**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): **February 11, 2020**

**Enzo Biochem, Inc.**
(Exact Name of Registrant as Specified in Its Charter)

**New York**
(State or Other Jurisdiction of Incorporation)

| **001-09974** | **13-2866202** |
|---|---|
| (Commission File Number) | (IRS Employer Identification No.) |

| **527 Madison Avenue**<br>**New York, New York** | **10022** |
|---|---|
| (Address of Principal Executive Offices) | (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 8.01. Other Events.**

On February 11, 2020, Enzo Biochem, Inc., ("***Enzo***") issued a press release.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

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

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release, dated February 11, 2020. |

**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: February 11, 2020

By: /s/ Barry W. Weiner
Barry W. Weiner
President

**For Immediate Release**

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

New York State Department of Health Approves Tests on GenFlex Platform, Enzo Biochem's First Commercially Available High-Throughput Open Platform

Approval of Gynecological Tests (CT/NG/TV) on GenFlex Platform Represents Sea-Change in Providing Cost-Effective Comprehensive Menu of Molecular Diagnostic Tests

Genflex addresses the $450 million annualized global CT/NG/TV diagnostic market as well as the $1.3 billion Women's Health market

Further Validation of Company's Ability to Leverage Leading Intellectual Property

NEW YORK, NY, February 11, 2020 – Enzo Biochem, Inc. (NYSE: ENZ) today announced that its wholly owned subsidiary, Enzo Clinical Labs, Inc. has received New York State approval for its CT/NG/TV tests using liquid-based cytology sample collection on its proprietary GenFlex platform. GenFlex is a commercially available sample-to-result molecular diagnostic platform that includes sample collection, sample processing, amplification and detection. The GenFlex open system delivers high-throughput, high capacity, workflow efficiency and flexibility at a much greater level of affordability than existing systems.

This is the latest successful development in Enzo's strategic plan to provide a cost-effective, comprehensive menu of molecular diagnostic products and services. This significant milestone achievement highlights Enzo's continued ability to deliver high performance, open, flexible, adaptable and cost-effective products, devices and services. Compared favorably to all other proprietary platforms dominating the diagnostic testing market, Enzo's GenFlex platform offers 30-50% cost-savings over current closed systems.

GenFlex addresses the $450 million annualized global CT/NG/TV diagnostic market as well as the $1.3 billion Women's health market. Extensions of the Genflex platform, which Enzo is currently developing, could eventually address the entire $7 billion molecular diagnostic market.

Enzo CEO Dr. Elazar Rabbani commented, "We are extremely pleased to announce this approval of GenFlex as we remain on track on our development program. Enzo's previously validated Ampiprobe detection system has been transformed into a complete end-to-end solution, GenFlex. This platform is a direct response to the critical industry need to offer lower cost solutions in the dramatically shrinking reimbursement rate environment as we can now offer users cost savings of 30-50% and the scalability necessary for a full commercial roll out. In fact, GenFlex's robust platform is being expanded beyond CT/NG/TV to a vast menu of tests within molecular diagnostics including sexually transmitted diseases, a category that is rising exponentially in both men and women in all sites of the body, including anal, oral and cervical-vaginal sites."

Barry Weiner, President of Enzo, said "This New York State approval is transformative as we now evolve from having the tests to having a validated entire end-to-end solution to run a series of tests without users being tied to existing closed systems. We know that the affordability of Enzo's testing on GenFlex makes it possible to deliver clinical results to other medical establishments. The pathway to commercialization is clear."

According to the Centers for Disease Control and Prevention (CDC), there are more than 1.7 million cases of Chlamydia (CT), 500,000 cases of Neisseria Gonorrhea (NG) and 3.7 million cases of Trichomonas Vaginalis (TV) in the United States per annum.

The approval of the GenFlex platform is directly related to the successful development work completed on Enzo's proprietary Ampiprobe detection technology which was initially validated on third-party research-only instrumentation. GenFlex overcomes challenges inherent in existing platforms which may include: the extraction system necessitating expensive sample processing reagents, multi-year provider contracts, low-capacity throughput, and multiple independent instruments for extraction, PCR set-up, and detection.

Adopting Ampiprobe detection technology into third-party platforms was a necessary first step towards Enzo's development of a fully automated system. However, with Enzo's GenFlex approval, Enzo's goal of commercializing a fully automated high-throughput platform with 30-50% cost savings is being realized.

## 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.

## Important Additional Information and Where to Find It

Enzo Biochem, Inc. (the "Company") has filed and mailed to shareholders a definitive proxy statement and proxy supplement on Schedule 14A and accompanying WHITE proxy card with the Securities and Exchange Commission (the "SEC") in connection with the solicitation of proxies from the Company's shareholders with respect to its 2019 Annual Meeting of Shareholders. The Company has filed in preliminary form and intends to file and mail to shareholders a new definitive proxy supplement and new GOLD proxy card. Shareholders are strongly encouraged to read the Company's proxy statement, proxy supplements, accompanying GOLD proxy card and all other documents filed with the SEC as they become available carefully and in their entirety as they contain important information.

## Certain Information Regarding Participants to the Solicitation

The Company, its directors and certain of its executive officers are participants in the solicitation of proxies from shareholders in connection with the Company's 2019 Annual Meeting of Shareholders. Information regarding the direct and indirect interests, by security holdings or otherwise of the Company's participants is set forth in the Company's definitive proxy statement and proxy supplement for the 2019 Annual Meeting of Shareholders filed with the SEC on December 5, 2019 and December 31, 2019, respectively. The Company's definitive proxy statement and proxy supplement can be found on the SEC's website at www.sec.gov or the Company's website at http://www.enzo.com/corporate/investor-information.

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, 2019. 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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