



*Source: Microbix Biosystems Inc.*

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## **Microbix & Ulisse Biomed Collaborate on HPV Controls & Assays**

### **Onboarding Tools and Quality Controls for Extended Genotype HPV Assays**

MISSISSAUGA, Ontario and TRIESTE, Italy, Nov. 10, 2023 (GLOBE NEWSWIRE) -- Microbix Biosystems Inc. (**TSX: MBX, OTCQX: MBXBF, Microbix<sup>®</sup>**), a life sciences innovator, manufacturer, and exporter, announces a collaboration with Ulisse Biomed S.p.A. (**BIT: UBM, Ulisse**), a company developing innovative diagnostics, theranostics, and therapeutics. The companies are collaborating to make Microbix's Quality Assessment Products ("**QAPs<sup>™</sup>**") available and optimized to support the clinical use and accuracy of Ulisse molecular tests for high-risk types of Human Papilloma Virus ("**HPV Assays**").

Molecular (i.e., "**PCR**") HPV Assays are used to diagnose infections and distinguish between the virus types that generate higher or lower risks of fatal cancers. HPV is a family of approximately 100 sub-types of virus, of which 14 are directly implicated to cause human cancers – most notably cervical tumors. Molecular tests for high-risk types of HPV identify at-risk patients years before cancers arise, thereby permitting them to be carefully monitored to prevent the development of invasive and potentially lethal tumors. However, HPV Assays must be stringently monitored to ensure their accuracy – ideally with Microbix QAPs.

Ulisse has obtained EU "CE mark" approval for its high-risk extended genotype HPV Assays, which will now be commercialized on an automated sample-to-result closed system with an installed base of over 1,500 instruments. Moreover, Ulisse's HPV Assays are validated with the most widely used open platforms and with Hyris bCUBE<sup>™</sup>, a miniaturized PCR instrument particularly suitable for small-medium laboratories that Ulisse is proposing to clients in conjunction with its assays. Ulisse has validated Microbix's HPV QAPs as tools to support the ongoing accuracy of its HPV Assays and will recommend their usage in its instructions for use ("**IFUs**"). Additionally, Microbix has created custom ONBOARDx<sup>™</sup> kits of QAPs to assist the Ulisse sales teams in demonstrating the HPV Assays to prospective customers, as well as for training operators and for qualifying new HPV Assay installations.

Phil Casselli, SVP of Business Development at Microbix, commented, "We met the Ulisse senior team at a conference in Europe. Shortly thereafter we began working with them as they finalized the performance evaluation of their assays. We are proud to be selected as their preferred controls and to be referenced on their IFUs. This is another success as we bring these sophisticated high-risk HPV control products to the global markets for HPV screening".

Bruna Marini, COO of Ulisse, also commented, "We were looking for a set of controls that fully covered the range of high-risk HPV types and Microbix is the only company to have such a portfolio. After an extensive evaluation process, we concluded the performance of Microbix QAPs are exactly what Ulisse needs and the interactions with their team are delightful."

### **About Microbix Biosystems Inc.**

Microbix Biosystems Inc. creates proprietary biological products for human health, with over 100 skilled employees and annualized sales targeting C\$ 2.0 million per month. It makes a wide range of critical ingredients and devices for the global diagnostics industry, notably antigens for immunoassays and its laboratory quality assessment products (QAPs<sup>™</sup>) that support clinical lab

proficiency testing, enable assay development and validation, or help ensure the quality of clinical diagnostic workflows. Its antigens drive the antibody tests of approximately 100 diagnostics makers, while QAPs are sold to clinical lab accreditation organizations, diagnostics companies, and clinical labs. Microbix QAPs are now available in over 30 countries, supported by a network of 10 international distributors. Microbix is ISO 9001 & 13485 accredited, U.S. FDA registered, Australian TGA registered, Health Canada establishment licensed, and provides CE marked products.

### **About Ulisse Biomed S.p.A**

Ulisse Biomed S.p.A. is a healthcare biotech company operating in diagnostics, theranostics and therapeutics with the mission to develop innovative solutions in these fields. The company has three proprietary technology platforms capable of generating innovative and competitive products: Sagitta (molecular diagnostics), NanoHybrid (theranostics & diagnostics), and Aptavir (therapeutics). UBM owns a portfolio of nine patent families that cover those three technology platforms. The core business of the company is the design, manufacturing and distribution of assays based on Sagitta technology which allows real-time PCR, deep multiplexing capabilities, and high sensitivity that can be executed even without nucleic acid extraction and purification. Ulisse is ISO 9001 & 13485 accredited and provides CE marked products. More information about the company is available at <https://ulissebiomed.com>.

### **Forward-Looking Information**

This news release includes “forward-looking information,” as such term is defined in applicable securities laws. Forward-looking information includes, without limitation, discussion of Ulisse and its HPV Assays, Microbix and its QAPs, their relevance, or others’ products or services, business and business results, goals or outlook, risks associated with financial results and stability, development projects such as those referenced in its presentations, regulatory compliance and approvals, sales to foreign jurisdictions, engineering and construction, production (including control over costs, quality, quantity or timeliness of delivery), currency exchange rates, maintaining adequate working capital or raising new capital on acceptable terms or at all, and other similar statements about anticipated future events, conditions or results that are not historical facts. These statements reflect management’s current estimates, beliefs, intentions, and expectations; they are not guarantees of future performance. Microbix cautions that all forward-looking information is inherently uncertain and actual performance may be affected by many material factors, some of which are beyond its control. Accordingly, actual future events, conditions and results may differ materially from the estimates, beliefs, intentions, and expectations expressed or implied in the forward-looking information. All statements are made as of the date of this news release and represent Microbix’s judgement as of the date of this new release, and it is under no obligation to update or alter any forward-looking information.

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For further information, please contact Microbix at:

Cameron Groome,  
CEO  
(905) 361-8910

Jim Currie,  
CFO  
(905) 361-8910

Deborah Honig,  
Investor Relations  
Adelaide Capital Markets  
(647) 203-8793  
[ir@microbix.com](mailto:ir@microbix.com)

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