing COVID-19 pandemic. As the market has evolved, Enzo has focused on targeting many new opportunities, including testing services customized for schools, pharmacies and businesses. The Company is also extending the successful marketing and delivery model developed in response to COVID-19 to expand product and service offerings in additional areas including women’s health and sexually transmitted disease.

“Enzo’s GENFLEX® sales and marketing strategy is undergoing multiple regulatory approvals for test submissions. The Company’s vigorous R&D program includes a focus on cytology, immunodiagnostics, and immunohistochemistry (IHC) involving locating antigens in biopsy tissue to diagnose some types of cancer. Enzo is also actively involved in the development and future commercialization of point-of-care platforms that are gaining increasing interest in clinical diagnostics. In addition, the Company’s LoopRNA technology, now increasingly used for the study of gene structure, potentially allows for better medical interpretation, accelerated drug development and improved research capabilities and can reduce the risk of false positives and false negatives for early detection on RNA-based infections such as HPV.”

“Our emphasis continually is on higher margin products including many for specialized needs as well as cost-limited products and testing applications,” Mr. Weiner added. “Specialization is our hallmark and has enabled us to carve out a growing and important niche as an innovator, with an eye on efficiencies and effectiveness. It is a proud tradition, one that we take seriously in our pursuit of melding opportunities with enhanced value for all stakeholders.”

Fiscal 2021 Financial Results

- Total revenues of \$117.7 million during the twelve-month period ended July 31, 2021, an increase of 55% compared to revenues of \$76.0 million for the same period in 2020. The increase is primarily due to COVID-19 testing services and accelerated growth in the product segment.
- Consolidated gross profit totaled \$53.6 million, compared to \$23.8 million a year ago. The Company's gross margin was 46%, as compared to 31% in the year-ago period. Services gross margin increased to 45%, primarily due to its favorable mix from increased COVID-19 testing as well as from ongoing cost-saving initiatives. Product gross margin was relatively consistent at 48%.
- Research and development expenses were \$3.3 million for the year ended July 31, 2021, or 3% of total revenue, compared to \$4.4 million, or 6% of total revenue, for the same period in 2020. The reduction is due to a shift in personnel to production.
- Selling, general and administrative expenses for fiscal 2021 were \$44.9 million, or 38% of total revenue, compared to \$43.0 million, or 56% of total revenue for fiscal 2020. The increase is primarily due to costs related to COVID-19 testing, counterbalanced by cost efficiency measures. Legal expenses, including proxy related costs, amounted to \$4.7 million, down from \$6.7 million.
- Net income amounted to \$7.9 million, or \$0.16 per diluted shares, compared to a year ago net loss of \$(28.5) million, or \$(0.60) per share. Included in fiscal 2021 results was the aforementioned PPP loan forgiveness.
- EBITDA amounted to \$10.5 million, compared to a year ago negative EBITDA of \$26.2 million, an improvement of \$36.7 million.
- Enzo Clinical Lab fiscal 2021 total revenues increased 81%, to \$87 million, year over year. Operating profit grew to \$11.9 million compared to a year ago operating loss of \$(14.6) million, an improvement of over \$26 million.
- Enzo Life Sciences (ELS) fiscal 2021 revenues amounted to \$30.7 million, up 16% from fiscal 2020. Operating profit reached \$1.2 million, or 3.8% of revenues, compared to \$0.5 million, or 1.8%, in fiscal 2020, an improvement of 140%.
- Cash, cash equivalents, and short-term investments totaled \$43.5 million at the end of the fiscal year and working capital amounted to \$44.5 million. Cash, cash equivalents, and short-term investments are slightly lower compared to year-end 2020 due primarily to investments in inventory and capital expenditures. As of July 31, 2021, the Company had 48.5 million shares outstanding.

Fourth Quarter 2021 Financial Results

- Total fourth quarter revenues were \$24.8 million, an increase of 27% from \$19.5 million in the fourth quarter last year, but a decrease of 24% sequentially. Results reflect strong product sales, moderated by a slow-down in COVID-19 testing during the summer months. A subsequent uptick in activity has resulted from growing evidence of increasing incidence of new virus variants, leading to heightened infections and hospitalizations, in addition to reduced preventive measures including masking.
- Consolidated margin was 40% for both fiscal 2021 and fiscal 2020 fourth quarters.
- Enzo Clinical Lab revenue increased 30% to \$16.8 million from \$12.9 million in the fourth quarter 2020. The year-over-year improvement was driven by increased

accession count and a 6% growth in net revenue per accession due to factors related to the COVID-19 pandemic. Clinical services gross margin decreased to 36% from 49% in the sequential third quarter 2021, primarily due to fewer COVID-19 tests.

- Enzo Life Sciences revenue of \$8.1 million increased 38% from \$5.8 million in the fourth quarter 2020 due to the impact of COVID-19 pandemic globally in the 2020 period. Gross margin was 47%, compared to 46% in the previous year's quarter and 47% in the sequential third quarter.
- Research and development expenses decreased 26% to \$0.9 million, or 3% of total revenues, from \$1.2 million, or 6% of total revenues, in the year ago period. The decrease is mostly attributable to lower personnel expenses related to platform and pipeline test development.
- Selling, general and administrative expenses of \$11.8 million increased 18% over the previous year period. The increase was due to investment in sales incentives, marketing and client support to promote company growth. However, as a percentage of revenues, SG&A for fourth quarter 2021 equaled 48%, compared to 51% a year ago.
- GAAP net income was \$3.3 million or \$0.07 per share versus a net loss of \$(3.3) million, or (\$0.07), in the year-ago quarter.

As we have announced in the previous quarters, the Company's strategic initiatives and succession planning are ongoing. The investment banking firm retained earlier this year remains highly engaged with the Company and the executive search, within the context of the Company's strategic objectives, is ongoing. Updates will be provided when appropriate. The Company, management and board are working in unison to translate Enzo's capabilities and resources to benefit all shareholders and enhance and maximize shareholder value.

Conference Call and Webcast Information

The Company will host a conference call on Tuesday, October 12, 2021, at 8:30 am, 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: 13723500
Webcast: <http://public.viavid.com/index.php?id=146658>

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 or 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. For additional information please visit: <http://www.enzo.com/>

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, 2021. 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.

Contacts:

For Enzo Biochem, Inc.

David Bench, CFO
212-583-0100
dbench@enzo.com

Investors:

Bob Yedid
LifeSci Advisors, LLC
646-597-6989
bob@lifesciadvisors.com

Steve Anreder
Anreder & Company
212-532-3232
Steven.anreder@anreder.com

Media:

Lynn Granito
Berry & Company Public Relations
212-253-8881
lgranito@berrypr.com

ENZO BIOCHEM, INC.

(in thousands, except per share data)

<i>Selected operations data:</i>	Three months ended		Fiscal year ended	
	July 31, (unaudited)		July 31, (unaudited)	
	2021	2020	2021	2020
Total revenues	\$ 24,813	\$ 19,527	\$ 117,731	\$ 76,021
Gross profit	\$ 9,813	\$ 7,850	\$ 53,577	\$ 23,770
Gross profit %	40%	40%	46%	31%
Income (loss) before income taxes	3,268	(3,325)	7,875	(28,520)
Net income (loss)	\$ 3,268	\$ (3,325)	\$ 7,875	\$ (28,520)

Basic net income (loss) per share	\$0.07	(\$0.07)	\$0.16	(\$0.60)
Diluted net income (loss) per share	\$0.07	(\$0.07)	\$0.16	(\$0.60)
Weighted average shares outstanding - basic	48,472	47,892	48,191	47,696
Weighted average shares outstanding - diluted	48,840	47,892	48,325	47,696

<i>Selected balance sheet data:</i>	<u>7/31/2021</u> <u>(unaudited)</u>	<u>7/31/2020</u> <u>(unaudited)</u>
Cash and cash equivalents including restricted cash of \$750 and marketable securities	\$43,502	\$48,615
Working capital	\$44,506	\$35,964
Stockholders' equity	\$68,586	\$58,381
Total assets	\$113,691	\$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 and fiscal year ended July 31, 2021 and 2020:

ENZO BIOCHEM, INC.

Non-GAAP Reconciliation Table

(Unaudited, in thousands, except per share data)

	Three months ended		Fiscal year ended	
	July 31,		July 31,	
	2021	2020	2021	2020
Reported GAAP net income (loss)	\$ 3,268	\$ (3,325)	\$ 7,875	\$ (28,520)
Adjusted for:				
Contested proxy expenses	-	-	1,973	4,042
Separation expenses	154	-	154	235
Non-GAAP net income (loss)	\$ 3,422	\$ (3,325)	\$ 10,002	\$ (24,243)

Weighted Shares Outstanding:

Basic	48,472	47,892	48,191	47,696
Diluted	48,840	47,892	48,325	47,696

Basic and diluted earnings per share:

Basic net income (loss) per share GAAP	\$0.07	(\$0.07)	\$0.16	(\$0.60)
Diluted net income (loss) per share GAAP	\$0.07	(\$0.07)	\$0.16	(\$0.60)
Basic net income (loss) per share non- GAAP	\$0.07	(\$0.07)	\$0.21	(\$0.51)
Diluted net income (loss) per share non-GAAP	\$0.07	(\$0.07)	\$0.21	(\$0.51)

The following table presents a reconciliation of reported GAAP net income (loss) for the three months and fiscal year ended July 31, 2021 and 2020, respectively to EBITDA and Adjusted EBITDA:

ENZO BIOCHEM, INC.

EBITDA & Adjusted EBITDA Reconciliation Table
(Unaudited, in thousands)

	Three months ended		Fiscal year ended	
	July 31,		July 31,	
	2021	2020	2021	2020
GAAP net income (loss)	\$ 3,268	\$ (3,325)	\$ 7,875	\$(28,520)
Plus (minus):				
Depreciation and amortization	678	629	2,653	2,780
Interest expense (income)	(48)	41	(8)	(454)
EBITDA	\$ 3,898	\$ (2,655)	\$ 10,520	\$(26,194)
Adjusted for:				
Paycheck Protection Program (PPP) loan forgiveness	(7,000)	-	(7,000)	-
Foreign exchange loss (gain)	158	(994)	(270)	(905)
Contested proxy expenses	-	-	1,973	4,042
Separation expenses	154	-	154	235

Adjusted EBITDA

\$	(2,790)	\$	(3,649)	\$	5,377	\$	(22,822)
----	---------	----	---------	----	-------	----	----------



Source: Enzo Biochem, Inc.