

## **Aytu BioScience Announces First Commercial Sales for Company's MiOXSYS™ System for Male Infertility**

ENGLEWOOD, Colo., Feb. 9, 2016 — **Aytu BioScience, Inc.** (OTCQX: AYTU), a commercial-stage specialty healthcare company focused on commercializing treatments for urological conditions, today announced the first commercial sales of its MiOXSYS™ System in Europe and the Middle East. MiOXSYS is the company's *in vitro* diagnostic platform for assessing the level of oxidative stress in semen as an aid in the diagnosis of infertility in men. In January, MiOXSYS obtained CE Marking in Europe and other markets.

Josh Disbrow, Chief Executive Officer of Aytu, stated, "Within just weeks of receiving CE Marking, MiOXSYS has begun contributing to Aytu's portfolio of commercial products focused on the urology market. MiOXSYS is already showing itself to be a valuable product for our urology customers given the widespread need for improved diagnosis in the field of male infertility. We look forward to additional sales in these regions as clinicians integrate MiOXSYS into their routine assessments of infertility status and monitoring of treatment effects. As we seek Food and Drug Administration (FDA) clearance in the United States, commercial use in foreign markets will contribute not only to Aytu's growing revenues, but to clinical understanding of the role of MiOXSYS in the diagnostic and treatment paradigms of male infertility. Given the early market interest following our CE Marking, we expect to begin building a distribution network for MiOXSYS in Europe, the Middle East and other key markets around the world."

A significant proportion of male infertility remains unexplained in part because of the lack of standardized, clinically feasible tests available to clinicians to assess oxidative stress, which is a well established contributor to idiopathic male infertility. This lack of standardization has resulted in poor implementation of oxidative stress testing in semen analysis. Aytu is currently working with major research institutions around the world to gain substantial, robust clinical experience using MiOXSYS to fulfill the unmet medical need in male infertility testing.

### **About Aytu BioScience, Inc.**

Aytu BioScience is a commercial-stage specialty healthcare company focused on global commercialization of novel products in the field of urology. Aytu's current portfolio of commercial and late-stage urology products addresses prostate cancer, urinary tract infections, male infertility and male sexual dysfunction, and the company plans to expand into other urological indications for which there are significant medical needs. The company currently markets ProstaScint® (capromab pendetide), the only radio-labeled monoclonal antibody that targets prostate specific membrane antigen (PSMA), a protein highly expressed by prostate cancer cells. ProstaScint is FDA-approved as an imaging agent for use in both newly diagnosed, high-risk prostate cancer patients and patients with recurrent prostate

cancer. Aytu also markets Primisol<sup>®</sup> (trimethoprim hydrochloride) – the only FDA-approved trimethoprim-only oral solution for urinary tract infections. Additionally, Aytu markets the CE Marked MiOXSYS<sup>™</sup> System outside the US and is conducting US-based clinical trials, following which the company expects to receive 510k de novo medical device clearance. The MiOXSYS System is a novel, rapid semen analysis system with the potential to become a standard of care in the diagnosis and management of male infertility. MiOXSYS is the only rapid test for assessing oxidative stress in semen and seminal plasma, a leading contributor of idiopathic male infertility. Aytu's strategy is to continue building its portfolio of revenue-generating urology products and late-stage development assets, leveraging its commercial team and expertise to further build those brands within well-established markets.

### **For Investors & Media:**

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### **Forward Looking Statement**

This press release includes 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, or the Exchange Act. All statements other than statements of historical facts contained in this presentation, including statements regarding our anticipated future clinical and regulatory events, future financial position, business strategy and plans and objectives of management for future operations, are forward-looking statements. Forward looking statements are generally written in the future tense and/or are preceded by words such as "may," "will," "should," "forecast," "could," "expect," "suggest," "believe," "estimate," "continue," "anticipate," "intend," "plan," or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. These statements are just predictions and are subject to risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: risks relating to gaining market acceptance of our products, obtaining reimbursement by third-party payors, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaborations. We also refer you to the risks described in "Risk Factors" in Part I, Item 1A of Aytu BioScience, Inc.'s Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

To view the original version on PR Newswire,

visit:<http://www.prnewswire.com/news-releases/aytu-bioscience-announces-first-commercial-sales-for-companys-mioxsys-system-for-male-infertility-300217092.html>

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