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 17, 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)

527 Madison Avenue New York, New York

(Address of Principal Executive Offices)

13-2866202 (IRS Employer Identification No.)

> 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 *kee* 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 \Box

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 8.01

On December 15, 2020, Enzo Biochem, Inc. (the "Company") issued a press release titled "Enzo Biochem Hosting Key Opinion Leader Call on GENFLEXTM Molecular System for COVID-19 and the Role of Testing in a Post-Vaccine Treatment Environment" and related materials.

Item 7.01. Regulation FD Disclosure.

The information provided in Item 8.01 of this Current Report on Form 8-K is incorporated herein by reference in its entirety.

The information discussed under Item 8.01 above 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.

Exhibit No.	Description
99.1	Press Release of Enzo Biochem, Inc., dated December 15, 2020.
99.2	Presentation materials for Key Opinion Leader call on December 17, 2020.

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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.

Date: December 17, 2020

ENZO BIOCHEM, INC.

By: /s/ David Bench David Bench

Chief Financial Officer

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Enzo Biochem Hosting Key Opinion Leader Call on GENFLEX[™] Molecular System for COVID-19 and the Role of Testing in a Post-Vaccine Treatment Environment

Thursday, December 17th @ 12:00pmET

New York, NY, December 15, 2020 -- Enzo Biochem, Inc. (NYSE:ENZ), a leading biosciences and diagnostics company, today announced that it will host a key opinion leader (KOL) webinar discussing the use of the GENFLEX[™] Molecular System for COVID-19 testing and the role of testing in a post-vaccine treatment environment, on Thursday, December 17, 2020 at 12:00pm Eastern Time.

Infectious disease specialists Bruce Hanna, PhD, NYU Grossman School of Medicine, and Gerard Nuovo, MD, Ohio State University College of Medicine, will discuss the GENFLEXTM Molecular System for COVID-19 and the role of testing in a post-vaccine treatment environment. Included in this discussion will be the advantages of Enzyme-Linked Immunosorbent Assay (ELISA) kit technology for COVID-19 related serological testing. Drs. Hanna and Nuovo will be available to answer questions following the formal presentations.

Enzo Biochem's management team will also give an update on the applications of GENFLEXTM Molecular System and ELISA kit testing platforms as access to vaccines expands in 2021. The GENFLEXTM Molecular System, which received FDA Emergency Use Authorization (EUA), is an all-in-one solution for COVID-19 molecular testing from extraction, detection and analysis to clinical results. The ELISA kit is designed for the qualitative detection of IgG antibodies specific to COVID-19 in human serum samples. Enzo's serological solutions aid in identifying individuals with an adaptive immune response to COVID-19.

To register for the call, please click here.

Bruce Hanna, PhD, has served as a Clinical Professor of Pathology and Clinical Professor of Microbiology at the New York University School of Medicine since 1979 and Adjunct Professor of Science at New York University College of Dentistry since 2010. From 2006 to 2015, he served on the ASM International Committee and WHO Global Committee; from 2000 to 2012, he served as the Editor of the Clinical Microbiology Review; from 1982 to 2010, he was a director of Clinical Microbiology and Immunology; and from 2008 to 2010 he was Interim director of Pathology, Bellevue Hospital Center. Dr. Hanna earned a Bachelor of Science in Biology from Saint Bonaventure University, a Masters in Science in Microbiology from Northeastern University and a Ph.D. in Microbiology from Saint John's University. Dr. Hanna's post-doctorate work in Clinical Microbiology was at Mt. Sinai Hospital.

Dr. Gerard Nuovo is a board-certified anatomic pathologist and has spent his entire 30+ year career correlating the histologic features with the in situ detection of DNA, RNA, and proteins. He currently is medical director of a Molecular Pathology Laboratory (Phylogeny) that serves as a satellite laboratory for the OSUCCC. His group has invented several methodologies that can be used for the enhanced in situ detection of mRNA, viral nucleic acids, and microRNAs, including RT in situ PCR and the ultramer extension method for the latter. Further, he has extensive experience with the in situ co-localization of RNA/DNA molecules and proteins. He has published over 333 peer review manuscripts, written 6 textbooks, has done over 40 invited chapters, and has been a co-PI on over 20 grants. His group was the first to show that human papillomavirus induced a type specific immunity and was one of the first groups to show that HIV-1 caused a massive infection prior to the development of AIDS. He has done extensive work on the molecular events that underlie the use of viruses as oncolytic agents in cancer.

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, 2019 and Form 10-Q for the period 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.

Contacts: Enzo Biochem, Inc. David Bench, CFO 212-583-0100 dbench@enzo.com

Investors: LifeSci Advisors, LLC Jeremy Feffer 212-915-2568 jeremy@lifesciadvisors.com



Source: Enzo Biochem, Inc.

Exhibit 99.2



COVID-19: The Vaccine is Out, Now What Does that Mean for Testing ?

KOL Event December 17, 2020

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.



Elazar Rabbani, PhD



Dr. Elazar Rabbani, PhD is an Enzo Biochem founder and has served as the Company's Chairman of the Board and Chief Executive Officer since its inception in 1976. Dr. Rabbani has authored numerous scientific publications in the field of molecular biology, in particular, nucleic acid labeling and detection. He is also the lead inventor of many of the Company's pioneering patents covering a wide range of technologies and products.

Dr. Rabbani received his Bachelor of Arts degree from New York University in Chemistry and his Ph.D. in Biochemistry from Columbia University. He is a member of the American Society for Microbiology. He has published over 19 publications and has 110 U.S. Patents (with 125 foreign counterparts).







Introduction

Company Snapshot

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



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</u> <u>demand</u> for unique diagnostic platform technologies



<u>COVID-19 Testing & Platform-Flexible Solutions</u> Our rapid response provided tests in the first months of the global pandemic



FY(JUL)'21-reach profitability & \$115m revenue run rate Expanded margin profile & product mix



Extensive portfolio of innovative, revenue generating intellectual property <u>450+ patents and patent applications</u>

extensive experience across the entire healthcare and

Global management team: industry leaders with

lab services business



Enzo's Expanded Market Reach of Product & Services By transforming to a modernized decentralized approach Central Lab \rightarrow Point-of-Care \rightarrow Direct-to-Consumer



Integrated Approach: Enzo offer a complete suite of products and services, enabling innovation & disruption



Extensive Capabilities Products & Services



Bruce Hanna, PhD



Bruce Hanna, PhD, has served as a Clinical Professor of Pathology and Clinical Professor of Microbiology at the New York University School of Medicine since 1979 and Adjunct Professor of Science at New York University College of Dentistry since 2010. From 2006 to 2015, he served on the ASM International Committee and WHO Global Committee; from 2000 to 2012, he served as the Editor of the Clinical Microbiology Review; from 1982 to 2010, he was a director of Clinical Microbiology and Immunology; and from 2008 to 2010 he was Interim director of Pathology, Bellevue Hospital Center. Dr. Hanna earned a Bachelor of Science in Biology from Saint Bonaventure University, a Masters in Science in Microbiology from Northeastern University and a Ph.D. in Microbiology from Saint John's University. Dr. Hanna's postdoctorate work in Clinical Microbiology was at Mt. Sinai Hospital.



A virus is a DNA/RNA delivery system into the host cell.

The virus binds to a receptor on the host cell, enters the cell and replicates. (lysogenic cycle).



Angiotensin-converting enzyme 2 (ACE2) attached to the membrane of host cells located in many parts of the body including the lungs, arteries, heart, kidney, and intestines.

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SARS-CoV-2 Targets For Diagnostic Tests And Vaccines



How To Test Patients For COVID-19

The NEW ENGLAND JOURNAL of MEDICINE

Perspective

Infection — acquire the pathogen & it persists aka latent/incubation period - vaccine effect unknown

lgG

Disease - develop symptoms from mild to severe m-RNA vaccines 95% effective preventing



"Not all tests are the same"

	Molecular Test	Antibody Test	Antigen Test
	(Gold Standard)	(Post-virus)	(Faster Results)
<i>èEnzo</i>	Ampiprobe® Commercially Approved – US	IgG/IgM ELISA Commercially Approved – US	
Sample Types	Nasal, Throat & Saliva	Blood Draw; finger stick	Nasal, Throat & Saliva
Advantages	Very accurate	Confirm exposure to COVID- 19 virus	POC, quick turn around
Disadvantages	Sent to large laboratory, 📰 testing (1-4 hours)	Not a Dx tool for active infection	Limit of detection varies
Turn around time (processing sample)	1-3 days	1-3 days	Hours

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CDC Interim Guidance for Antigen Testing for SARS-CoV-2

Updated Dec. 5, 2020



Enzo's molecular solutions using RT-PCR



AMPICOLLECT for sample collection

AMPIXTRACT SARS-CoV-2 Extraction Kit for sample processing - nucleic acid extraction from patient specimens

AMPIPROBE SARS-CoV-2 Assay Kit and Controls for amplification and detection

AMPIPROBE SARS-CoV-2 Test can be performed on the GENFLEX, an open, high-throughput, automated, and scalable platform for easy and accurate processing of common molecular diagnostic tests within a clinical production setting. The system is a flexible and fully automated platform for nucleic acid amplification, detection, and data analysis.

A flexible, adaptable, multi-analyte platform

Antibody Test (Blood) by ELISA

Detect immune response to past SARS-CoV-2 exposure or disease (seroconversion)



Enzo SARS-CoV-2 ELISA Sensitivity = 100% Specificity = 96.5%



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Issues Post Vaccine: How will testing algorithms be modified?

How will the vaccine impact the need for testing? What type of testing will be needed going forward?

- Vaccine acceptance: incidence of adverse reaction time to herd immunity
- Will the virus mutate: *i.e.* in humans or in the animal reservoir
- **Antibody testing will become standard of practice** do Ab positive patients, from prior exposure need vaccine?
- Will testing be de-centralized: direct Antigen tests for detection of virus is limited by low sensitivity requires high numbers for reliable detection. = poor Negative Predicitive Value (NPV) requiring NAAT confirmation
- Cost to patient: self-pay, third party payers, state/local governments
- Who will be the ongoing test pool: worried well, travelers, contact tracing, returning workers/students, HCW's, referred by HCP i.e. GoTestMeNow™

Gerard Nuovo, MD



THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER Dr. Gerard Nuovo is a Professor of Pathology at the Wexner Medical Center at Ohio State University and a board-certified anatomic pathologist. He has spent his entire 30+ year career correlating the histologic features with the in situ detection of DNA, RNA, and proteins. He currently is medical director of a Molecular Pathology Laboratory (Phylogeny) that serves as a satellite laboratory for the OSUCCC. His group has invented several methodologies that can be used for the enhanced in situ detection of mRNA, viral nucleic acids, and microRNAs, including RT in situ PCR and the ultramer extension method for the latter. Further, he has extensive experience with the in-situ co-localization of RNA/DNA molecules and proteins. He has published over 333 peer review manuscripts, written 6 textbooks, has done over 40 invited chapters, and has been a co-PI on over 20 grants. His group was the first to show that human papillomavirus induced a type specific immunity and was one of the first groups to show that HIV-1 caused a massive infection prior to the development of AIDS. He has done extensive work on the molecular events that underlie the use of viruses as oncolytic agents in cancer.



Complete, Affordable Solutions for COVID-19

Enzo is well-equipped to provide the testing, processing and detection/analytics for this large and growing market





Inflammation

Cytokine Storm Immunoassay for Inflammation Monitoring

- Commercialization of full inflammation panel including detection of Interleukin 6 (IL-6) levels to enable administration of immunosuppressant to treat Coronavirus patients demonstrating hyper immune response
- Enzo 96-well ELISA plate test is performed in a clinical lab using common lab workflow
- Turnaround time is 24 hours and results are accurate and economical
- Easily scalable





Pathophysiology of SARS-CoV2 infection Gerard Nuovo, MD and Cynthia Magro, MD (Professor of Pathology, Cornell Medical Center)

• Initial infection in the nasopharynx by SARS-CoV2

Annals of Diagnostic Pathology 48 (2020) 151565



Original Contribution

Cytologic and molecular correlates of SARS-CoV-2 infection of the nasopharynx



Gerard J. Nuovo $^{\mathrm{a,b,*}}$, Cynthia Magro $^{\mathrm{c}}$, Adel Mikhail $^{\mathrm{b}}$

Cytologic And Molecular Corelates Of SARS-CoV-2 Infection Of The Nasopharynx

MAIN FINDINGS

✓ The target cell of the COVID-19 virus is the ACE2+ GLANDULAR CELL of the nasal cavity

 \checkmark The infected cells contain very large amounts of infectious virus, which kills the cell

✓ This allows for a strong immune response against the virus

Cytologic And Molecular Corelates Of SARS-CoV-2 Infection Of The Nasopharynx

MAIN FINDINGS





Pathophysiology of SARS-CoV2 infection Gerard Nuovo, MD and Cynthia Magro, MD (Professor of Pathology, Cornell Medical Center)

• Infection in lung associated with massive infection and complement mediated death of virus

Complement associated microvascular injury and thrombosis in the pathogenesis of severe COVID-19 infection: A report of five cases



CYNTHIA MAGRO, J. JUSTIN MULVEY, DAVID BERLIN, GERARD NUOVO, STEVEN SALVATORE, JOANNA HARP, AMELIA BAXTER-STOLTZFUS, and JEFFREY LAURENCE

NEW YORK, NEW YORK; POWELL, OHIO; AND NEW YORK, NEW YORK

Translational Research 2020; 220:113)

Virus Infection Of The Lung

MAIN FINDINGS

- ✓ The target cells of the COVID-19 virus in the lung are the ACE2+ macrophages, endothelia, and alveolar pneumocytes
- ✓ The infected cells contain very large amounts of infectious virus
- ✓ The body's response is to activate complement cascade which causes small blood clots in the alveolar septa which kills the cells and the virus

SARS-CoV-2 Infection Of The Lung

MAIN FINDINGS

Infected macrophage

Infection spreads to endothelial cells

Degenerating virus





WHAT IS THE CONSEQUENCE OF THE DEGENERATED VIRAL PROTEINS ENTERING THE CIRCULATION?

Human Pathology (2020) 106, 106-116



Human PATHOLOGY www.elsevier.com/locate/humpath

Original contribution



Docked severe acute respiratory syndrome coronavirus 2 proteins within the cutaneous and subcutaneous microvasculature and their role in the pathogenesis of severe coronavirus disease 2019

Cynthia M. Magro MD^{a,**}, J. Justin Mulvey MD, PhD^b, Jeffrey Laurence MD^c, Surya Seshan MD^a, A. Neil Crowson MD^d, Andrew J. Dannenberg MD^e, Steven Salvatore MD^a, Joanna Harp MD^f, Gerard J. Nuovo MD^{g,*}

Circulating Viral Proteins Can Cause A Lot Of Damage

MAIN FINDINGS

- ✓ Viral spike protein enters circulation and binds to ACE2+ endothelia in microvessels
- ✓ The sites with the highest amount of ACE2+ endothelia are the SKIN/FAT and brain (also heart, liver, kidney)
- ✓ The docked spike protein kills the endothelial cell, activates the complement cascade, and increases cytokine expression (TNFa, IL6, IL8, IL1 beta).

HENCE, THIS IS THE SOURCE OF THE INCREASED COAGULABILITY AND CYTOKINE STORM OF SEVERE COVID-19

Docked Spike Protein In The Skin

MAIN FINDINGS





WHAT IS THE CONSEQUENCE OF THE DEGENERATED VIRAL PROTEINS ENTERING THE CIRCULATION?

Annals of Diagnostic Pathology 50 (2021) 151645



Original Contribution

Severe COVID-19: A multifaceted viral vasculopathy syndrome Cynthia M. Magro^a, Justin Mulvey^b, Jeffrey Kubiak^a, Sheridan Mikhail^c, David Suster^d,

A. Neil Crowson^{e,g}, Jeffrey Laurence^a, Gerard Nuovo^{c,f,*,1}



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Circulating Viral Proteins Can Cause A Lot Of Damage

MAIN FINDINGS

This paper demonstrated that the observation of ACE2+ endothelia in microvessels was not limited to the subcutaneous fat of the skin

- ✓ It was also found in the brain, liver, heart, and other organs
- ✓ Again, the docked spike protein kills the endothelial cell, activates the complement cascade, and increases cytokine expression (TNFa, IL6, IL8, IL1 beta).



Conclusions

- ✓ Large reservoirs of infectious virus are limited to the nasopharynx and lung
- ✓ The microthrombi in lung kills virus, but this releases the spike (capsid) protein into the circulation (NOT infectious but still dangerous)
- ✓ The docked spike protein kills the ACE2+ endothelial cell, activates the complement cascade, and increases cytokine expression (cytokine storm). If this could be detected at an early stage, and stopped, it would save many lives



Questions & Answers









NYU Langone Health

THE OHIO STATE UNIVERSITY WEXNER MEDICAL CENTER







Thank You

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