

Enzo Biochem Gets Rights to Potential HPV Test

NEW YORK--([BUSINESS WIRE](#))--Enzo Biochem Inc. (NYSE:ENZ), as part of its continuing program to offer novel molecular tests, announced that its Enzo Clinical Labs subsidiary has reached an agreement with IncellDx Inc. of Menlo Park, CA, for the rights to market a proprietary laboratory test. The test is based upon HPV OncoTect™, an advanced molecular diagnostic technology for quantifying specific biomarkers that have been associated with an increased risk of progression to cervical cancer and will further expand Enzo's approach to providing comprehensive clinical information to physicians for managing diseases associated with women's health. Upon receiving the appropriate approvals, Enzo will become the first New York licensed reference laboratory to offer the test.

"This addition to our growing line of molecular diagnostic tests for women's health underscores our expanding specialization in advanced clinical and diagnostic testing. We intend to use this test initially for patients who have been shown to be HPV positive by standard techniques" HPV OncoTect™ is a novel method for screening for the likelihood of progression to cervical carcinoma by measuring potential oncogenic activity of the [human papillomavirus \(HPV\)](#) in infected cervical cells. The assay functions by detecting and quantifying the expression of viral oncogenes responsible for triggering progression to cervical cancer, thus improving the specificity that existing tests lack. As with other assays developed at Enzo Clinical Labs, HPV OncoTect™ will be validated during in-house studies prior to seeking New York State approval under a "LDT" regulatory pathway. Favorable reimbursement already exists for this type of testing.

"The HPV OncoTect™ technology is a flow-cytometry based method that can be used to identify the genetic expression of HPV that has already integrated into the cell, offering a better indicator of serious HPV infections than can be accomplished by identifying the presence of the virus alone," said Dr. Robert Boorstein, MD, PhD., Medical Director of Enzo Clinical Labs. "This addition to our growing line of molecular diagnostic tests for women's health underscores our expanding specialization in advanced clinical and diagnostic testing. We intend to use this test initially for patients who have been shown to be HPV positive by standard techniques"

HPV is one of the most common sexually transmitted diseases and is the major cause of [cervical cancer](#). Published consensus guidelines recommend high risk HPV testing for cervical cancer in women over 21 who have abnormal PAP smears and in screening women over 30 years of age when used in conjunction with a Pap test. The US HPV testing market is estimated to be \$300 million and growing at an annual rate of 14%.

About IncellDx, Inc.

IncellDx, Inc. is a molecular diagnostics company dedicated to the detection and monitoring of life threatening diseases such as cervical cancer, HIV/AIDS, hepatitis, and organ transplant rejection. IncellDx's technology is believed to have broad application for many additional infectious disease tests, which can all be performed on the same diagnostic platform.

About Enzo Biochem

Enzo Biochem, Inc., is a growth-oriented integrated life sciences and biotechnology company focused on harnessing biological process to develop research tools, diagnostics and therapeutics, and serves as a provider of test services, including exotic tests, to the medical community. Since our founding in 1976, our strategic focus has been on the development of enabling technologies in the

life sciences field. Enzo Life Sciences develops, produces and markets proprietary labeling and detection products for gene sequencing, genetic analysis and immunological research, among others. Its catalog of over 30,000 products serves the molecular biology, drug discovery and pathology research markets worldwide. Enzo Clinical Labs provides laboratory services for a growing roster of physicians in the New York Metropolitan area, Pennsylvania and New Jersey. Its tests include, in addition to routine tests, capabilities for detecting molecular infection disease, molecular oncology, autoimmune disorders and genetics. Enzo Clinical Labs also provides clinical diagnostic services that allow Enzo to capitalize on its extensive advanced molecular and cytogenetic capabilities and the broader trends in predictive and personalized diagnostics. Enzo Therapeutics is a biopharmaceutical venture that has developed multiple novel approaches in the areas of gastrointestinal, infectious, ophthalmic and metabolic diseases. It has focused its efforts on developing treatment regimens for diseases and conditions for which current treatment options are ineffective, costly, and/or cause unwanted side effects. In the course of the company's research and development activities, Enzo has also developed a substantial portfolio of intellectual property asset with patent coverage across a number of key 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. 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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