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Enzo Biochem Announces Key Transformative Initiatives to Propel and Accelerate Growth In its Lab Business

New York State Health Department Approval of Oral and Rectal STI Testing

Enzo to Create Direct to Consumer Testing Business for Sexually Transmitted Infections

Also, Building a New Model for Lab-to-Labs Diagnostic Testing Business, and Expanding Offerings to CRO's, Academic Research and Pharmaceutical Industry

NEW YORK--(BUSINESS WIRE)-- Enzo Biochem, Inc. (NYSE: ENZ) today announced several key transformative initiatives in its labs business unit designed to propel and accelerate growth. The initiatives are part of a company-wide commitment to expand its market opportunity in diagnostic testing, capitalizing on Enzo's history of innovation, differentiated business strategy and emerging market dynamics.

The three key initiatives are:

1. **New York State Health Department Approval for Gonorrhea and Chlamydia Tests for Oral and Rectal Specimens; Creates Direct to Consumer Testing Business for Sexually Transmitted Infections (STIs)**

Enzo, a recognized market leader in the development of diagnostic molecular testing for a wide range of sexually transmitted diseases, recently won New York State Health Department approval for use of its AmpProbe[®] Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) DNA tests with oral (pharyngeal) and rectal specimens. This expands Enzo's menu, allowing the Company to provide one of the most comprehensive panels for STI testing for not only women but also men, who represent a rapidly growing segment for such testing.

Over the last decade, the nature of pathogens and the sites of infection have undergone significant changes due to the changing sexual behaviors in the broader population. For example, although the presence of viruses such as HPV are commonly tested in the female population as part of the Women's Health Panel, HPV is substantially found in the male population, where the Center for Communicable Diseases ("CDC") estimates that almost 50% of the male population aged 18-60 have a genital HPV infection. Changes in the sites of infection are also reflected in population statistics where the focus on the association with cervical cancer is being overtaken by increases in oral and anal cancers associated with HPV. In 2017, according to CDC, 11 million men and 3.2 million women tested positive for oral HPV infections, underscoring the disproportionate growth in infections among men.

Enzo's comprehensive Ampiprobe[®] Sexually Transmitted Infection Panel, which has already been approved by New York State, is a multiplex nucleic acid amplification test that can detect 16 common sexually transmitted diseases including Candida, Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Ureaplasma, Mycoplasma, and Bacterial Vaginosis (BV) using a single collection swab. With this latest approval, Enzo now provides expanded specimen collection options from multiple relevant body sites for NG and CT testing.

Enzo also provides testing from both anal and genital specimens for HPV (Human Papilloma Virus), a sexually transmitted virus associated with the development of cancer, as well as tests for other sexually transmitted diseases, including HIV and Herpes Simplex Virus (HSV). The Company is also developing an application for the detection of HPV from oral specimens of both men and women. Enzo's STI and women's health related pathogen testing menu addresses three important health contexts - diagnosis of infection and other general health issues, control of transmission, and infection risk at birth.

"Given our market position in diagnostic testing in STIs and the urgent and growing demand for these tests in particular populations, we believe the time is right to launch a direct-to-consumer testing application where, in permitted jurisdictions, patients can avail themselves of these tests simply and effectively, with privacy, but without the unnecessary red tape and oversight of insurance carriers and shifting reimbursement policies. We are working with a number of medical professionals, urgent care facilities and other intermediaries to launch this business this fiscal year. We will offer a comprehensive series of all STI molecular tests across all relevant sites of infection as a complete package of services. Initial response has been very strong due to our comprehensive menu, ability to provide privacy, and cost effective approach. We believe this business model and expansion of our product line has significant potential," said Barry Weiner, President and Chief Financial Officer of Enzo.

2. Building a New Model for the Diagnostic, Lab to Labs Marketplace

As previously stated in the recent 2Q19 earnings announcement, Enzo is rolling out a new lab-to-labs business model. With it, Enzo will serve as the "central capability" for smaller labs, capitalizing on the Company's scale in high value and lower cost operations, proprietary intellectual property and products, decades of innovation and commitment to medical solutions.

"We continue to be very energized by this growth initiative," continued Mr. Weiner. "We see immense opportunity in expanding the market for diagnostic testing and offering labs the ability to serve their customers in a cost effective and collaborative model. This business model is predicated on our foundational approach to innovation, to science, to manufacturing and to cost-efficient product development. We remain on track to announce our first partners in this program by the end of calendar 2019."

3. Expanding Offerings to CRO's Academic Research Institutions and the Pharmaceutical Industry

Identifying and capitalizing on another important market niche, Enzo is expanding its service offerings to clinical research organizations (CRO's), academic research institutions, and the pharmaceutical industry. Over the next few months, Enzo plans to rapidly extend these services to a broader array of customers, who can benefit from the depth of science as well as the scale and scope of Enzo's diagnostic lab.

This area of focus is a natural extension of Enzo's clinical lab capabilities. Large organizations today not only require speed and scale, but also cost-effectiveness in testing. Enzo is the ideal provider of solutions for institutions looking to outsource their testing. Enzo hopes to have meaningful updates to announce over the course of the next six months as it ramps up marketing and discussions with current and prospective customers.

[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.

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, 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, 2018. 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.

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For: Enzo Biochem, Inc.

Steve Anreder, 212-532-3232

steven.anreder@anreder.com

or

Michael Wachs, CEOcast, Inc., 212-732-4300

mwachs@ceocast.com

Source: Enzo Biochem, Inc.