Aytu BioScience Further Demonstrates Clinical Utility for MiOXSYS™ System as an Aid in the Diagnosis of Male Infertility

Presents Clinical Findings at 72nd Annual Meeting of the American Society of Reproductive Medicine

ENGLEWOOD, Colo., Nov. 1, 2016 — Aytu BioScience, Inc. (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced that it presented five posters demonstrating the clinical potential of MiOXSYS™, Aytu's rapid *in vitro* diagnostic system for the qualitative measurement of static oxidation-reduction potential (sORP) in human semen, to be used as an aid in the diagnosis of infertility in men.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, Inc., stated, "This represents the first demonstration of MiOXSYS's clinical application in three leading clinical centers and further validates the significance of oxidative stress as a diagnostic marker for male infertility. MiOXSYS is the only easily accessible, rapid, in-office option to measure oxidative stress in semen. Identifying high levels of oxidative stress can help determine the cause of poor semen quality and lead to strategies designed to improve semen quality and male fertility. Aytu is committed to conducting research to validate the potential for the MiOXSYS System to fill this clinical gap. Aytu is in the process of initiating clinical studies to support potential FDA clearance of MiOXSYS."

The posters are as follows:

Title: OXIDATION-REDUCTION POTENTIAL – A NOVEL TEST FOR EVALUATING MALE INFERTILITY
Poster: P-503
Session: Male Reproduction and Urology – Clinical
Presenter: Ashok Agarwal, Ph.D., Director of the Andrology Center and Director of the American Center for Reproductive Medicine under the Glickman Urological & Kidney Institute, Cleveland Clinic
Results: Semen samples were obtained from 51 normal healthy controls and 106 infertile men. The mean ORP (mV/10^6 sperm/mL) in the semen of the infertile patients was 6.22±1.10 mV/10^6 sperm/mL whereas that of the control group was 1.59±0.29 mV/10^6 sperm/mL ($p = 0.004$).
Conclusion: ORP can distinguish between male factor infertility patients and healthy normal men, making it an accurate method for ruling in oxidative stress in male factor infertility patients

Title: OXIDATION-REDUCTION POTENTIAL: A NOVEL MARKER OF VARICOCELE PATHOPHYSIOLOGY

Poster: P-499
Session: Male Reproduction and Urology – Clinical
Presenter: Ashok Agarwal, Ph.D., Director of the Andrology Center and Director of the American Center for Reproductive Medicine under the Glickman Urological & Kidney Institute, Cleveland Clinic
Results: Thirty-eight patients with clinical varicocele presenting with primary infertility were subdivided into 3 groups according to clinical grade. Compared with controls, a direct relationship ($p<0.05$) was seen between high ORP levels and men with grade 3 varicocele.
Conclusion: ORP measurement may have potential benefit before and after varicocele surgery to assess surgical success

Title: EVALUATION OF INTRA- AND INTER-OBSERVER RELIABILITY OF THE ORP (OXIDATION-REDUCTION POTENTIAL) TEST FOR OXIDATIVE STRESS (OS) IN MALE FACTOR INFERTILITY
Poster: P-516
Session: Male Reproduction and Urology – Clinical
Presenter: Ashok Agarwal, Ph.D., Director of the Andrology Center and Director of the American Center for Reproductive Medicine under the Glickman Urological & Kidney Institute, Cleveland Clinic

Results: A total of 120 measurements of ORP ($mV/10^6$ sperm/mL) were taken by three experienced observers from ten semen samples measured in four replicates. The coefficient of variation across observers was 3.61%.
Conclusion: Intra-observer and inter-observer reliability experiments confirm the reproducibility of the MiOXSYS System for use in a clinical setting

Title: INFERTILE MEN HAVE A REDOX IMBALANCE THAT DISTINGUISHES THEM FROM FERTILE MEN
Poster: P-343
Session: Male Reproduction and Urology – Research
Presenter: Ahmet Ayez, Ph.D., Yildiz Technical University, Istanbul, Turkey
Results: Semen samples were obtained from 50 infertile and fertile patients. Semen analysis was done according to WHO 2010 and sORP was measured using the MiOXSYS System.
Conclusion: Infertile donors had higher sORP values then fertile. The odds of being infertile with a sORP value greater than 1.38 mV/sperm concentration were 9.76 times higher than if the sORP was lower. 63% of donors had abnormal morphology, including 38% of fertile and 97% of infertile.

Title: SEMINAL OXIDATION-REDUCTION POTENTIAL CAN DIFFERENTIATE FERTILE FROM INFERTILE MEN
Poster: P-340
Session: Male Reproduction and Urology – Research
Presenter: Mohamed Arafa, Ph.D. Urology Department-HMC, Doha, Qatar
Results: Semen samples were obtained from 365 infertile and 50 fertile patients. Semen

analysis was done according to WHO 2010 and sORP was measured using the MiOXSYS System. Sperm count, total motility and progressive motility were significantly lower in the infertile group than the control groups ($p<0.001$). The measured sORP (mean ± SE) in infertile men was 24.06 ± 4.13 $mV/10^6$ sperm/mL, while that of fertile men was 1.15 ± 0.12 $mv/10^6$ sperm/mL ($P<0.001$).

Conclusion: sORP provides an objective and repeatable measure for identification of patients more likely to be infertile

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 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 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.

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