## Aytu BioScience Demonstrates Expanded Clinical Utility of MiOXSYS<sup>™</sup> for Assessing Oxidative Stress as a Marker for Male Infertility with New Study

Confirms Accuracy using Frozen and Thawed Semen Samples, Increasing Potential Use Clinical Results Presented at 111th American Urological Association Annual Meeting

ENGLEWOOD, Colo., May 10, 2016 — **Aytu BioScience, Inc.** (OTCQX: AYTU), a specialty pharmaceutical company focused on global commercialization of novel products in the field of urology, today announced new clinical findings that further validate and expand the potential utility of its MiOXSYS System as an advanced tool for assessing oxidative stress in human semen, which is broadly implicated as a major cause of male infertility. The results demonstrate that the level of oxidative stress reported by MiOXSYS from semen samples that had been frozen and thawed did not differ significantly from readings taken before freezing. This is significant, as it eliminates the need for fresh sampling and enables MiOXSYS to be used by regional or national reference laboratories that can receive and store shipped frozen samples, in addition to rapid, on-site testing by local urologists' offices, hospital, and fertility clinical laboratories.

The poster, titled, "Validation of oxidation-reduction potential in fresh and frozen semen samples with MiOXSYS<sup>™</sup> System," was presented yesterday by the study's principal investigator, 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, at the 111<sup>th</sup> American Urological Society Annual Meeting in San Diego, CA.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "These latest clinical findings add robustness to our MiOXSYS System, which we've already demonstrated to be a uniquely dynamic tool for assessing oxidative stress levels in semen as it relates to male infertility, offering substantial clinical benefit beyond the complicated and highly time-sensitive methods used today. Being able to use MiOXSYS to analyze frozen then thawed semen samples is another key differentiator for our product that further reduces the burden and increases efficiency for routine oxidative stress testing. It also enables Aytu to potentially engage with large laboratory networks to offer MiOXSYS testing through their current frozen sample collection channels. As we continue to pursue FDA clearance of MiOXSYS in the U.S. by conducting larger, multicenter studies, these commercial implications may add significantly greater value to the product upon potential launch."

In the study, semen samples were collected from 20 healthy normospermic men and oxidative stress was induced using varying concentrations of cumene hydroperoxide (CH). Using MiOXSYS, the differences in oxidative stress readings between pre-freeze and post-thaw samples were not significant, either for controls or samples exposed to CH, indicating that MiOXSYS can measure real-time oxidative stress levels accurately in both fresh and

frozen semen samples. Furthermore, MiOXSYS was sensitive enough to detect CH-induced changes when compared with control (Mean  $\pm$  standard error of mean) in oxidative stress as

measured by static ORP (millivolts (mV)/ $10^6$  sperm/mL) both prior to freezing (0.52  $\pm$  0.24; 95 % confidence interval (0.03, 1.01); p=0.04) and after post-thaw change (0.75  $\pm$  0.31; 95 % confidence interval (0.10, 1.39); p=.025), as an indicator of strong test performance under both conditions. There was also a dose-dependent decrease in sperm motility in samples upon exposure to CH, confirming a decline in sperm quality as a result of oxidative stress.

The MiOXSYS System received CE Marking in the European Union in January 2016 and approval from Health Canada in March 2016, and it is currently being commercialized in Europe and the Middle East. Aytu has established and will continue to seek additional partnerships with prominent hospitals, academic centers, and other early MiOXSYS users in order to develop these markets.

## 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 two products: ProstaScint<sup>®</sup> (capromab pendetide), the only FDA-approved imaging agent specific to prostate cancer, and Primsol<sup>®</sup> (trimethoprim hydrochloride), the only FDA-approved trimethoprim-only oral solution for urinary tract infections. Aytu recently acquired exclusive U.S. rights to Natesto<sup>®</sup>, the first and only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), which the company plans to launch in July 2016. Additionally, Aytu is developing MiOXSYS<sup>™</sup>, 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.

## 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 related to our planned launch and commercialization of Natesto and the integration of Natesto into our existing operations; our plans for product growth, expansion and acquisition; the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials; 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 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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