

Enzo Biochem Reports Fourth Quarter and Fiscal Year 2022 Financial Results and Provides Business Update

- Enzo Life Sciences reports revenue of \$32.6 million and 8% growth in FY 2022, net of FX
- Company successfully launched AMPIVIEW™ gene expression platform powered by LoopRNA™ ISH technology
- Continues to engage with previously announced investment bank to provide advisory services including the evaluation of strategic alternatives for the Company
- Under the leadership of a new CEO, Enzo has been reorganized to leverage on our 'focused return' strategy including the appointment of new executive management and augmenting the sales team to position the Company for continued growth in a cost-effective manner

Conference call and live webcast scheduled for today, Friday, October 14, 2021 at 8:30 am (ET)

NEW YORK, Oct. 14, 2022 (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, 2022 and provided a business update on recent corporate and operational developments.

"Enzo Biochem has maintained positive momentum on multiple strategic initiatives and has achieved growth on key metrics critical for the future success of the business despite substantial macroeconomic and geopolitical headwinds as well as a broad decline in global COVID-19 testing over the last year," said Hamid Erfanian, CEO of Enzo Biochem. "Our focus is fixed firmly on strategies to support both the short and long-term future of Enzo Biochem. We remain committed to our 'focused return' strategy of investment in areas where we will recognize the best returns.

"Despite COVID-related retraction in some operational areas, we remain very optimistic about our Enzo Clinical Laboratory service business going forward, building on a 15% increase in our highly profitable molecular testing services in this last quarter compared to the same quarter the previous year. Our capabilities in molecular testing leverage our proprietary AMPIPROBE® technology, which will be one of the core pillars driving growth in our emerging diagnostics division. For our Enzo Clinical Lab business, this strategy positions us to target new customer groups including urgent care facilities with a renewed focus on testing services including addition of novel tests in high-demand areas such as

rheumatology, monkeypox and APOE.

"In our Enzo Life Sciences division, we continue to see overall revenue growth with consistently strong gross margins. Our average product order increased 5.6% year-over-year, the highest average achieved over the past four years, due to our focused strategy on moving across the drug development pipeline.

"On the Enzo Life Sciences side of our business, we continue to generate value through innovation, as with our proprietary LoopRNATM ISH technology and the related AMPIVIEW™ gene expression platform. Together, these advanced technologies open up entirely new opportunities in oncology and spatial biology for us. We also continue to invest in geographic, commercial and distribution expansion.

"Finally, Enzo Biochem is preparing to launch its Enzo Diagnostics (EDX) division, which will focus specifically on clinical diagnostic platforms for laboratories and physician offices. We are determined to be a global leader in innovation and service in point-of-care diagnostic testing by leveraging our long history of life science testing experience and expertise. Additionally, we continue our steady advancement along the regulatory path with GENFLEX[®], our flexible and fully automated molecular testing platform, with pending submission for monkeypox Emergency Use Authorization (EUA) approval and other regulatory filings."

Operational Highlights:

- In October 2022, the Company announced the opening of an expanded life sciences laboratory and office facilities in Farmingdale, New York. The 100,000 square foot facility will support plans for continued growth in clinical laboratory services, drug development services and product innovations. Our recent launch event featured updates on Enzo plans for business growth and perspectives on prospects for the Long Island business community from community leaders.
- In September 2022, powered by Enzo's LoopRNA™ in-situ hybridization technology, the Company announced the launch of its AMPIVIEW™ gene expression platform, with first products targeting detection of HPV and SARS-CoV-2. AMPIVIEW™ significantly expands Enzo's position in the oncology market and paves the way for expansion into the growing spatial biology space.
- In August 2022, building on the Company's decades of experience processing specimens for the detection of viral pathogens, Enzo Biochem announced that its fullservice clinical laboratory would begin accepting specimens for monkeypox testing with an FDA-cleared, PCR-based DNA assay developed by the United States Centers for Disease Control and Prevention (CDC).
- In August 2022, the Company announced the addition of Matthew Kupferberg as inhouse General Counsel to provide a more cost-effective legal strategy. Mr. Kupferberg brings experience leading transactional and legal activities for health and wellness companies and providing counsel regarding corporate governance issues.
- In April 2022, the Company announced that it had received approval from the New York State Department of Health (DOH) for its AMPIPROBE® HPV test. The

AMPIPROBE® HPV test, run on Enzo's proprietary GENFLEX® platform, is designed to detect 14 high-risk human papillomavirus (HPV) variants. This test adds to our already robust menu of lab developed tests on GENFLEX®.

- In October 2021, the Company launched its GoTestMeNow™ platform for STIs, enabling individuals to instantly and privately access physician-authorized testing for a broad range of STIs including chlamydia, gonorrhea, syphilis, HIV-1/2, hepatitis and herpes, with an expanded menu addressing increased patient demand for direct access to other convenient diagnostic tests.
- In September 2021, Enzo completed the closure of its Ann Arbor manufacturing facility.
 The transfer of this facility enabled the consolidation of Enzo operations at its
 Farmingdale, NY campus. It was a paramount achievement this year not only from a
 logistical point of view but also from a finance standpoint, enabling significant future
 cost savings.

Financial Highlights:

Enzo Life Sciences (ELS)

- Revenue growth of 8% and 2% on an annual and fourth quarter basis, respectively (excluding FX impact), driven by ongoing stabilization of supply chain issues.
- Q4 FY22 revenues of \$7.9 million in line with previous year quarter, one of our largest quarters in the past several years.
- FY22 revenues of \$32.6 million reflect growth in most segments, largest increase driven by GMP initiatives.
- FY22 margin of 41.1% vs. 48.0% and Q4 margin 36.4% compared to 35.9% sequentially, impacted by reorganization of structure to support growth, industry-wide increases in salaries, and inflation impact on material costs.
- Average Product order value strongest in 4 years and trending positively with an increase of 5.6% on a year-over-year basis.

Enzo Clinical Lab (ECL)

- Q4 FY22 and FY22 revenues declined on an aggregated basis, but we are observing a recovery in Q1 FY23 core business
- Molecular testing revenue increased 15% in comparison to Q4 FY21
- The Company is less reliant on COVID-19 Revenues (19% of clinical lab revenue in Q4 2021 vs. 32% in the previous year's fourth quarter)

Fiscal 2022 Financial Results

 Total revenues of \$107.1 million during the twelve-month period ended July 31, 2022 compared to revenues of \$117.7 million for the same period in 2021. The slight decrease is primarily related to reduction in COVID-19 testing volumes and lower reimbursement rates. Fiscal year 2022 was the second highest historical annual revenue for Enzo from its operating divisions.

- Consolidated gross profit totaled \$42.0 million, compared to \$53.6 million a year ago.
 The Company's gross margin was 39%, as compared to 46% in the year prior.
 Services gross margin for fiscal year 2022 was 38%, compared to 45% the year prior primarily due to the lower COVID-19 testing mix. Product gross margin was reduced to 41%, as compared to 48% in 2021 primarily due to investments to support future growth and inflation impact.
- Research and development expenses were higher at \$3.8 million for the year ended July 31, 2022, or 3.5% of total revenue, compared to \$3.3 million, or 2.8% of total revenue, for the same period in 2021, due to investment in resources, translation, and Lab Developed Tests.
- Selling, general and administrative expenses for fiscal 2022 were \$48.0 million, or 44.8% of total revenue, compared to \$44.9 million, or 38.1% of total revenue for fiscal 2021. Legal and other expenses and legal settlements amounted to \$5.2 million net, an increase from \$4.7 million in the previous year.
- Net income (loss) amounted to \$(18.3) million, or \$(0.38) per diluted shares, compared to a year ago net income (loss) of \$7.9 million, or \$0.16 per share.
- Adjusted EBITDA amounted to (\$5.2) million, compared to a year ago adjusted EBITDA of \$5.5 million.
- Enzo Clinical Lab fiscal 2022 total revenues were \$74.4 million, compared to \$87.0 million in fiscal 2021, primarily due to reduction in COVID testing volume and reimbursement rates. Enzo's accessions declined by approximately 165,000 compared to FY21. Operating profit for fiscal 2022 was \$0.8 million compared to a year ago operating profit of \$11.9 million.
- Enzo Life Sciences fiscal 2022 revenues amounted to \$32.6 million, up 6% from fiscal 2021, or 8% on an FX adjusted basis. This increase of \$1.9 million represents growth in most product categories, with the increase driven by GMP bulk sales. Operating loss for 2022 was \$(0.2) million compared to operating income of \$1.2 million in 2021.
- Cash and cash equivalents totaled \$21.6 million at the end of the fiscal year and working capital amounted to \$29.8 million. Cash and cash equivalents are lower compared to year-end 2021 due primarily to corporate legal and strategic expenses, investments in inventory, and capital expenditures. The company's current ratio remains strong at 2.2x. As of July 31, 2022, the Company had 48.7 million shares outstanding, a less than 1% increase from the previous year.

Fourth Quarter 2022 Financial Results

 Total fourth quarter 2022 revenues were \$20.3 million, compared to \$24.8 million in the fourth quarter 2021. The decline reflects a continued slow-down in COVID-19 testing.
 We anticipate the rate of decline to taper in the months ahead as COVID-19 testing becomes a regular part of influenza panel testing. Also, Q4/22 revenue includes a more balanced mix of services & products (61% ECL & 39% ELS in Q4/22 vs. 68% & 32%, respectively, in the fourth quarter of 2021).

- Consolidated gross margins were 21.4% in the fiscal fourth quarter as compared to 39.5% for the comparable quarter in the previous fiscal year.
- Enzo Clinical Lab revenue was \$12.4 million in the fiscal fourth quarter as compared to \$16.8 million in the fourth quarter of 2021. The decrease was predominantly attributable to reduced COVID-19 testing. Clinical services gross margin decreased to 11.8% from 35.9% in the fourth quarter period of 2021, due to a one-time charge related to cash collections and due to fewer COVID-19 tests and lower reimbursement rates. Enzo's accessions declined by approximately 42,500 compared to the fourth quarter of fiscal 2021.
- Enzo Life Sciences revenue in the fourth quarter was \$7.9 million as compared to \$8.1 million in the fourth quarter 2021, but organic growth of 2% when accounting for the FX impact. Gross margin was 36.4%, compared to 47.2% in the previous year's quarter, largely due to reorganization of operational structure, increasing industry wide salaries and impact of inflation on materials.
- Research and development expenses were \$1.07 million in the fourth quarter of 2022, or 5.3% of total revenues, an increase from \$0.9 million, or 3.5% of total revenues, in the same quarter in the year prior. This increase was primarily related to investments made in Translation, LDT and GENFLEX® systems.
- Selling, general and administrative expenses were \$11.1 million in the fourth quarter as compared to \$11.8 million in the previous year's fourth quarter, primarily due to reduced selling expenses. However, as a percentage of revenues, SG&A for 4Q22 equaled 54.5%, compared to 47.5% a year ago.
- GAAP net loss was (\$8.4) million or (\$0.17) per share versus a net profit of \$3.3 million, or \$0.07, in the year-ago quarter.

"Enzo Biochem remains focused on our near-term goals and confident in the future yield from our recent and ongoing investments," said Hamid Erfanian, CEO of Enzo Biochem. "We are cognizant of the need for cost savings, and are working towards our goal of \$5 million in operational savings this calendar year, with an additional \$5 million next year. Most importantly, we reiterate our fixed attention on creating value for shareholders through a commitment to customer service, product excellence and innovation. We are progressing on our engagement with Jefferies LLC, a multinational independent investment bank, to provide advisory services including the evaluation of strategic alternatives for the Company, its Enzo Clinical Lab and Enzo Life Sciences divisions and its various assets."

Conference Call and Webcast Information

The Company will host a conference call on Friday, October 14, 2022, 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:

Friday, October 14th @ 8:30 am ET

 Domestic:
 877-407-0792

 International:
 201-689-8263

 Conference ID:
 13733235

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1573424&tp_key=a9eeb4284d

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.

For more information, please visit <u>www.Enzo.com</u> or follow Enzo Biochem on Twitter and LinkedIn.

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, 2022. 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)

Selected operations data:	Three months ended July 31, (unaudited)					Fiscal year ended July 31, (unaudited)						
		2022		2021		2022		2021				
Total revenues	\$	20,284	\$	24,813	\$	107,071	\$	117,731				
Gross profit	\$	4,340	\$	9,813	\$	41,967	\$	53,577				
Gross profit %		21%		40%	39%			46%				
(Loss) income before income taxes		(8,433)		3,268		(18,261)		7,875				
Net (loss) income	\$	(8,433)	\$	3,268	\$	(18,261)	\$	7,875				
Basic net (loss) income per share		(\$0.17)	\$	0.07		(\$0.38)	\$	0.16				
Diluted net (loss) income per share		(\$0.17)	\$	0.07		(\$0.38)	\$	0.16				
Weighted average shares outstanding - basic		48,720		48,472		48,594		48,191				
Weighted average shares outstanding - diluted		48,720		48,840		48,594		48,325				
Selected balance sheet data:		7/31/2022 (unaudited)		7/31/2021 (unaudited)								
Cash and cash equivalents including restricted cash of \$1,000 at 7/31/22 and \$750 at 7/31/21 and marketable securities at 7/31/21	\$	21,603	\$	43,502								
Working capital	\$	29,804	\$	44,506								
Stockholders' equity	\$	54,462	\$	68,586								
Total assets	\$	95,857	\$	113,691								

The following table presents a reconciliation of reported net (loss) income and basic and diluted net (loss) income per share to non-GAAP net (loss) income and basic and diluted net (loss) income per share for the three months and fiscal years ended July 31, 2022 and 2021:

ENZO BIOCHEM, INC.

Non-GAAP Reconciliation Table

(Unaudited, in thousands, except per share data)

	Three months ended July 31,				Fiscal year ended July 31,			
		2022		2021		2022		2021
Reported GAAP net (loss) income Adjusted for:	\$	(8,433)	\$	3,268	\$	(18,261)	\$	7,875
Discrete severance and other related compensation expenses		102		154.00		1,991		-
Discrete legal and settlement expenses		45		-		2,516		1,973
Strategic initiatives expenses		144		-		2,374		-
Facility closure and separation expenses		-		-		384		154
Legal settlement, net		(350)		-		(350)		-
Paycheck Protection Program (PPP) loan forgiveness		-				-		(7,000)
Non-GAAP net (loss) income	\$	(8,492)	\$	3,422	\$	(11,346)	\$	3,002
Weighted Shares Outstanding:								
Basic		48,720		48,472		48,594		48,191
Diluted		48,720		48,840		48,594		48,325
Basic and diluted earnings per share:								
Basic net income (loss) per share GAAP		(\$0.17)	\$	0.07		(\$0.38)	\$	0.16
Diluted net income (loss) per share GAAP		(\$0.17)	\$	0.07		(\$0.38)	\$	0.16
Basic net income (loss) per share non-GAAP		(\$0.17)	\$	0.07		(\$0.23)		0.06
Diluted net income (loss) per share non-GAAP		(\$0.17)	\$	0.07		(\$0.23)	\$	0.06

The following table presents a reconciliation of reported GAAP net (loss) income for the three months and fiscal years ended July 31, 2022 and 2021, respectively to EBITDA and Adjusted EBITDA:

ENZO BIOCHEM, INC.

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

	Three months ended July 31,				Fiscal year ended July 31,			
		2022		2021		2022		2021
GAAP net income (loss)	\$	(8,433)	\$	3,268	\$	(18,261)	\$	7,875
Plus (minus):								
Depreciation and amortization		678		678		2,827		2,653
Interest expense (income)		(48)		(48)		(159)		(8)
EBITDA	\$	(7,803)	\$	3,898	\$	(15,593)	\$	10,520
Adjusted for:								
Paycheck Protection Program (PPP) loan forgiveness		-		(7,000)		-		(7,000)
Foreign exchange loss (gain)		335		158		2,222		(270)
Discrete severance and other related compensation expenses		102				1,991		-
Discrete legal and settlement expenses		45		-		2,516		1,973
Strategic initiatives expenses		144				2,374		-
Facility closure and separation expenses		-		154		384		154
Realized/unrealized loss on marketable securities		-		83		1,283		83
Legal settlement, net		(350)		-		(350)		-
Adjusted EBITDA	\$	(7,527)	\$	(2,707)	\$	(5,173)	\$	5,460



Source: Enzo Biochem, Inc.