Aytu BioScience Announces Peer-Reviewed Publication of Fourth Clinical Study Demonstrating the Utility of MiOXSYS® in the Assessment of Male Infertility

ENGLEWOOD, Colo., March 14, 2017 — **Aytu BioScience, Inc.** (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced the publication of a peer-reviewed journal article demonstrating the clinical utility of the Company's MiOXSYS® System for assessing the level of oxidative stress in semen as an aid in the diagnosis of infertility in men. The article, titled, "Clinical Relevance of Oxidation-Reduction Potential in the Evaluation of Male Infertility," will be published in the high profile medical journal *Urology*, the "Gold Journal", and is currently available online ahead of print.

Josh Disbrow, Chief Executive Officer of Aytu, stated, "Based on research spanning more than 25 years, there is now little doubt that oxidative stress is a leading cause of damage to sperm function, leading to failure to conceive or lack of embryo development. Yet until recently there have been no clinically feasible options for rapid, in-office testing for oxidative stress in semen. We are therefore pleased with the results of this study, which demonstrate that MiOXSYS may overcome many of the specific limitations of current methods for assessing sperm oxidative stress. The study provides the first indication of how specific oxidative stress cut offs, as measured by MiOXSYS, might be used to help predict important parameters such as sperm motility, potentially distinguishing men with good semen quality from those with poor semen quality in a much simpler and cost-efficient manner than is used in andrology laboratories today."

Oxidative stress in sperm stems from excessive production of reactive oxygen species (ROS), which are found in 25-40% of infertile men yet remains difficult to measure with current laboratory methods. Currently, a combination of independent assays, both direct and indirect, are used to measure seminal ROS. These antiquated methods, such as the chemiluminescence assay, are highly time sensitive, time consuming and expensive, limiting their feasibility for routine in-office or laboratory use. They also provide an incomplete picture of the true oxidative stress environment since they are based on single-biomarker assays rather than on a global measure of oxidative stress. MiOXSYS measures oxidation-reduction potential (ORP), which provides a comprehensive measure of oxidative stress by simultaneously accounting for all the known and unknown oxidants and antioxidants in the semen sample.

The results of the latest study demonstrated MiOXSYS's ability to accurately identify sperm quality and established OS as a key mechanism in patients suffering from oligozoospermia. Furthermore, the study also showed that ORP levels declined with increases in sperm concentration and motility in patients who had repeated semen analyses and ORP levels

analyzed, demonstrating that ORP can serve as an indicator of sperm quality over time.

Receiver operating characteristic (ROC) analysis was used to establish the updated ORP cutoffs associated with infertile and fertile men. Based on the cutoffs for infertile men (1.57 $mV/10^6$ sperm) and oligozoospermia (2.59 $mV/10^6$ sperm), the results indicated that men with poor sperm quality can be identified by the ORP values with a high degree of accuracy and repeatability. Based on these cutoff values, the specificity was 88% and sensitivity 70%, whereas in oligozoospermia, sensitivity and specificity were higher at 88% and 91%.

Ashok Agarwal, Ph.D., Director of the Andrology Center at the Glickman Urological & Kidney Institute of Cleveland Clinic and Director of the American Center for Reproductive Medicine, concluded, “In this study we were able to identify a major etiological factor, oxidative stress, of male infertility along with predicting abnormal sperm quality. Our study has shown that ORP levels were able to predict poor sperm quality at the time of diagnosis and during repeated semen analysis testing, indicating its ability to monitor sperm quality throughout the patient continuum. This makes it easier to diagnose oxidative stress-related infertility.”

MiOXSYS has obtained CE Marking for commercialization in Europe and other markets, as well as medical device clearance from Health Canada. Aytu is currently pursuing an FDA clearance pathway in the United States. Men who may benefit from the measurement of ORP include infertile men with varicocele, infection, spinal cord injury, severe oligozoospermia, asthenozoospermia and teratozoospermia, and unexplained and idiopathic infertility.

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on global commercialization of novel products in the field of urology. The company currently markets three products: Natesto®, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), ProstaScint® (capromab pendetide), the only FDA-approved imaging agent specific to prostate specific membrane antigen (PSMA) for prostate cancer detection and staging, and Primsol® (trimethoprim hydrochloride), the only FDA-approved trimethoprim-only oral solution for urinary tract infections. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside the U.S. where it is a CE Marked, Health Canada cleared product, and Aytu is conducting U.S.-based clinical trials in pursuit of 510k medical device clearance by the FDA. Aytu’s strategy is to continue building its portfolio of revenue-generating urology products, leveraging its focused commercial team and expertise to build leading brands within well-established markets. For more information visit aytubio.com.

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.

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