

## **Aytu BioScience Presents Clinical Findings for its MiOXSYS® System at 73rd Annual Meeting of the American Society of Reproductive Medicine**

ENGLEWOOD, Colo., Nov. 1, 2017 — Aytu BioScience, Inc. (NASDAQ: AYTU), a specialty life sciences company focused on global commercialization of novel products in the field of urology, today announced that it presented six posters demonstrating the clinical potential of MiOXSYS®, the company'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 males.



Josh Disbrow, Chief Executive Officer of Aytu BioScience, Inc., stated, “These studies demonstrate the robustness of our MiOXSYS System as a stable and accurate measure of oxidative stress, that can be standardized globally within clinical andrology and IVF laboratories to aid in the assessment of male infertility. MiOXSYS represents an easily accessible, rapid, in-office diagnostic option to measure oxidative stress in semen. Identifying high levels of oxidative stress can help rule in the cause of poor semen quality and lead to intervention strategies associated with the improvement of semen quality and male fertility. Aytu has been committed to conducting research in male infertility with leading centers around the world to continue to validate the ability of MiOXSYS to address this area of high clinical need.”

The posters are as follows:

**Title:** MULTI-CENTER EVALUATION OF OXIDATION-REDUCTION POTENTIAL ASSAY IN THE INFERTILE MALE

**Poster Number:** P-553

**Session:** Male Factor

**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

**Conclusion:** ORP levels can serve as an adjunct to routine semen analysis in men undergoing infertility evaluation. A reference value of 1.34mV/10<sup>6</sup> sperm/mL for ORP provided

the greatest predictability when distinguishing abnormal from normal semen quality among the 1,644 patients undergoing infertility evaluation. Abnormal ORP levels will be especially useful in pinpointing the altered functional status of the sperm in patients with idiopathic male infertility and thereby directing those men toward accurate therapeutic management

**Title:** OXIDATION-REDUCTION POTENTIAL: A RELIABLE AND REPRODUCIBLE METHOD

**Poster Number:** P-552

**Session:** Oxidative Stress

**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

**Conclusion:** The measurements for ORP among infertile men were consistent between centers in the USA and Qatar and with previous studies conducted by our group. ORP remains stable even with measurable differences in other sperm parameters, and it therefore can be used in addition to semen analysis to confirm poor semen quality or as a possible independent diagnostic tool for assessing infertility. Overall, ORP is a reliable method of measuring OS and can be used by laboratories worldwide as a standard part of assessing semen quality.

**Title:** RELATIONSHIP BETWEEN SEMINAL OXIDATION-REDUCTION POTENTIAL AND SPERM DNA FRAGMENTATION IN INFERTILE MEN

**Poster Number:** P-550

**Session:** Oxidative Stress

**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

**Conclusion:** Correlation of ORP levels with SDF confirms the causal relationship between the oxidative stress (OS) and sperm DNA fragmentation (SDF.) ORP could be used as a surrogate marker for SDF in clinics which lack access to highly complex sperm function testing due to the expense or need for highly trained laboratory personnel.

**Title:** HIGH SEMINAL OXIDATION-REDUCTION POTENTIAL IN CRYOPRESERVED SEMEN FROM INFERTILE MEN IS A MARKER OF POOR POST-THAW SPERM QUALITY

**Poster Number:** P-554

**Session:** Sperm Biology

**Presenter:** Ramadan Saleh, M.D Ph.D., University of Sohag, Sohag, Egypt

**Conclusion:** Sperm cryopreservation in infertile men was associated with high seminal ORP, low sperm motility and reduced cryopreserved sperm rates (CSR). Sperm cryodamage is related to high seminal ORP generated during freeze-thaw process. Future efforts should be directed towards reduction in oxidant production to improve sperm recovery following cryopreservation.

**Title:** OXIDATION-REDUCTION POTENTIAL: A NEW SURROGATE MARKER OF OXIDATIVE STRESS AND SPERM QUALITY

**Poster Number:** P-082

**Session:** Male Reproduction and Urology

**Presenter:** Rakesh Sharma, Ph.D., American Center for Reproductive Medicine under the Lickman Urological & Kidney Institute, Cleveland Clinic

**Conclusion:** There is a direct relationship between poor semen quality and high oxidation-reduction potential (ORP). The ORP levels can serve not only as an accurate measure of oxidative stress but has the potential to increase the reliability of routine semen analysis in the prediction of sperm quality.

**Title:** VARICOCELE-INDUCED MALE INFERTILITY – A MITOCHONDRIAL DISEASE:

**Poster Number:** P-533

**Session:** Male Reproduction and Urology

**Presenter:** Luna Samanta, Department of Zoology, Ravenshaw University, Cuttack, India

**Conclusion:** Impaired mitochondrial function in infertile males with varicocele leads to oxidative stress (OS) and sperm dysfunction. Reduction in cAMP levels due to declining ATP synthesis results in dysregulated protein kinase initiating a vicious cycle by impairing mitochondrial activity. Therefore, along with conventional management, therapy targeted towards the mitochondria may improve the treatment outcome in infertile men with varicocele.

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

Aytu BioScience is a commercial-stage specialty life sciences company focused on global commercialization of novel products in the field of urology, with a focus on products addressing vitality, sexual wellness, and reproductive health. The Company currently markets two prescription products in the U.S.: Natesto®, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”) and ProstaScint® (capromab pendetide), the only FDA-approved imaging agent specific to prostate specific membrane antigen (PSMA) for prostate cancer detection and staging. 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 planning 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 products, leveraging its focused commercial team and expertise to build leading brands within growing markets. For more information visit [aytubio.com](http://aytubio.com). Aytu also now owns wholly-owned subsidiary Aytu Women’s Health (formerly Nuelle, Inc.), a personal health and wellness company focused on women’s sexual wellbeing and intimacy. Aytu Women’s Health markets Fiera, a personal care device for women that is scientifically proven to enhance physical arousal and sexual desire. Fiera is a consumer

device and is not intended to treat, mitigate, or cure any disease or medical condition. For more information about the Fiera personal care device visit [fiera.com](http://fiera.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: the results of any ongoing or planned clinical studies conducted with our MiOXSYS platform, risks relating to gaining market acceptance of any 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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