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

ENGLEWOOD, Colo., July 21, 2016 — **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 the first 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, "MiOXSYS: a novel method of measuring oxidation reduction potential in semen and seminal plasma," will be published in the high profile medical journal *Fertility and Sterility* 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 causes damage to the function of sperm, leading to the inability to achieve conception or lack of development of the embryo. Yet currently there are 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 suggest that MiOXSYS may overcome many of the specific limitations of current methods for assessing sperm oxidative stress. The study not only highlights the convenience and robustness of our testing platform for routine use, it also 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 today."

Oxidative stress in sperm stems from excessive production of reactive oxygen species (ROS), which are found in 25-40% of infertile men and in 40-88% of infertile patients with spinal cordinjury. Currently, a combination of independent assays, both direct and indirect, are used to measure seminal ROS. These antiquated methods are highly time sensitive, time consuming and expensive such as the chemiluminescence assay, limiting their feasibility for routine use. They also provide an incomplete picture of the true oxidative stress environment due to the fact that they are based on single-biomarker assays. MiOXSYS measures oxidation-reduction potential (ORP), which provides a comprehensive measure of oxidative stress by simultaneously accounting for all of the known and unknown oxidants and antioxidants in the sample.

The results of the study indicate very strong correlation of ORP, as measured with MiOXSYS, across different sample preparations, suggesting that ORP can be measured accurately irrespective of sample type (semen or seminal plasma) and time (either immediately or up to 120 minutes after liquefaction). Furthermore, high ORP correlated negatively with sperm

concentration and total sperm count, as well as sperm morphology and motility, which are key factors impacting fertility.

Receiver operating characteristic (ROC) analysis was used to establish the ORP cutoffs associated with normal (≥40%) versus abnormal (<40%) sperm motility. Based on the cutoffs for semen (1.48 mV/10^6 sperm) and seminal plasma (2.09 mV/10^6 sperm), the results indicated that men with poor sperm motility can be identified by the ORP values with high accuracy. Based on these cutoff values, the specificity was 75% and sensitivity 60%, whereas in seminal plasma, sensitivity was lower at 46.7%, but with higher specificity of 81.80%. Future studies that include a more homogenous control group (i.e. men with proven fertility) may improve the ORP cutoff values and increase the sensitivity of the assay.

Ashok Agarwal, Ph.D., Director of the Glickman Urological & Kidney Institute's Andrology Center at Cleveland Clinic and Director of the American Center for Reproductive Medicine, stated, "In this study we've demonstrated that ORP can be reliably measured in both semen and seminal plasma up to 120 minutes of liquefaction, demonstrating its clear advantage over existing tests of measuring individual markers of oxidative stress. This makes it easier to employ this new technology for clinical use."

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 approval 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 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 de novo 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 Investors & Media:
Tiberend Strategic Advisors, Inc.
Joshua Drumm, Ph.D.: jdrumm@tiberend.com; (212) 375-2664
Janine McCargo: jmccargo@tiberend.com; (646) 604-5150

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 with and future outcomes and events under our current and potential future collaborations; 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; and our anticipated future cash position. We also refer you to the risks described in “Risk Factors” in Part I, Item 1A of Aytu BioScience, Inc.’s most recent 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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