

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): **January 5, 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 7.01 Regulation FD Disclosure.**

Beginning January 6, 2021, officers of the Company will present to various investors and stockholders using the presentation materials furnished as Exhibit 99.1 hereto and which are incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 8.01**

On January 5, 2021, Enzo Biochem, Inc. (the "Company") issued a press release titled "Enzo Biochem to Participate in the LifeSci Partners 1<sup>st</sup> annual Healthcare Corporate Access Event". A copy of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

**Item 9.01. Financial Statements and Exhibits.**

**(d) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Presentation materials to be used by officers of the Company</a>
99.2	<a href="#">Press Release of Enzo Biochem, Inc., dated January 5, 2021</a>

**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: January 6, 2021

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

The cover features a dark blue background with a glowing, multi-colored molecular structure in the center. The structure is composed of numerous spheres in shades of green, yellow, orange, and red, arranged in a complex, interconnected pattern. In the top left corner, the Enzo logo is displayed, consisting of a stylized 'E' made of three curved lines in blue, green, and yellow, followed by the word 'Enzo' in a bold, blue sans-serif font. Below the logo, the tagline 'Scientists Enabling Healthcare™' is written in a smaller, white font. In the top right corner, a white box contains the text 'NYSE: ENZ'. The main title 'A Year of Challenges, Opportunities & Achievements' is centered in a large, white, sans-serif font. Below it, the words 'Investor Presentation' are written in a slightly smaller, white, sans-serif font. At the bottom right, the date 'January 2021' is written in a smaller, white, sans-serif font. The background also features faint, glowing binary code (0s and 1s) and a faint DNA double helix structure.

## Forward Looking Statements

Except for historical information, the matters discussed in this presentation 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 and Form 10-Q for the period ended October 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 presentation.

## Promises Delivered – Enzo Biochem

- The company recently announced its best financial results in Enzo’s history and the fulfilling of its three core objectives:
  1. Building infrastructure for strategic diagnostic products and services growth
  2. Implementing efficiency measures with a return to operating profitability
  3. Transforming from a bifurcated life sciences company to an integrated end-to-end diagnostics company
- Enzo delivered on these objectives in the most challenging business environment
- Enzo’s two recently elected independent board members have vast industry experience



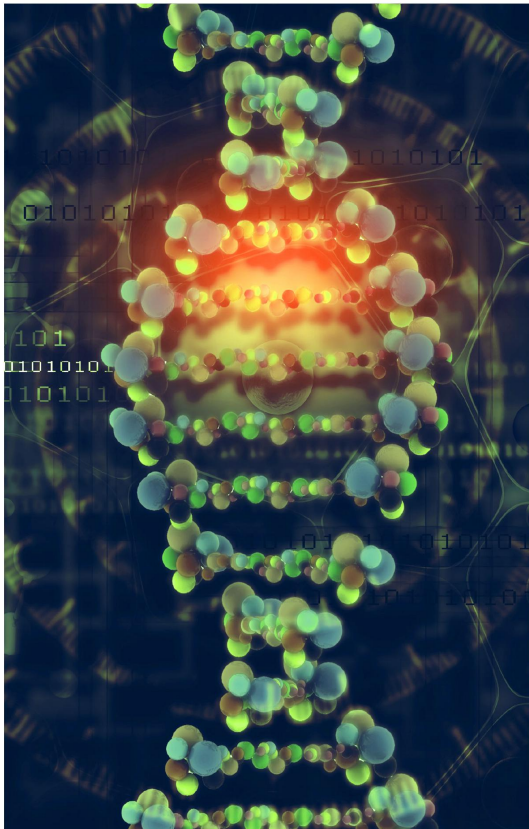
Dr. Walters has diverse leadership experience in drug development and business strategy. As a physician, scientist and entrepreneur, his deep expertise spans clinical development, regulatory affairs, and strategic planning.



Dr. Tagliaferri has broad global experience in a range of operational areas including business development, clinical research and development, world-wide regulatory matters and medical affairs.



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## 2020: A Year Of Innovation & Important Achievements For Enzo



## Company Snapshot

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 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.

*“ Our assets, infrastructure and capabilities have most recently been directed to address a growing market need in the area of diagnostic products and services.”*



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+40% YoY Revenue Growth → FY21E ~ \$115M  
Achieved Profitability



445 Global Employees operating across 9 countries



Extensive revenue-generating IP Portfolio:  
448 Patents Granted & 64 Patents Pending  
Actively Growing Under Dr. Rabbani's leadership:  
42 new patents granted & 23 patent applications filed in 2020



Global HQ in NYC with a worldwide distribution network



GMP compliant, CAP Accredited & CLIA Certified



## Products & Services to Meet Every Healthcare Need

Molecular Diagnostics

Immunoassays

Genetics & Genomics

Anatomical Pathology



Physicians / Urgent Care

Hospitals / Health Networks

Direct to Consumer

Concierge Services

Contract Research Organizations

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## Notable 2020 Achievements

*In the face of unprecedented challenges, Enzo's strategic forethought and decisive responsiveness led to significant achievements- in terms of both financial performance and strategic accomplishments.*

**Enzo Biochem's Clinical Labs Subsidiary Launches Drive-Through Facility to Provide COVID-19 Testing on Long Island**  
Company Ramping up Availability and Access to Testing

**Enzo Biochem Appoints Rebecca J. Fischer to Board of Directors**

**Enzo Biochem Reports Publication of Study Detailing Promising Activity of Drug Candidate SK1-I in a Model of Lupus**

**ENZO LAUNCHES PORTABLE MICROPLATE READER FOR USE WITH ITS ELISA AND ASSAY KITS TO SIMPLIFY LABORATORY WORKFLOW**

- Powerful and precise compact instrument enables Enzo to offer a complete solution to advance drug discovery  
- Microplate reader can be retrofitted for point-of-care clinical testing at urgent care facilities, hospitals or physicians' offices

**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.

**ENZO BIOCHEM LAUNCHES GOTESTMENOW™ ONLINE PLATFORM FOR CONSUMERS TO DIRECTLY ORDER COVID-19 LABORATORY TESTS**

**Enzo Announces Issuance of U.S. Patent for Methods of Treating Liver Cancer Using Proprietary Compound SK1-I**

**Enzo Biochem Launches Proprietary COVID-19 Diagnostic Test Under FDA's Emergency Use Authorization**

First Test Offering Within Enzo's Comprehensive COVID-19 Program  
Proprietary Molecular Diagnostic Kits Offer Improved Scale, Throughput, and Sensitivity

**Enzo Announces Issuance of U.S. Patent for Methods of Producing Monoclonal Antibodies Against Osteoporosis Drug Target Sclerostin**

**ENZO BIOCHEM ANNOUNCES APPOINTMENT OF MARY TAGLIAFERRI, MD, TO ITS BOARD OF DIRECTORS**

**Enzo Biochem Announces Significant Milestone with Approval of Proprietary GenFlex Platform**

**ENZO BIOCHEM DOUBLES CAPACITY IN RESPONSE TO INCREASING DEMAND FOR COVID-19 TESTING**

**Enzo Biochem Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Update**

• Company reports \$19.5 million in revenue and EPS of (\$0.07) in the fourth quarter with significant margin expansion supported by rapid response to COVID-19 market opportunities  
• Q1 21 first two months' revenue reflect continued positive trend

**Enzo Biochem Receives Emergency Use Authorization for Proprietary Test System for Detection of Coronavirus SARS-CoV-2**

Authorization Enables Clinical Labs to Purchase and Use Enzo's AMPiPROBE® SARS-CoV-2 Test System without Further Validation

**ENZO BIOCHEM TO PROVIDE ACCESS TO COVID-19 TESTING AT MORE THAN 50 NY PHARMACIES IN COLLABORATION WITH CPESN NY**

**Enzo Biochem to Provide COVID-19 Testing to Farmingdale State College Staff and Students as They Return to Campus**

First Collaboration under Enzo's School and Institution Testing ("SIT") Program

**ENZO BIOCHEM ANNOUNCES APPOINTMENT OF IAN B. WALTERS, MD, TO ITS BOARD OF DIRECTORS**

**Enzo Announces Issuance of U.S. Patent for Methods of Using Proprietary Compound SK1-I in Patients; Exploring Options for Development as a Potential Treatment for COVID-19**

**Enzo Biochem Launches Proprietary Test for Detection of Coronavirus SARS-CoV-2 IgG Antibody Under FDA's Emergency Use Authorization**



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## Strategic / Operational Accomplishments

- Our foresight and strategic investment in the GENFLEX™ platform drove our operational success in 2020
- Stabilized and grew business while ensuring safety, job security, and morale of employees during the pandemic
  - PPP: \$7 million loan to help address early challenges presented by COVID-19
  - Navigated “new normal” to coordinate efficient workflow with partners, vendors, and customers

### Under Dr. Rabbani's leadership & operational guidance:

- Increased lab productivity by doubling shifts to improve response time of COVID-19 tests to less than 24 hours vs. national average of 2-3 days
- Launched comprehensive suite of COVID-19 testing products and services under FDA EUA
- Introduced serological IgG antibody detection testing services
- Rolled out a drive-thru facility for COVID-19 testing on Long Island, NY
- Launched School and Institution Testing (SIT) Program to keep students/faculty safe
  - Stony Brook University, Farmingdale State College, NYIT, etc.

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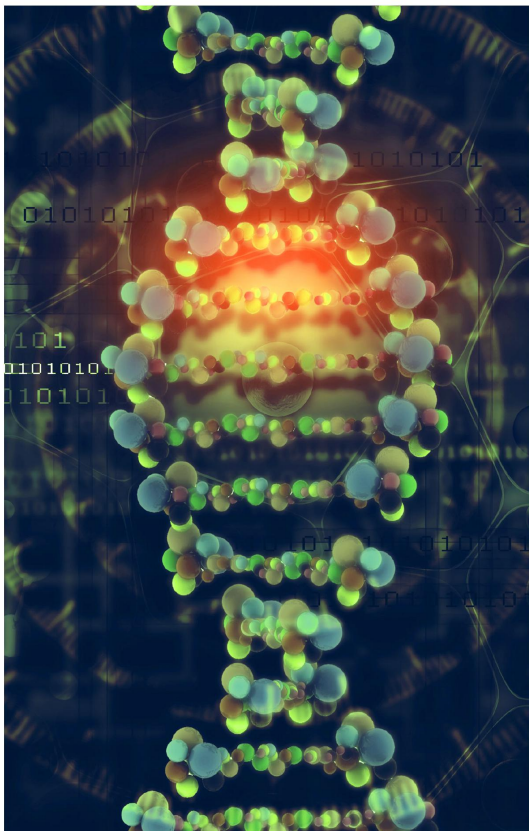


## Strategic / Operational Accomplishments (continued)

Continued focus on core growth initiatives delivered strong results:

- FDA EUA approval for diagnostic products and services
  - GENFLEX™ platforms now running in our lab
- Continued expansion of prolific patent portfolio
  - 42 new patents granted & 23 new patent applications filed in 2020
- Build-out of Farmingdale, NY facility, increasing capacity with favorable tax structure & financing
- Greater than 50% increase in accessions in last quarter
- Expanded Point-Of-Care Potential of Microplate Reader
- Formalized labs-to-lab partnerships and actively negotiated additional relationships with small to medium-sized clinical labs
- Received \$10 million of funding (including Medicare Cares Act grant & Swiss Corona Krise loan)
- Reinstated \$20 million at-the-money shelf offering for financial flexibility to grow the business

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## Transforming Molecular Diagnostics to a Modern Platform



# Enzo's Decentralized Approach

Investing in the future of fully integrated end-to-end diagnostic solutions

Witnessing the external **industry challenges** firsthand such as:

Affordable Care Act (ACA)

Protecting Access to Medicare Act (PAMA)

Centralized Laboratory Testing (Commoditization)

Legacy Equipment (Pre-miniaturization/ Technological Integration)

Consolidation and transition to uniformity



Proactively **invested into building proprietary** platforms which focus on key differentiating features:

**Open Platform Architecture**  
(capable to adapt reagents/supplies from diverse providers)

**Prioritizing Cost Reduction** and Positive ROI for Enzo's Customers

**Providing Superior Accuracy**, High-Throughput that remains Flexible & Adaptable over time

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## ENZO's Proprietary GENFLEX™ Platform

Developed to address systemic issues across the Molecular Diagnostics Industry

### GENFLEX™

FDA Approval (EUA) July 2020 for its **COVID-19** test, which positioned Enzo as a leader in molecular diagnostics and services.

Capabilities are being extended to Women's Health, STDs, Viral Load, Flu, RSV and other infectious disease diagnostic tests.



#### Currently Processing COVID-19 Tests

- FY21 capacity: Over 1 Million Tests Annually
- Molecular: AMPIPROBE® SARS-CoV-2
- Serology: SARS-CoV-2IgG ELISA



#### Cost Effective Approach

- Provides customers improved ROI and access to consumables for the lab



#### Applications Across Multiple Testing Segments:

- Viral Load Testing: HIV, HCV, HBV
- Women's Health Testing: Chlamydia, N.Gonorrhoeae, Trich, Bacterial Vaginosis,



#### High Unmet Industry Need

- Adaptable → Open System methodology
- Ultra Fast → High throughput
- Superior Accuracy → Sensitivity & Specificity






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# Accelerated Demand for Molecular Diagnostics

## Renewed Appreciation for Molecular Testing

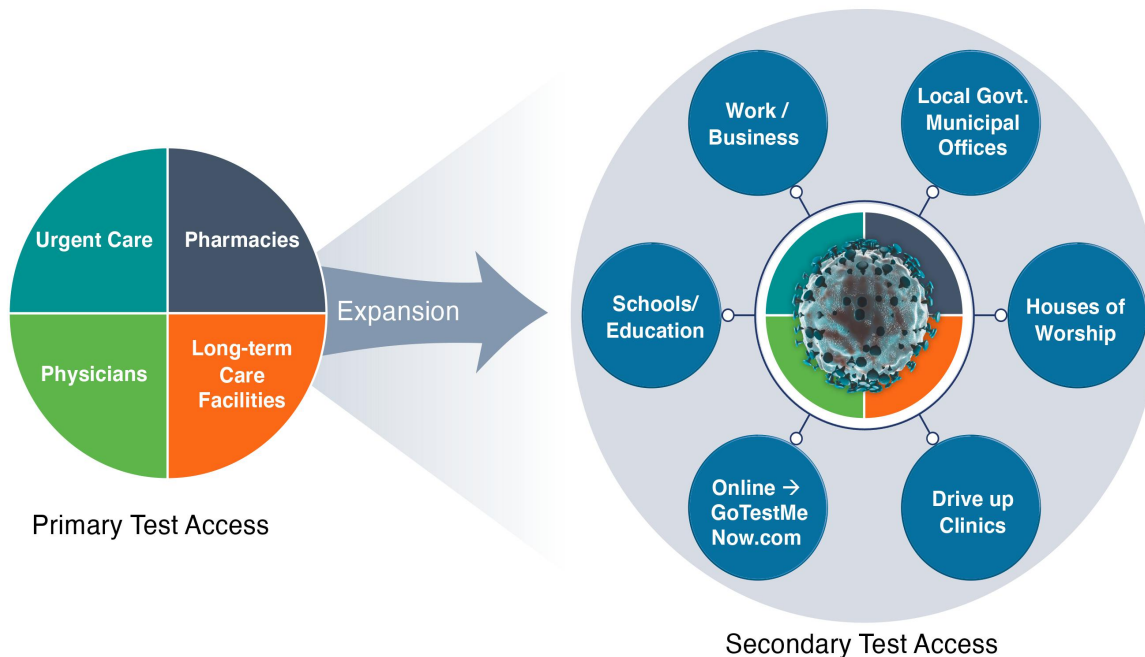
 <b>Unified Need</b>	<ul style="list-style-type: none"><li>• Awareness of the risk of pandemic has reinforced the critical role that diagnostic testing plays in global health.</li><li>• Stakeholders including Patients, Providers, Government Agents and Payers understand the need to meet testing requirements.</li></ul>
 <b>Continued Demand</b>	<ul style="list-style-type: none"><li>• Molecular Dx, while still a smaller segment within the ~\$170 bn clinical lab market, is estimated to reach \$15bn in 2020.</li><li>• COVID-19 testing revenues will likely remain significantly elevated for the next few years, even when a vaccine is available.</li></ul>
 <b>Panel Dx Approach</b>	<ul style="list-style-type: none"><li>• Renewed appreciation for syndromic multiplex respiratory panels such as Influenza A &amp; B, SARS-CoV-2 and RSV.</li><li>• Reduced time with a healthcare Provider benefits Patients, Physicians and Payers</li></ul>

**Increased Demand for Infectious Disease Testing Should Continue for 12-18 months**

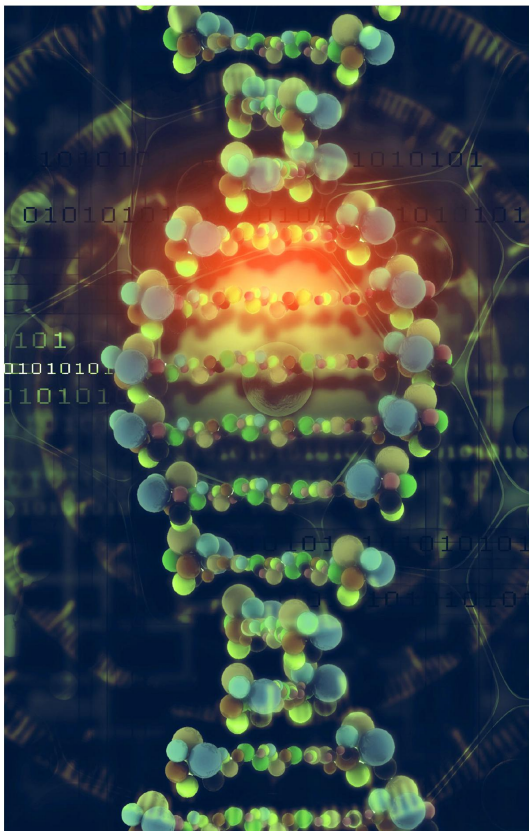
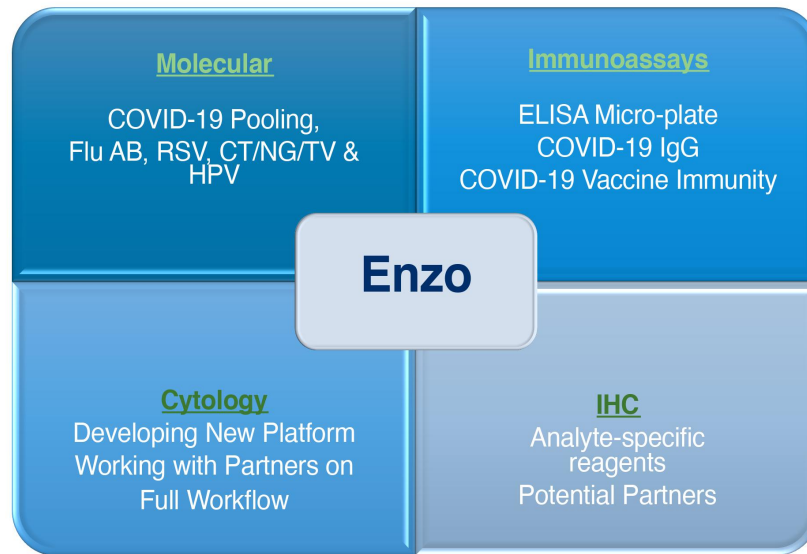


# Commercial Approach To Expanding Test Access

## Serve Multiple Constituents

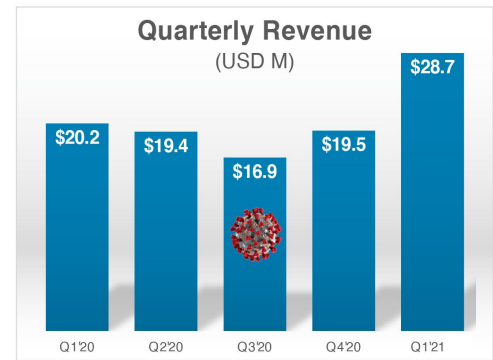
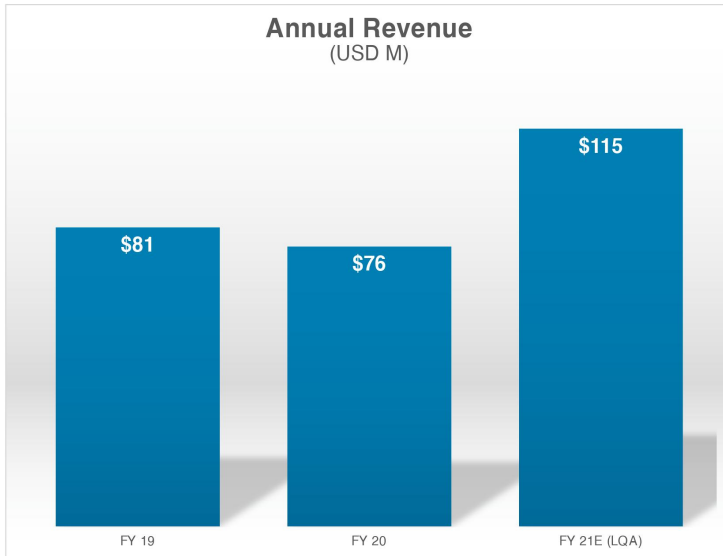


# Focus Areas – Progress on Novel Diagnostic Platforms

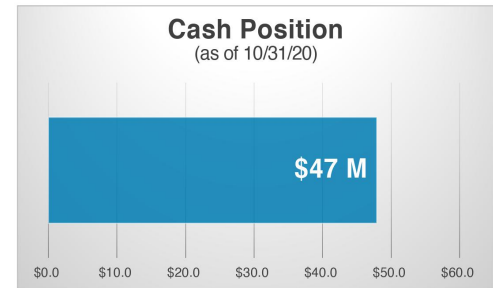


## Enzo's Financial Performance

# Financial Snapshot



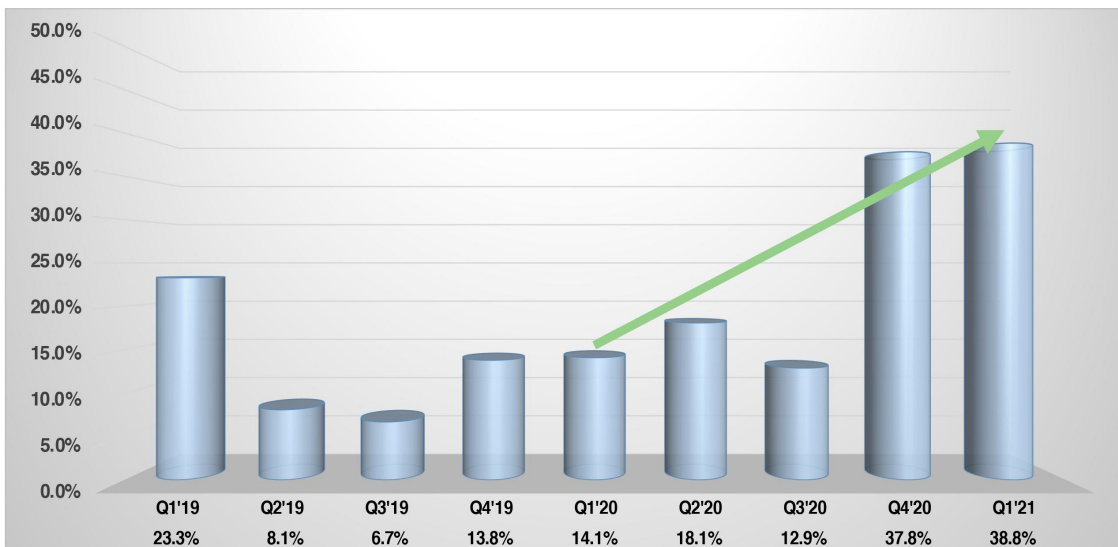
Initial COVID effect in Q3 (Feb-Apr)



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# Enzo Services Gross Margin



- ✓ GM in Services division increased to 38.8% in Q1 vs. 14.1% in previous year's quarter
- ✓ Rapid increase due to favorable test mix and continued cost savings initiatives

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## Quarterly EBITDA and EPS

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	<b>Q1 2021</b>	<b>Q1 2020</b>	<b>YoY Change</b>
<b>EBITDA</b>	\$1.0mm	(\$7.1mm)	\$8.1mm
<b>Adj. EBITDA</b>	\$1.0mm	(\$5.7mm)	\$6.7mm
<b>EPS</b>	\$0.01	(\$0.16)	\$0.17
<b>Adj. EPS</b>	\$0.01	(\$0.13)	\$0.14

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## Well Positioned for New Levels of Success in 2021

- ✓ Our expanded operations and enhanced capabilities position Enzo as an integrated end-to-end diagnostics company able to deliver the full range of innovative products and services the market demands
- ✓ Facility Expansion: With favorable tax incentives, expanded state of the art facilities in Farmingdale, NY to position Enzo to rapidly meet customer and consumer demand related to COVID-19 and other emerging needs
- ✓ Margin expansion through identification and implementation of operational efficiencies in all areas of our business achieved target goal of \$10 million in cost reductions
- ✓ Additional margin improvement achieved via development and utilization of home-grown tests, validating Enzo's strategy of leveraging internal platforms


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# Investment Highlights

Best In Class MDx Platform Supported By Fully-integrated Biotech, Life Sciences And Lab Services Business

	Capitalizing on <u>industry tailwinds amid accelerated global demand</u> for unique diagnostic platform technologies		FY(JUL)'21-reach <u>profitability &amp; \$115m revenue run rate</u> Expanded margin profile & product mix
	<u>COVID-19 Testing &amp; Platform-Flexible Solutions</u> Our rapid response provided tests in the first months of the global pandemic		Extensive portfolio of innovative, revenue generating intellectual property <u>450+ patents and patent applications</u>
	<u>Enzo's Expanded Market Reach</u> By transforming to a modernized decentralized approach <b>Central Lab → Point-of-Care → Direct-to-Consumer</b>		<u>Global management team</u> : industry leaders with extensive experience across the entire healthcare and lab services business
		<u>Integrated Approach</u> : Enzo offer a complete suite of products and services, enabling innovation & disruption	

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## Primed for Continued Success

- ✓ Unique vertical integration enables innovation and disruption within the healthcare market
- ✓ Capitalizing on industry tailwinds amid tremendous demand for molecular diagnostics
- ✓ Actively addressing COVID-19 from multiple angles



❖ Virus Detection → Ampiprobe® SARS-CoV-2



❖ Immunity Detection → SARS-CoV-2 IgG ELISA

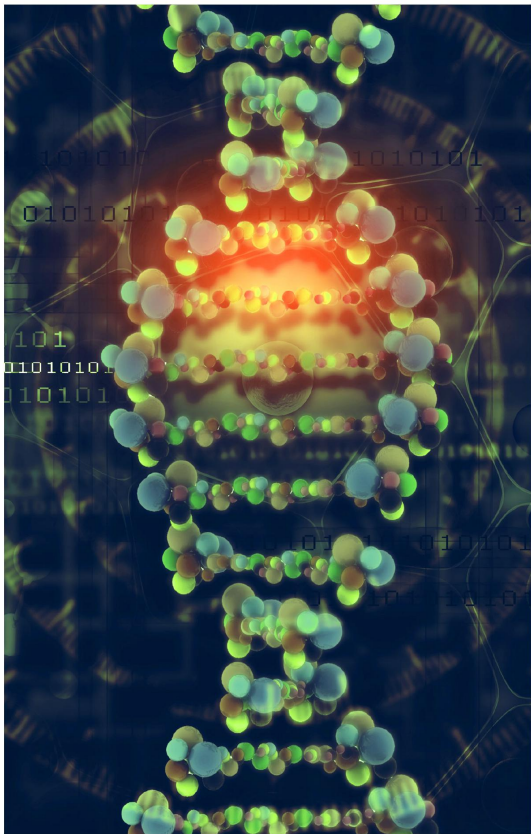


❖ Inflammation Testing

- ✓ Delivering significant operational cost reductions while maintaining healthy margins
- ✓ Extensive, innovative intellectual property estate with over 450 patents including
- ✓ 42 patents issued and 23 filed during past year led by Dr. Rabbani
- ✓ Global presence and strategically positioned for substantial growth and value creation
- ✓ Significantly Improved Financial and Corporate Governance Profile

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Thank You

[www.enzo.com](http://www.enzo.com)

IR@enzo.com

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*news  
release*

Enzo Biochem, Inc.  
527 Madison Avenue  
New York, NY 10022

**FOR IMMEDIATE RELEASE**

**ENZO BIOCHEM TO PARTICIPATE IN THE LIFESCI PARTNERS  
10<sup>TH</sup> ANNUAL HEALTHCARE CORPORATE ACCESS EVENT**

NEW YORK, NY, January 5, 2021 – Enzo Biochem, Inc. (NYSE:ENZ) (“Enzo” or “The Company”), a leading biosciences and diagnostics company, today announced that it will participate in the 10<sup>th</sup> Annual LifeSci Partners Corporate Access Event, January 6-8 and 11-14, 2021 in concurrence with J.P. Morgan’s 39<sup>th</sup> Annual Healthcare Conference.

Barry Weiner, President, and David Bench, Chief Financial Officer, will host virtual 1x1 meetings during both sessions of the event as well as present a corporate update on Wednesday, January 6<sup>th</sup> at 1pm EST.

To register or to listen to the presentation as well as to request a meeting, please visit the following registration link: <http://lifesci.events/LifeSci2021>

**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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