



Microbix Enhances Quality Management System

ISO 13485:2016 Medical Devices Certification Attained

TORONTO, Dec. 24, 2018 -- Microbix Biosystems Inc. (TSX: MBX, Microbix®), an innovator of biological products and technologies, announces that it has attained the ISO 13485:2016 Medical Devices certification – an enhancement to its quality management system that is expected to accelerate the growth of its QAPs™ lines of quality assessment products.

Microbix has operated under the ISO 9001:2015 general quality standard or its predecessors since 2009, manufacturing its antigen products under that system. Microbix antigen products are sold as materials for the further manufacture of medical tests and are thereby further regulated at the end-user level.

The ISO 13485:2016 standard is designed for and specifically applicable to organizations involved in the design, production, installation, or servicing of medical devices and related services. Under the standard, a medical device is a product, such as an instrument, machine, implant or *in vitro* reagent that is intended for use in the diagnosis, prevention and treatment of diseases or other medical conditions.

At Microbix, the ISO 13485:2016 standard will apply to the design and manufacturing of all its QAPs lines. Ultimately, ISO 13485:2016 certification will enable Microbix to target the largest and most rewarding segment of the market for QAPs – providing quality control materials for clinical labs.

Microbix's QAPs contain a precise quantity of stabilized antigen and have been engineered to closely resemble patient samples – to thereby support quality assessment of each critical step of complex medical tests. There are three identifiable market segments for QAPs, namely:

1. Proficiency Testing. Under the PTDX™ brand, QAPs are sold to laboratory accreditation organizations for use in their laboratory proficiency testing programs. This is a smaller market into which Microbix has been selling since 2009, under the ISO 9001 standard.
2. Validation, Verification and Training. Under the PROCEEDx™ brand and used for research, assay development, validation/verification of instruments, troubleshooting, and operator training. This is a mid-sized market to which Microbix began offering products in 2018, also under ISO 9001.
3. Clinical Laboratory Quality Control. Under the REDx Controls™ brand, Microbix intends to offer QAPs to clinical laboratories to support their patient-focused quality control objectives. This is believed to be the largest market for QAPs and requires a medical devices quality management system (ISO 13485:2016), due to such products directly affecting patient-care decisions.

Microbix's attainment of ISO 13485:2016 certification will enable it to target all three segments of the QAPs market and should accelerate the growth in sales of all its branded QAPs applications. Attainment of the ISO 13485:2016 certification was the result of many months of work across the Microbix executive team, led by Mrs. Bo Hollas, Microbix's Director of QA Compliance.

About Microbix Biosystems

Microbix Biosystems Inc. specializes in the development of proprietary biological and technology solutions for human health and well-being. The Company manufactures a wide range of critical biological materials for the global diagnostics industry, notably antigens used in immunoassays or quality assessment and proficiency testing products. Microbix's products are sold to more than 100 customers worldwide, primarily to multinational diagnostics companies and laboratory accreditation organizations.

Microbix also applies its biological expertise and technology platforms to create other innovative products and technologies. Currently it has two; (1) Kinlytic® urokinase, a biologic thrombolytic drug (used to dissolve blood clots) and (2) LumiSort™ cell-sorting, a technology platform for ultra-rapid and efficient sorting of somatic cells that can be used to enrich cell populations of interest, such as in sexing semen. Established in 1988, Microbix is a publicly traded company, listed on the Toronto Stock Exchange and headquartered in Mississauga, Ontario, Canada.

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, management's discussion of quality management system certifications or goals, new products being introduced or exhibited, industry needs or trends, financial results or the outlook for the business, the risks

associated with its financial results and stability, its biologicals business, development projects, operations in foreign jurisdictions, engineering and construction generally, production (including control over costs, quality, quantity and timeliness of delivery of products), foreign currency and exchange rates, maintaining adequate working capital and raising further capital on acceptable terms or at all, and other similar statements concerning 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. The Company cautions that all forward looking information is inherently uncertain and that actual performance may be affected by a number of material factors, many of which are beyond the Company's 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 the Company's judgement as of the date of this new release, and the Company is under no obligation to update or alter any forward-looking information.

Please visit www.sedar.com for recent Microbix filings.
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