Zacks Small-Cap Research

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Aytu Bioscience (AYTUD-OTC)

AYTUD: Gearing Up To Launch Natesto; Bolsters Leadership Team; Pursues NASDAQ Listing

Based on our ten year DCF model using an 18% discount rate AYTU is valued at $8.20/share. Our financial model and assumptions will be updated based on relevant news.

OUTLOOK

Aytu BioScience (OTCQX: AYTU) headquartered in Englewood, CO is focused on the urological disorders market, particularly in hypogonadism ("Low T"), prostate cancer and male infertility. The company is commercial-stage with a nationwide urology-focused sales force.
With $15 million in cash and cash equivalents as of May 22, 2016, we think AYTU should be well positioned to run its operations until 2017. Our target price for Aytu Bioscience is $8.20/share.

Current Price (07/18/16)	$3.92
Valuation	**$8.20**

SUMMARY DATA

52-Week High	**$8.28**
52-Week Low	**$3.60**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**7,017**
Shares Outstanding (mil)	**4**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**5**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**-1.4**
P/E using 2018 Estimate	**-1.6**
Zacks Rank	**3**

Risk Level	**N/A,**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2015					$0.3 A
2016	$0.5 A	$0.5 A	$0.7 A	$0.7 E	$2.3 E
2017					$3.9 E
2018					$6.9 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2015					-$0.84 A
2016	-$0.16 A	-$0.23 A	-$0.39 A	-$0.78 E	-$1.23 E
2017					-$1.10 E
2018					-$0.69 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

AYTU: Gearing Up To Launch Natesto; Bolsters Leadership Team; Pursues NASDAQ Listing

Aytu held a conference call on July 6, 2016 to provide details to investors on Natesto's launch, which is expected by end of this month.

Acerus Pharmaceuticals Corporation (TSX: ASP) terminated the agreement relating to the commercialization of Natesto in the U.S. and Mexico with Endo Ventures Bermuda Limited (an affiliate of Endo International plc) (NASDAQ: ENDP) on June 30, 2016. In April 2016 Aytu acquired the exclusive rights from Acerus Pharmaceuticals to market Natesto in the U.S. Aytu paid $2 million at signing, and will pay the remaining $6 million in September 2016 and January 2017. Additionally, Aytu is expected to pay up to $37.5 million based on the achievement of certain sales milestones. Further, Aytu is expected to make royalty payments of 25% on net sales. Acerus will be continuing to supervise manufacturing of Natesto. In the initial months after launch, Acerus will be working closely with Aytu to ensure a smooth transition of Natesto from Endo.

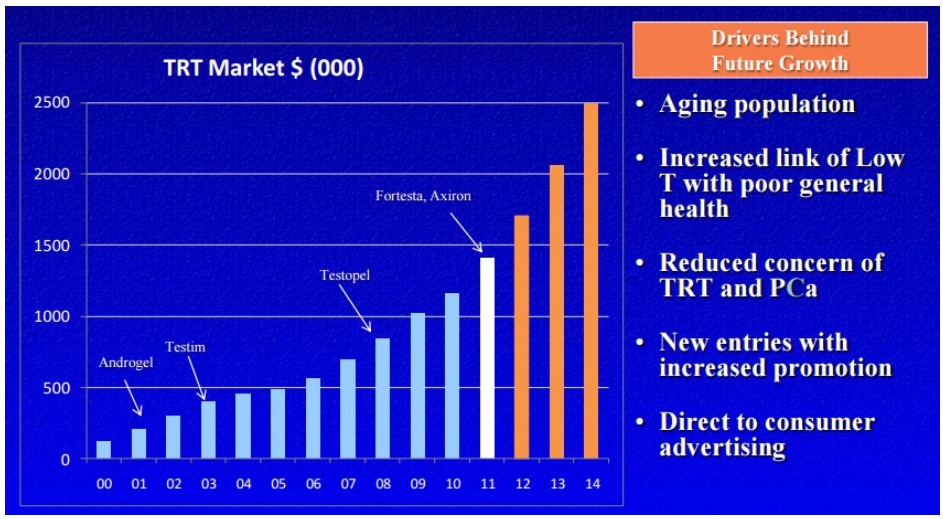
The reasons we think management found potential in Natesto, after assessing all opportunities and challenges in the evolving TRT market, are listed below.

- ✓ The U.S. testosterone replacement therapy (TRT) market generated ~$2 billion in annual sales in 2013 and sales are expected to double by 2018.
- ✓ There is a lot of capacity in Aytu's urology-centric sales force and therefore Natesto is a nice addition to the portfolio.
- ✓ Natesto was not Endo's prioritized product and consequently Natesto under performed generating only $1.2 million in revenue in the past year as per Acerus' 2015 annual report. Natesto's promotional labeling requirements are largely expected to remain the same as when marketed by Endo. We think Natesto has the following advantages over other TRT drugs:

- ✓ It is the first FDA approved, patented, nasally-administered TRT product for men with Low-T.
- ✓ It requires 2-3x dosing per day which mimics the natural testosterone cycle in men.
- ✓ It is easy and convenient to use. It offers a non-messy, no-touch application.
- ✓ Unlike Axiron (Eli Lilly) and AndroGel (AbbVie), its two leading TRT competitors, Natesto's label does not contain a black-box warning against transference risk.
- ✓ Natesto has demonstrated significant improvements in erectile function, intercourse satisfaction, orgasmic function, sexual desire, overall satisfaction and positive mood when compared to baseline.

Aytu has beefed up its marketing and sales team to launch Natesto.in the U.S. in late July 2016. Management noted on the call that they have not appointed sales personnel to focus their marketing efforts solely on Natesto. We believe that they have an adequate sales force who are familiar with marketing TRT products. Additionally, they have existing relationships with prescribing physicians that should help optimize Natesto's potential sales in this market. Currently, majority of reimbursement plans cover Natesto.

Aytu's urology sales force is planning to promote Natesto to the highest TRT prescribing physicians, endocrinologists and few primary care physicians totaling about 5500 specialists in metropolitan areas. We believe this focused messaging will help in driving adoption of Natesto. Management is planning to prioritize the sales of Natesto to the untapped urologist audience (where other TRT drugs have not been targeting). The initial sales strategy is to approach dissatisfied patients (using other TRT therapies), followed by those using injectable drugs and then new patients. We think Aytu is making strong headway in the commercialization efforts of Natesto.



(Source: Update on Late Onset Male Hypogonadism, M.Khera, Baylor College of Medicine, TX)

Based on the guidance management has given, we are not expecting an immediate revenue increase in Q1 2017 as the firm will not have sufficient time within the launch of Natesto to make a serious impact. However, we do expect sequential but modest growth in commercial sales in the coming year. We think Natesto sales will gain traction and follow an upward growth trend in the subsequent quarters following Q2 2017. Management expects to gain 5% market penetration sometime in the out years. Also tilling the soil for Aytu's growth could be the overall uptick in the TRT market segment.

In 2000, the first topical gel was introduced and according to IMS, it accounted for ~73% of the total prescriptions in the TRT market. As per IMS, the total number of prescriptions written within the TRT market increased three times (to about three million prescriptions) between 2000 and 2008. However, the gel market growth slowed down in 2013 due in large part to formulary changes, patients switching from gels to injectables and non-availability of newer therapies.
In the beginning of June 2016 the firm began patient enrollment and dosing at Princess Margaret Cancer Centre in Canada for their three-arm, open label prostate cancer study. The study is being led by Dr. Antonio Finelli in collaboration with Hybridyne Imaging Technologies to investigate the efficacy of Hybridyne's ProxiScan compact gamma cameras to detect local prostate cancer using ProstaScint. Currently the study has enrolled twenty of the sixty total patients. Patient enrollment is expected to be completed by end of calendar 2016 (1H 2017).

In January 2016 the MiOXSYS system received CE Mark and by June 2016 the company entered into agreements with five leading European specialty medical distributors to commercialize the system. The European commercial network includes Tani Medikal in Turkey, TECOmedical in Switzerland and Germany, Parallabs in the U.K. and France, THP Medical Products in Austria, and Durviz S.L. in Spain. Aytu anticipates expanding its ex-U.S. distribution channel to ramp up commercial sales in CE Mark territories. Although management has not disclosed specific sales numbers of the MioXSYS system, there seems to be considerable interest as five distributors have quickly signed contracts.

Additionally, in order to meet the requirements for uplisting shares to NASDAQ, Aytu underwent a 1 for 12 reverse stock split that became effective on July 1, 2016. The reverse stock split was approved by the company's stockholders and board of directors during the annual meeting held in May 2016. Following the reverse split, the number of outstanding shares is approximately 3.7 million. We have updated our financial model to reflect the share count following the reverse stock split. After adjusting the numbers based on the reverse stock split our target price comes out to $8.20/share.

More recently, the firm added pharmaceutical industry veterans, John Donofrio, Jr. and Gary Cantrell to its board of directors. All board members have impressive credentials and we believe the recent addition has strengthened the management team immensely. They have the necessary financial and commercial experience in the pharmaceutical industry to carry Aytu through its business operations.

Bio

Mr. Donofrio is the Chief Financial Officer and Head of North American Business Development for Merz North America, or Merz, since August 2013. Over his 24-year career in pharmaceuticals he has a broad range of experience in consolidated financial reporting, international accounting and internal controls, budget and forecast planning, mergers and acquisitions, business development and other strategic and financial areas. Mr. Donofrio has been instrumental in Merz North America's growth; sales and profits have more than doubled since he joined the company. Previously, he served as interim CFO and vice president of Stiefel Global Finance, U.S. specialty business and Puerto Rico, for Stiefel, a GlaxoSmithKline plc. company (GSK). He was also the senior finance partner for the U.S. specialty business units of GSK. Mr. Donofrio holds a degree in accounting from North Carolina State University.

Mr. Cantrell's thirty years' experience in the life sciences industry ranges from clinical experience as a respiratory therapist to his current executive-level consulting role with Mayne Pharma (MYX.AX), as business development executive focused on acquiring branded prescription assets for Mayne Pharma's U.S. specialty brands division. Prior to forming his professional consultancy, Mr. Cantrell served as CEO of Yasoo Health Inc., a global specialty nutritional company from 2007 to 2015, highlighted by the sale of its majority asset, AquADEKs, to Actavis in March 2015. He was also president of the Catevo Group, a North Carolina-based healthcare consulting firm, and executive vice president, sales and marketing at TEAMM Pharmaceuticals, an Accentia Biopharmaceuticals company. Mr. Cantrell started his pharmaceutical career at GSK, where he held multiple senior management positions in sales, marketing and business development over a period of 22 years. He has served as an advisor or board member of several emerging life science companies including his role as a board member at Flexible Stenting Solutions, Inc., which was sold to Cordis, while a division of Johnson & Johnson in March 2013. Mr. Cantrell is a graduate of Wichita State University.

We are keeping a close watch on Aytu’s events in the second half of 2016 as the company executes its goals of up listing to a U.S. premier stock exchange and ramping up sales of their urology products.

SNAPSHOT



- Aytu BioScience (OTCQX: AYTU) headquartered in Englewood, CO is focused on the urological disorders market, particularly in hypogonadism ("Low T"), prostate cancer and male infertility. The company is commercial-stage with a nationwide urology-focused sales force, and AYTU expects to expand their commercial infrastructure in order to grow sales of its current products and to launch its recently licensed product.

- The company's current sources of revenue come from ProstaScint®, an FDA approved biologic imaging agent specifically indicated for the diagnostic staging of prostate cancer patients, and Primsol®, the only FDA-approved trimethoprim oral solution for urinary tract infections and MioXSYS™, a novel, diagnostic device and disposable testing strips that together measure the presence of oxidative stress in semen and seminal fluid.

- AYTU acquired an exclusive U.S. license to Natesto® on April 22, 2016 from Acerus Pharmaceuticals Corporation and is preparing to launch Natesto in the U.S. by end of July 2016.

- AYTU has a therapeutic candidate in the pipeline: Zertane™, an oral drug for the treatment of premature ejaculation that is currently Phase 3-ready with an open IND with the U.S. Food and Drug Administration (FDA) .

- With $15 million in cash and cash equivalents as of May 22, 2016, AYTU is well positioned to run its operations.

- The company's executive team includes enterprising and experienced industry professionals with complementary skills to guide AYTU's strategic plans, primarily oriented around commercialization of its urology products.

- Our price target for Aytu Bioscience is $8.20/share.

INVESTMENT THESIS

AYTU BioScience (OTCQX: AYTU) headquartered in Englewood, CO is a specialty pharmaceutical company that is focused on developing and commercializing products in urology, particularly addressing hypogondadism, prostate cancer, male sexual dysfunction and male infertility. Aytu was formed by a reverse merger in April 2015 of Vyrix Pharmaceuticals and Luoxis Diagnostics, both former subsidiaries of Ampio Pharmaceuticals, Inc. and incorporated the pipeline assets of both firms. Aytu is now planning to expand its footprint in the urological specialty by acquiring or licensing commercial-stage assets or late-stage development assets that may be in the final stages of development or require/have approvals for commercialization in global markets and in the U.S. AYTU's products are in the nascent stages of commercialization. Since the firm's business model involves marketing, sales, and life-cycle management of the acquired products, it has been essential to augment the sales and distribution infrastructure to help market the products to physicians, healthcare centers, and clinics throughout the U.S.

By acquiring late-stage products (those with appropriate regulatory approvals and positive clinical trial results) primarily for the U.S. market, AYTU's business model is considerably de-risked. We expect that by expanding the sales force, increasing their customer base and expanding their portfolio with diverse urological products, the company will be able to significantly increase their revenue and achieve positive cash flow in the next couple of years.

The company currently has three revenue generating products; ProstaScint is a monoclonal antibody FDA-approved imaging agent that has been used for identifying treatment options in patients who are suspected to have recurrent, metastatic prostate cancer as well as those who are newly diagnosed, high risk prostate cancer patients. Primsol is an FDA-approved liquid antibiotic used to treat acute ear infections and uncomplicated urinary tract infections. The MiOXSYS system is a rapid in vitro diagnostic semen analysis test for the quantitative measurement of static oxidation reduction potential in human semen – as an aid in the diagnosis of male infertilty. In addition to these products, AYTU has Zertane in the pipeline, an oral drug candidate for the treatment of premature ejaculation. The company has an open IND with the FDA for Zertane to move into Phase 3 studies, but given the company's current focus on commercialization, AYTU is not progressing the Zertane clinical development program at this time. On April 22nd, 2016 the company announced the acquisition of exclusive U.S. rights on Natesto from Acerus Pharmaceuticals Corporation.

The company is headed by Josh Disbrow, CEO. While he was with Arbor Pharmaceuticals, a company that marketed prescription drugs for pediatric and cardiovascular, markets, he served as Vice President of Commercial Operations and oversaw the build out of the company's commercial infrastructure that was instrumental in growing the company's net sales to ~$130 million in 2014.

With $15 million in cash and cash equivalents as of May 22, 2016, we think AYTU should be well positioned to run its operations until 2017. Our price target for AYTU is $8.20/share .

MARKETED PRODUCTS



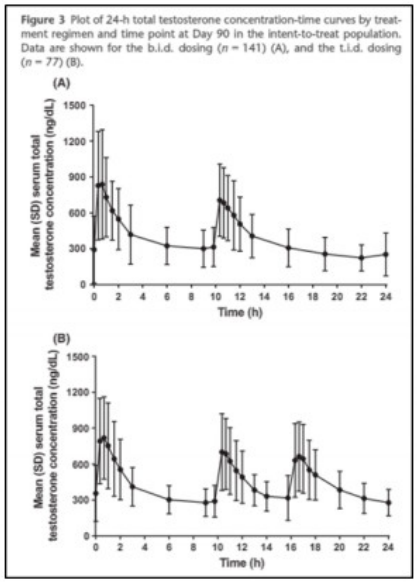
Indication: Deficiency or absence of male gonadal function results in insufficient testosterone secretion and is termed as male hypogonadism (Low T). The condition can be a result of age-related declines in circulating testosterone levels or congenital or develop later in life from an injury or infection. Some types of Low T can be treated with testosterone replacement therapy to restore levels within normal range.[1,2]

Natesto (Trimel/Endo): Natesto is a gel and offers convenient and simple metered dose administration nasally. It does not have the risk of testosterone transference which is associated with other topical products such as AndroGel® (a gel) and Axiron® (a spray), which carry "black box" warnings on their product labels. AndroGel and Axiron are administered once daily, to the upper body and underarm areas. The metered dose pump contains 60 actuations with each pump delivering 5.5mg of testosterone.

A randomized, open-label, dose-ranging study was conducted at 39 U.S. outpatient sites in 306 men (mean age 54.4 years) to study the safety and efficacy of Natesto. Natesto was self-administered using a multiple-dose dispenser as two or three daily doses (5.5 mg per nostril, 11.0 mg single dose).

On day 90, 70% of the patients in the 'titration arm' (n=141) and 91% of the patients in the T.I.D. group (n=77) achieved normalization of testosterone levels, with a low incidence of rising PSA levels. Natesto restored normal serum total testosterone levels in most hypogonadal men. Erectile function, mood, body composition, and bone mineral density improved from baseline. Treatment was well tolerated; adverse event rates were low. This study lacked a placebo or an active comparator control which limited the ability to adequately assess the drug.

[1] http://www.mayoclinic.org/diseases-conditions/male-hypogonadism/basics/definition/con-20014235.
[2] http://www.mayoclinic.org/diseases-conditions/male-hypogonadism/basics/tests-diagnosis/con-20014235.



(Source: Aytu BioScience)

Market: Hypogonadism affects older men. A study published in 2006 in The International Journal of Clinical Practice showed that 39% of men over the age of 45 have low testosterone levels (less than 300 ng / dL). Regardless of age, hypogonadism also affects men with chronic conditions, such as obesity, diabetes and hypertension. Low sex drive, erectile dysfunction, fatigue, depressed mood, reduced muscle mass and strength, increased fat body mass and decreased bone mineral density are some of the symptoms associated with Low T. As per IMS Health report, the number of prescriptions for testosterone replacement therapy grew from one million in 2000 to about three million in 2008. An estimated 13 million men in the U.S. are known to suffer from this condition.

Natesto® is classified as a schedule III controlled substance and.was approved by the FDA in May 2014 and is protected by multiple patents. It is also the first and only nasal testosterone replacement therapy approved by Health Canada (January 2016). In April 2016, AYTU acquired the U.S. commercial rights to Natesto Nasal Gel. Natesto is the first and only nasal formulation of testosterone approved by the FDA as a replacement therapy for men diagnosed with hypogonadism (low testosterone, or "Low T"). Aytu anticipates expanding its current urology-centric sales force and promoting Natesto into the $2 billion U.S. testosterone replacement market in July 2016.

Reimbursement: Due to the controversy and uncertainty concerning the diagnostic criteria for hypogonadism, CMS has no National Coverage Determination (NCD) applicable to testosterone testing or treatment of hypogonadism. The Natesto copay card allows for savings of ~$150 per use for up to thirteen uses on every prescription or refill (three dispensers).

Competitors: Several treatment options that are currently available for testosterone replacement include oral preparations of testosterone derivatives, intramuscular injections of long-acting testosterone esters, transdermal patches applied to the scrotum or other areas of the body (eg, upper arms, legs, abdomen, or back) or a 1% testosterone gel.

Replacement injections are the most common form of testosterone replacement therapy. Although this method is cost effective, testosterone levels surge approximately 72 hours after injection and then decrease for two to three weeks. Such fluctuations in serum testosterone is known to cause mood swings and changes in libido and sexual functioning.

ProstaScint®
(Capromab Pendetide)

Indication – Imaging Agent for Prostate Cancer: The outer most part of the prostate is the most prone site for adenocarcinoma. Metastatic prostate cancer spreads often to lymph nodes in the lower abdomen (stage N1) and pelvis as well as to other distant organs of the body (stage M1). Several factors such as age, genes, race/ethnicity, obesity and smoking have been found to increase the risk of developing prostate cancer in males.

Prostate-specific antigen (PSA) testing, along with a digital rectal exam (DRE), are the most widely used diagnostics for prostate cancer. The PSA test was used for detection of cancer in new patients and also for detection of recurrent cancer episodes. The probability of having prostate cancer increases to about 25% in men with PSA levels between 4-10ng/ml but dramatically rises to 50% as PSA level exceeds 10ng/ml. However, PSA tests are known to be unreliable and associated with high rates of false-positives[3]. Therefore, specialists recommend taking the rate of change of PSA level over time as well as a man's age into account when screening for cancer with the PSA level rather than using it as a sole indicator of presence/absence of cancer.

Prostate cancer is graded by pathologists using the Gleason system. A high Gleason score implies that the cancer will grow and spread more quickly. A low risk of prostate cancer is defined by a PSA under 10 ng/dl, and a Gleason score less than seven while a high risk of prostate cancer is defined by a PSA more than 20 ng/dl and a greater than eight Gleason score. The physician uses the DRE, PSA test and Gleason score to determine the likelihood of cancer spreading outside the prostate gland. The imaging methodologies used to identify prostate cancer spread include CT, MRI, bone scans, etc.

More recently, new screening methodologies are being developed for detecting prostate cancer.

ProstaScint (capromab pendetide) is a radio-immunoconjugate form of the anti-prostate-specific membrane antigen (PSMA) monoclonal antibody 7E11. PSMA is found in normal as well as cancerous cells. PSMA is expressed one thousand times greater in the prostate than in other tissues. However, PSMA is upregulated roughly twelve times higher in high-grade, hormone-independent and metastatic prostate cancer relative to normal epithelium. The ProstaScint scan was developed by radiolabeling the antibody (7E11C5.3) with indium-111. It is used as a diagnostic imaging agent for detecting nodal metastases in patients who are suspected of developing new or a recurring episode of prostate cancer. ProstaScint localizes the sites of soft tissue metastasis in patients. This test is recommended for patients with a known diagnosis of prostate cancer and who are suspected to be at high risk of having metastatic spread based on clinical staging, the PSA level, and the Gleason score or if other tests fails to identify the exact location of the cancerous cells.

ProstaScint is administered intravenously. Administration of the agent and imaging occur on two different days with imaging performed roughly after six days of administration. Thirty minutes after administration, single photon emission computed tomographic (SPECT) imaging lasting roughly one hour is performed. A second scan lasting approximately 2.5 hours is performed between 96 and 120 hours (4-5 days) after the infusion. The agent is excreted through the bladder and bowel and requires extra hydration for the patient.

[3] http://www.cancer.gov/types/prostate/psa-fact-sheet

Several studies have been conducted using ProstaScint and the data support the use of ProstaScint in prostate cancer diagnosis. ProstaScint has been widely used for identifying treatment options in patients who are suspected of having metastatic cancer as well as those who are at high risk for developing prostate cancer[4]. Since the ProstaScint scan is based on the expression of the PSMA molecule, it can image low volume cancer that is otherwise undetectable using conventional procedures. SPECT image data was co-registered with CT scans to identify cancerous cells for providing image-guided radiation therapy. It has been shown in studies that immunoscintigraphy with ProstaScint can help determine the extent of cancer spread in patients with increasing PSA after prostatectomy[5]. With advanced image reconstruction algorithms, concurrent anatomic SPECT imaging provides correlation to clarify the extent of the spread of tumor[6,7]. The limitation of In-111 is that the antibody remains in the blood and leads to high background signals and consequently reduced detection rates. SPECT scintigraphic techniques when compared to PET offer lower spatial resolution. Studies have shown that the second and third generation PSMA-binding antibodies have been successful at targeting the cancerous cells[8].

Market: After skin cancer, prostate cancer is the second most commonly occurring cancer and the second leading cause of death in men after lung cancer. National Cancer Institute estimates 2.8 million men having prostate cancer in the U.S. in 2012. When detected early, initial therapy typically results in most men living cancer-free for at least five years post treatment. Of this number, it has been estimated (Prostate Cancer Foundation) that about 30% of men will begin to show signs of disease recurrence after the five-year mark. As per the American Cancer Society's estimates, annually 220,800 new patients are suspected of developing prostate cancer in the U.S. and roughly fifteen percent of those are classified as high risk.

About 2.5 million imaging procedures are done annually to detect prostate cancer. In general, men of African-American origin and Caucasian men with a family history of prostate cancer have an increased risk of developing prostate cancer. In such populations, screening is recommended at forty years of age. About 80% of prostate cancers that are diagnosed are at the local stage (within the gland), 12% has spread to the lymph nodes and another 4% has metastasized.

Although results obtained using ProstaScint have been controversial, with some reporting false positives and others claiming no apparent advantage, to date, ProstaScint is the only monoclonal antibody-based agent that has obtained FDA approval for use in patients with a high clinical suspicion of metastasis and in which standard evaluation (PSA screening test) has resulted in a negative result. As per the FDA, ProstaScint is indicated as a diagnostic imaging agent in newly-diagnosed patients with biopsy-proven prostate cancer and patients suspected of recurrent disease.

Despite the positives offered by ProstaScint, it did not gain widespread acceptance by the medical community. Sales of ProstaScint have declined since 2012 as USPSTF guidelines were updated in that same year advising against routine PSA testing due to a high rate of false positive results. From 2010 to 2013, the PSA-based screening did not change significantly among men aged 40- 49-years (from 12.5% to 11.2%; P = .4) but significantly declined in men aged 50-59 years (from 33.2% to 24.8%; P < .01), 60-74 years (from 51.2% to 43.6%; P < .01), and more than 75 years old (from 43.9% to 37.1%; P = .03)[9]. This can lead to unnecessary and expensive treatment options, as well as result in a high risk of serious side effects. Another plausible reason for ProstaScint's low sales figures was that the imaging resolution from radiological images was not high enough to reveal critical anatomic details. Therefore, physicians often found it difficult to determine the exact site of In-111 accumulation. Further, since the prostate cancer mostly metastasized in bone and the scan did not clearly show bone, ProstaScint's utility was lessened.

[4] Reviews in Urology 2006, 8(1):11-19
[5] (111) INDIUM-CAPROMAB PENDETIDE IN THE EVALUATION OF PATIENTS WITH RESIDUAL OR RECURRENT PROSTATE CANCER AFTER RADICAL PROSTATECTOMY, KAHN, DANIEL et al. The Journal of Urology , Volume 159 , Issue 6 , 2041 - 2047
[6] Curr Top Med Chem. 2013; 13(8): 951–962.
[7] World J Nucl Med. 2015 Sep-Dec; 14(3): 209–211.
[88] Reports in Medical Imaging 2015:8 51–62
[9] J Clin Oncol. 2015 Aug 1;33(22):2416-23.

In general, a molecular scan provides functional data and more recent MRI/CT scans provide high-resolution anatomic details. For metastasis outside the gland and in non-bony regions, ProstaScint images are biologically and therapeutically useful since the areas that demonstrate In-111 uptake are segmented and superimposed on the CT/MRI data to better decipher the location of cancer spread and offer accurate diagnosis and treatment options[10].

Currently, the U.S. government (Medicare) provides coverage for annual PSA testing of men fifty years of age and older. While Medicare considers this as preventive care, Obamacare does not. Many private party payors follow Medicare policy.

PCPs reduced their testing recommendations after the USPSTF guideline, probably because PCPs shifted towards more selective screening practices instead of reflexively proceeding to a biopsy for a patient with elevated PSA level. However, the decrease in recommendation among urologists was from 38.7 to 34.5%. The disparity in the internist/specialist-specific testing practice was statistically significant and could be attributed to the differences in patient demographics. The majority of prostate cancer patients are managed by urologists. Additionally, recognizing the role of medical and radiation oncologists AYTU has initiated programs to approach these specialty physicians in order to promote ProstaScint.

ProstaScint is soon to be manufactured at a biologics manufacturing facility in Minneapolis, MN following a technology transfer from its historical site in New Jersey. The company has regional account managers and six regions in the U.S.: west, south, south-east, north-east, Great Lakes, central/mid-west.

Reimbursement: The CPT, HCPCS and ICD-9 codes if selection criteria are met for ProstaScint scan are listed below.

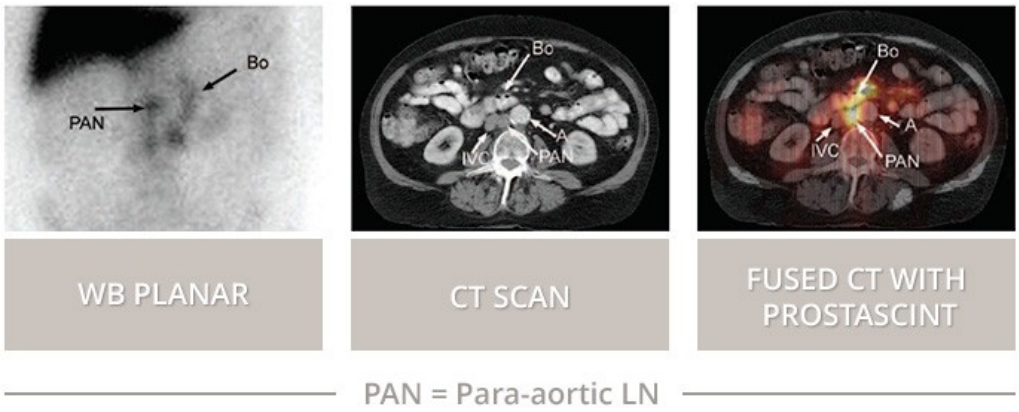
78800 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); limited area
78801 multiple areas
78802 whole body, single day imaging
78803 tomographic (SPECT)
78804 whole body, requiring 2 or more days imaging

HCPCS code: A9507 Indium In-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries

ICD-9 codes:
185 Malignant neoplasm of prostate
V10.46 Personal history of malignant neoplasm of prostate

Competitors: Prostate cancer is known to frequently metastasize to bones. Therefore, the imaging agent employed most commonly is technetium-99m-labeled bisphosphonate (eg, 99mTc-methylene diphosphonate) bone scintigraphy. However, it has limited sensitivity and specificity to detect smaller metastases. Prostate cancer cells rely more on fatty acid metabolism. The 11C/18F choline-based and 11C-acetate agents are lipid-metabolism PET agents that have shown high sensitivity for local recurrence, nodal metastases and bone metastases. Several companies have developed these agents for imaging prostate cancer.

[10] Int J Radiat Oncol Biol Phys. 2004 Oct 1;60(2):654-62.



(Source: http://prostascintscan.com/)

While the the ProstaScint Scan has remained controversial, it has been in use to evaluate the presence of metastasis in men who have failed radiation therapy. ProstaScint scan is known to have positive results with individuals who are known to be at high risk of having metastatic spread based on clinical evaluation, the PSA level and the Gleason score. Although the detection rate is low with ProstaScint scans, the specificity of the study in detecting recurrent prostate cancer is improved when images are superimposed with CT or MRI imaging performed concurrently[11]. Overlaying the ProstaScint SPECT with a CT or MRI scan has been shown to reduce false-positive findings since it aids in identifying physiological uptake capromab pendetide in anatomical structures[12].

Originally, ProstaScint was marketed for newly diagnosed prostate cancer patients who were candidates for radical prostatectomy, radiation therapy or brachytherapy. Management's game-plan to increase ProstaScint sales is by publishing ProstaScint's clinical performance results, targeted marketing to urology specialists, attempting to expand utilization to newly diagnosed, high-risk as well as recurrent prostate cancer patients and working towards improving reimbursement rates, all of which could help drive sales of the product. Further improvements in radiological image reconstructions when fused with ProstaScint scan has allowed more precise detection of prostate cancer. It seems like this advancement, along with the company's marketing efforts will lead to renewed interests among internists, and more specifically to specialists (urologists).

Since Aytu has the worldwide commercial rights to ProstaScint, the company has built sales and marketing infrastructure in the U.S. to support an aggressive marketing strategy to high-prescribing general urologists and specialists. The company believes that such a sales force across the U.S. could considerably improve physician interest and help boost revenue for ProstaScint. Further, management intends to invest in educating both doctors and patients in addition to developing promotional plans and campaigns to foster widespread adoption of ProstaScint. With regard to the commercialization efforts, we think the company may continue to incur significant expenses in 2016. However, we think that the higher expense could be offset by higher revenues.

[11] http://50.80.140.55/classwork/ecrd/reference/zeleznik/ben_new_20050207.pdf
[12] Youngho Seo, J. Kurhanewicz, B. L. Franc, R. A. Hawkins and B. H. Hasegawa, "Improved prostate cancer imaging with SPECT/CT and MRI/MRSI," Nuclear Science Symposium Conference Record, 2004 IEEE, 2004, pp. 2402-2406 Vol. 4.



Indication: Bacteria infections of the urinary tract. *Escherichia coli* accounts for over 80% of uncomplicated urinary tract infection (UTI). UTIs are one of the most common hospital-acquired infections. Treatment with antibiotics is usually the mainstay in treating such an infection. Although women are more susceptible to this infection than men, factors that increase the risk of acquiring a UTI are age, reduced mobility, urinary incontinence, kidney stones, and enlarged prostate, among many others.

Primsol (trimethoprim hydrochloride) is a liquid antibiotic that is recommended for use under current guidelines for treating uncomplicated UTIs caused by escherichia coli, enterobacter species, klebsiella pneumoniae, proteus mirabilis and staphylococcus saprophyticus. Primsol is an anti-infective and folic acid antagonist with slow bactericidal action. It binds and interferes with bacterial cell growth. Primsol is appropriate for elderly patients who have difficulty swallowing tablets, as well as for patients who experience adverse allergic reactions to sulfamethoxazole. Primsol is also indicated to treat acute otitis media (ear infections) in children over six months of age for the treatment of acute caused by streptococcus pneumoniae and haemophilus influenzae.

Market: Primsol is currently the only FDA-approved liquid formulation of trimethoprim. Primsol is only available as a prescription brand name drug. Primsol was promoted to pediatricians as it has a pleasant bubble gum flavor that caters to children's taste, does not require shaking or refrigeration, does not contain alcohol or dyes and has convenient twice-a-day dosing option. Otitis media is the leading pediatric infection in the U.S., which accounts for over twenty million annual outpatient visits.

UTI accounts for roughly eight million outpatient and ER visits annually in the U.S. Aging population requires frequent urinalysis for detecting various age-related diseases and is therefore, a major factor that contributes to growth in this market.

Single-dose therapy (Primsol) offers the advantages of high curing rates, increased compliance and a lower incidence of side effects but also has a high incidence of recurrence due to failure in eradicating the gram-negative pathogens responsible for the infection. Consequently, because of its low cost and high efficacy for uncomplicated UTI, Primsol is used as the first line of therapy with individuals whose resistance to uropathogens is less than 10% to 20%[13].

Reimbursement: This formulary typically falls in Tier 4 (non-preferred, high price, brand-name drugs) of most reimbursement plans and costs ~$90.00 before insurance. A co-pay card was authorized by the previous marketer (FSC labs) that allows the patient up to $40 discount off the normal pharmacy charges.

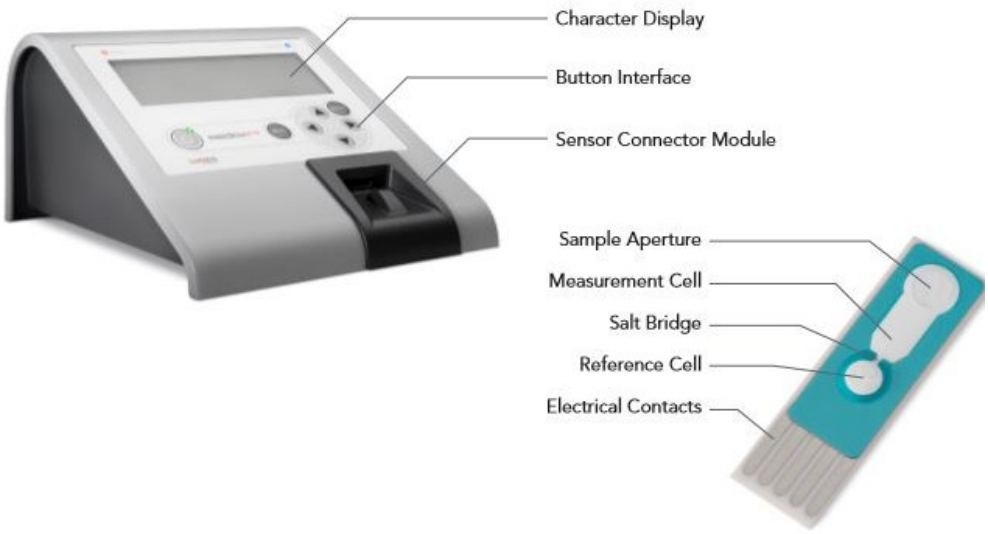
Competitors: UTI are common in patients with catheters, women, sexually active adults, diabetics, and in the elderly. The global antibacterial therapeutic market is valued at roughly $40 billion.

While Primsol has contraindications in certain patient population, similar to Septra and Bactrim, it is positioned as a safer alternative to these. Septra and Bactrim (trimethoprim with sulfamethoxazole) accounted for approximately four million prescriptions dispensed in the U.S. in 2000.

[13] Jancel, Timothy, and Vicky Dudas. "Management of Uncomplicated Urinary Tract Infections." Western Journal of Medicine 176.1 (2002): 51–55. Print.

Indication: Male infertility is defined as the inability of the male to produce mature, healthy, normal sperm with adequate motility. The main conditions affecting fertility may be due to anatomical obstructions, immunologic, hormonal factors as well as certain medications. There is considerable difficulty in accurately diagnosing male infertility since the presence or absence of a problem is ambiguous. After a physical examination, semen analysis (sperm concentration, motility, and morphology) is performed as a routine lab test to diagnose infertility.

One of the suspected reasons contributing to male fertility and idiopathic infertility is the role of oxidative stress. Oxidation-reduction potential (ORP) is a measure of oxidative stress or redox imbalance in biological fluids. Oxidative stress is caused by an excess of reactive oxygen species (ROS) and reduction in antioxidants that are responsible for neutralizing and removal of ROS. Consequently, this hinders the normal morphology and impairs functioning of healthy sperm[14,15]. ROS are known to be highly reactive and have a very short half-life. Although still under investigation, it is estimated by several research groups that 40% of male infertility is idiopathic and is linked to oxidative stress. One of the primary reasons for this assumption is that morphologically abnormal sperm have a higher capacity to produce ROS, and a reduced capacity to make antioxidants[16].



(Source: Aytu BioScience)

The chemiluminescence oxidative stress test measuring ROS (reactive oxygen species) requires a fresh semen sample produced after 2 – 3 days sexual abstinence. ROS is measured within 15 - 30 minutes of ejaculation using a luminol probe, which oxidises in the presence of ROS, resulting in chemiluminescence. The luminescence is measured using a luminometer. Such traditional methods of measuring ROS in semen are time consuming (centrifugation required in chemiluminescence assay preparation) and time sensitive thereby rendering it difficult to utilize

[14] Ghareeb DA, Sarhan EME (2014) Role of Oxidative Stress in Male Fertility and Idiopathic Infertility: Causes and Treatment. J Diagn Tech Biomed Anal 2:1
[15] J Hum Reprod Sci. 2015 Apr-Jun; 8(2): 61–69
[16] Hum. Reprod. Update (2008) 14 (3): 243-258

for routine diagnostic purposes – and virtually impossible to implement in small physician office labs, or IVF centers. ROS levels in the semen must be measured within an hour after collection to obtain the correct reading because (ROS) are highly reactive and have a very short half-life.

MiOXSYS is a programmed diagnostic device specific to the detection of ORP in semen and seminal fluid. This system provides results in real time and is independent of the age of semen post collection (within two hours) and independent of freshly collected or frozen/thawed specimens.

Currently, studies are underway to help determine the system's performance in semen analysis. The company presented the results from two clinical studies employing the MiOXSYS System at the 2015 American Society for Reproductive Medicine (ASRM) annual meeting, in Baltimore, MD.

In a study to evaluate the MiOXSYS system, semen samples from normal healthy volunteers were divided into two fractions. The study demonstrated that the MiOXSYS system measured ORP levels accurately in both the semen and seminal plasma ($P<0.001$). Additionally, data revealed significant inverse correlation between ORP levels and sperm motility in both semen ($p=0.004$) and seminal plasma ($p=0.002$). This implied that higher ORP values indicated low sperm motility. An ORP cutoff of $4.65mV/10^6$ sperm was predictive of an abnormal sperm motility with 100% sensitivity in both semen (specificity=89.5%) and seminal plasma (specificity=93.8%). These findings are currently being validated in a larger cohort of infertile men[17].

The second study was performed to evaluate the MiOXSYS system's ability in assessing oxidative stress levels in semen and seminal plasma samples over time. Traditionally oxidative stress is measured using a chemiluminescence assay which time intensive making it difficult to use for diagnosis and routine use. While traditional methods require thirty minutes to reveal results, the MiOXSYS system delivers results in roughly two minutes. This study revealed that ORP values were not affected by the age of semen or seminal plasma for up to 120 minutes ($P<0.05$) which makes it conducive to employ this system for diagnosis in a routine setting of care.[18]

More recently, 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, presented data from the study validating the oxidation-reduction potential in fresh and frozen semen samples with MiOXSYS™ System at the 111th American Urological Society Annual Meeting in San Diego, CA. The results demonstrated 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.

Market: As per Grand View Research, the male infertility market is growing globally due to the increase in the number of couples who are struggling to conceive. Some of these couples have opted to use expensive, state-of-the-art technology to help in conception. Several factors are responsible for driving the growth of male infertility market including an aging population, changes in lifestyle, smoking, alcohol consumption, environment, medications affecting spermatogenesis and genetic abnormalities. However, the high cost of treatments such as IVF amounting to more than $10,000 poses a high hurdle to many couples wanting to have a baby. Further, most couples require multiple treatments. Adding to this barrier are the private as well as public insurance payors who do not reimburse for infertility treatments.

[17] Establishing the oxidation-reduction potential in semen and seminal plasma, Fertility and Sterility, 104 (3), September 2015: e146,
[18] Effect of time on oxidation-reduction potential in semen and seminal plasma, Sharma, R. et al., Fertility and Sterility , 104(3): e295

Male infertility is caused by several factors including abnormal sperm morphology, genetics, hormonal imbalances, weight factors, smoking, and/or sexually transmitted disease. As per statistics gathered by Mayo clinic, globally about 15% of couples are infertile (roughly 48 million couples). Of this estimate, about a third could be attributed to male infertility. In North America, approximately 4.5-6% of males are infertile (roughly 2.3 million)[19,20]. Roughly 40% of male infertility cases are idiopathic in nature[21].

Male infertility tests such as sperm DNA fragmentation tests, microarray technologies and proteomics are available only in developed countries. Other tests including endocrine evaluation, ultrasonography, post-ejaculatory urinalysis, sperm viability tests, quantifying leukocytes in semen, sperm agglutination, oxidative stress analysis, sperm penetration assay tests, genetic screening help in identifying the underlying cause of male infertility.

As per the World Health Organization (WHO) in 2012 there were more than 48 million couples globally who had fertility issues. Of this estimated number of couples, 6.7 million are in the U.S. The U.S. fertility market is comprised of fertility medications and assistive reproductive procedures. According to a report by Research and Markets, the U.S. fertility market is expected to grow at a CAGR of 4.07% between the years 2016 and 2020. The key vendors in this space are Cellcura, CooperSurgical, Intramed, Ferring Pharmaceuticals, Merck, Intas Pharmaceuticals Ltd., Andrology Solutions, among others.

Aytu expects MiOXSYS to be classified as a Class II device by the FDA as it is a new device without a prior classification. But since it is not a high-risk device, management hopes to be able to follow the 510(k) de novo FDA clearance pathway – which, while still requiring supporting clinical data, affords a shorter and less expensive route as compared to the PMA pathway required of high-risk Class III devices. But this plan will have to first be confirmed by FDA. If and when AYTU obtains marketing approval in the U.S., the company will target payors who cover private, Medicaid, and Medicare plans, and will conduct advisory meetings, in order to assist in the pricing strategy to optimize coverage that will result in access and affordability for the patients. The company expects to utilize its growing commercial infrastructure in the U.S. to promote the MiOXSYS system but is considering various strategic options to maximize the market opportunity for MiOXSYS.

The current ORP/MiOXSYS patent portfolio consists of 14 issued patents and 56 pending applications worldwide. The patents are set to expire beginning 2028. The MiOXSYS system is CE Marked, and the company expects to commercialize in Europe, Asia (including the Middle East) through a network of medical distributors.

The company announced the first commercial sales of the MiOXSYS System in Europe and the Middle East in February 2015. AYTU is anticipating clinicians to integrate the MiOXSYS system into their routine tests and monitoring of treatment effects for infertility which can help augment sales in these regions.

Competitors: Although there may be tests that measure sperm concentration, motility and morphology, currently, there are no devices on the market for measuring male infertility based on seminal ORP in real time. Seminal ROS can be measured using chemiluminescence, nitroblue tetrazolium test, cytochrome C reduction test, and xylenol orange–based assay. In these procedures analysis needs to be performed within an hour of preparing the sperm sample. If not tested within the recommended time frame then a lower level of ROS in the semen is detected[22].

[19] Agarwal, Ashok et al. "A Unique View on Male Infertility around the Globe." Reproductive Biology and Endocrinology : RB&E 13 (2015): 37. PMC. Web. 2 Mar. 2016.
[20] http://www.harriswilliams.com/sites/default/files/content/fertility_industry_overview_-_2015.05.19_v10.pdf
[21] Baker HWG, Burger HG, de Kretser DM et al: Relative incidence of etiological disorders in male infertility. In Santen RJ, Swerdloff RS (eds): Male Reproductive Dysfunction, p. 341. Marcel Dekker, 1986)
[22] Curr Urol Rep. 2011 Feb; 12(1): 68–76.

Other Potential Applications: The RedoxSYS Diagnostic System has demonstrated systemic redox measurement that is correlated with severity of disease in various pathological conditions with a known redox imbalance. Therefore, we believe that the RedoxSYS Diagnostic System has a large market potential.

PIPELINE PRODUCTS

ZERTANE™
(tramadol HCl) 89 MG Orally Disintegrating Tablets

Indication: Premature Ejaculation (PE) occurs when a man does not have voluntary control over ejaculation. It is not a result of a physical problem but rather due to anxiety and/or excitement. Typically, in PE the ejaculation latency is roughly less than one minute. Although the condition is not serious, it can cause emotional distress in men and their partner.

The medical community opines that PE has psychological components and therefore some methods of treatment include antidepressants that have potentially serious side effects. Several OTC medications that are currently available are not entirely effective. Usage of devices and therapeutic techniques like the start-stop and "squeeze" methods are known to reduce sexual satisfaction. Topical creams, gels and sprays remain on the skin's surface and result in desensitizing the penis as well as the partner and consequently reduce sexual pleasure.

Zertane (tramadol hydrochloride): Tramadol, a centrally acting opioid analgesic, is sold as a generic medication and available as an off-label prescription to treat anxiety or depression. Zertane is a specially calibrated dose of tramadol. Tramadol delays the time to ejaculate with one or more of the following effects: inhibiting the neuronal reuptake of serotonin, inhibiting the neuronal reuptake of noradrenaline, enhancing serotonin efflux, antinociceptive effects and inhibiting spinal somatosensory evoked potentials.

Tramadol is recommended to be taken at least 2 hours before sexual activity in order for it to be effective. A multicenter study by Bar-Or et al to determine the efficacy of tramadol revealed a 2.5-fold increase in IELT (intravaginal ejaculation latency time). The result implied that a man who normally lasted about a minute would be expected to last about 2.5 minutes after taking tramadol[23].

Various research studies have shown tramadol HCl to have some efficacy in treating PE[24,25]

Clinical Trials:

- ***Phase 1 study:*** Two Phase 1 trials were conducted to assess the safety profile of 89 mg tramadol in plasma after oral administration in healthy volunteers.

- ***Phase 2 study:*** Two randomized, placebo-controlled, blinded Phase 2 clinical trials were conducted in 102 patients. The first study revealed that a single dose of 25-mg tramadol hydrochloride (i.e., immediate-release gelatin capsules) was

[23]Wong, BL and Malde, S. The use of tramadol "on-demand" for premature ejaculation: a systematic review. Urology 2013 Jan;81(1):98-103
[24] Evaluation of tramadol on demand vs. daily paroxetine as a long-term treatment of lifelong premature ejaculation. Alghobary M, El-Bayoumy Y, Mostafa Y, Mahmoud el-HM, Amr M, J Sex Med. 2010 Aug; 7(8):2860-7.
[25] Safety and efficacy of tramadol in the treatment of premature ejaculation: a double-blind, placebo-controlled, fixed-dose, randomized study. Safarinejad MR, Hosseini SY, J Clin Psychopharmacol. 2006 Feb; 26(1):27-31.

safe, well-tolerated and prolonged time to ejaculation in some patients. The second trial evaluated three higher doses of tramadol hydrochloride: 65 mg, 85 mg and 120 mg. The study demonstrated a clear dose response for both efficacy and safety and helped conclude that the optimal dose of tramadol required to treat PE was likely in the 60-90 mg range.

- ***Phase 3 study:*** Two identical twelve week randomized double-blind, placebo-controlled Phase 3 trials were conducted across 62 sites in Europe. Subjects were healthy men 18 to 65 years of age with a history of lifelong PE who had an IELT ≤120s. There were 604 intent-to-treat subjects included in the analysis. Subjects were randomized to receive placebo (n = 200), 62 mg tramadol ODT (orally dissolving tablet) (n = 206), or 89 mg tramadol ODT (n = 198). Tramadol ODT was well-tolerated and significantly increased median IELT by 0.6 min (1.6 fold), 1.2 min (2.4 fold), and 1.5 min (2.5 fold) for placebo, 62 mg tramadol ODT, and 89 mg tramadol ODT, respectively ($p < 0.001$ for all comparisons)[26].

Market: Doctors are of the opinion that about 30% of males suffer from PE. The sector is forecasted to expand globally at a CAGR of 10.3%. By 2018, the PE market is forecasted to be valued at $1.3 billion. Priligy (Dapoxetine) is currently in phase III clinical trials in the U.S. Priligy has been approved in more than 50 countries. The prevalence of PE in the male population is the driving factor this growth in this market.

Currently, there are no FDA-approved prescription products in the U.S. to treat PE. Experts in this field believe that the market for premature ejaculation treatments may be larger than that of erectile dysfunction. While we think the sales of Zertane may not reach as high as that of Viagra, we believe there is significant potential for this product as men are affected by PE more than by erectile dysfunction.

Since Zertane is being developed as tramadol in a specific dosage form, it is expected to follow the 505(b)(2) pathway for obtaining regulatory approval in the U.S. This alternative route is attractive and viable for AYTU. The reasons being that the application can incorporate data from previous clinical studies, which are otherwise expensive to replicate, as well as substantially save costs (505(b)(2) costs roughly between $3-$7 million). The company must successfully complete two Phase 3 clinical trials in the U.S. before receiving marketing approval, but given the company's current focus on launch Natesto and growing sales of ProstaScint and Primsol Zertane is not being advanced into its Phase 3 study at this time. The company may seek commercial partners or seek to monetize the asset in the form of a license or asset sale. AYTU has pending commercialization agreements for Zertane in other global regions, including Canada, Latin America, South Korea, and South Africa.

Competitors: Topical sprays/creams such as Stud100, EMLA, and EjectDelay are generally used to address PE.

Promescent is a lidocaine-based topical controlled-dose spray for preventing PE. Promescent is available as an OTC medication and recently became the most often ordered PE product on Amazon. Promescent is available in a metered-dose spray bottle, which enables delivery as a specific and reproducible amount thereby helping control penile sensitivity and delay ejaculation. It demonstrates efficacy and reduces transference to partners. Promescent takes effect in about 10 minutes and absorbs and dries in just a few minutes.

[26] European Urology 2012, 61(4): 736–743

Table 1: Medical treatment options for premature ejaculation [58]

Therapy type	Drug	Trade name	Dose	IELT fold increase
Topical therapy	Lidocaine/prilocaine cream [29]	EMLA® cream	25 mg/gm lidocaine, 25 mg/gm prilocaine	4-6
Oral therapy	Dapoxetine [35,49,31,39]	Priligy®	30-60 mg on demand	2.5-3
Oral therapy	Clomipramine [30,34,38]	Anafranil®	12.5-50 mg/day or	6
			12.5-50 mg on demand	4
Oral therapy	Fluoxetine [56,64,23,66–68]	Prozac®, Sarafem®	20-40 mg/day	5
Oral therapy	Paroxetine [36–38,60]	Paxil®, Seroxat®	10-40 mg/day or	8
			10-40 mg/day on demand	1.4
Oral therapy	Sertraline [59,64,61-66]	Zoloft®	50-200 mg/day	5
Oral therapy	Citalopram [67–68]	Celexa®, Cipramil®	20-40 mg/day	2
Oral therapy	Tramadol [69]	Zertane®	62 mg ODT on demand or 89 mg ODT on demand	2.4 2.5

(Source: Çayan, Selahittin, and E. C. Serefoğlu. Advances in treating premature ejaculation" F1000 Prime Rep 6 (2014): 55)

TEMPE containing both licocaine and prilocaine, is the most popular topical spray for PE and is created by the firm that developed Viagra. While TEMPE is a prescription drug that has gone through clinical trials and is not FDA-approved for PE, Promescent is an over the counter medication. From the European clinical trials involving TEMPE, it was revealed that average intravaginal ejaculatory latency time (IELT) went up from 1.1 minutes to 3.8 minutes. A new clinical trial involving TEMPE is expected to commence in the U.S. in 1H 2016 and the company anticipates filing an NDA in 1H 2017.

Priligy (Dapoxetine) is the first compound developed for the on-demand treatment of PE. Priligy acts by inhibiting the serotonin transporter thereby increasing serotonin's action at the neuron's postsynaptic cleft. Consequently, it delays ejaculation. Priligy is rapidly absorbed and eliminated from the body and therefore is suitable for the on-demand treatment of PE. It has been approved for treatment of PE in New Zealand, Sweden, Austria, Finland, Germany, Spain, Italy and Portugal but not approved for use in the U.S.

Although Priligy is more popular as it is an on-demand short-acting SSRI, and chronic use of SSRIs is associated with the serious psychiatric and neurologic consequences and side effects. Topical sprays and creams are generally not preferred as they run the risk of causing vaginal numbness from absorption. Tramadol HCl, an oral agent, was found to have a low incidence of abuse (addiction) and dependence[27].

Although the standard tramadol is prescribed at 50 mg dose, the non-standard dosage is not available in a generic form. The most effective dose of Zertane for PE was found to be between 62 mg and 89 mg (not a standard dose).

While Johnson & Johnson may be aiming for an FDA approval of Priligy, Pfizer and Bristol Myers-Squib have agents under development. Zertane has patents in U.S. through to 2022.

Based on the level of evidence from clinical trials involving Zertane, as well as based on the above discussion, we feel that Zertane is promising and may prove to be an effective agent with less side effects.

At this time, Aytu does not intend to immediately pursue the development of Zertane given the company's success in acquiring or licensing on-market assets in a short period of time. The FDA accepted an IND for Zertane at the end of 2015. The U.S. trial design, endpoints, and inclusion criteria will be similar to that of the European trial. Total enrollment for each trial will be approximately 350 – 400 subjects. Patients with a subset of disease symptoms described by the ISSM Ad Hoc Committee for the definition of PE will be included. Two different doses of tramadol

[27] Biol Psychol. 2006 Jul; 73(1): 90–99.

hydrochloride (62 and 89 mg) will be evaluated. The key efficacy assessments will include IELT and the subject's frustration due to PE. With this Phase 3-ready asset, the company is positioned to explore strategic options that may help maximize the Zertane commercial opportunity without directly investing in the Phase 3 clinical studies.

INTELLECTUAL PROPERTY

AYTU's products have patent protection in the U.S. and several other large markets globally. ProstaScint is protected by significant trade secrets and manufacturing know-how related to its production. Primsol is protected by a formulation patent as well as by manufacturing trade secrets. The patent portfolio related to MiOXSYS that is supported in the U.S., Europe, Japan, Canada and Israel consists of ten issued patents and eighteen pending applications and begin to expire in 2028. The 20-year patents related to Zertane in the U.S., Australia, Canada, China, Hong Kong, Japan, Korea and South Africa begin to expire in 2022.

FINANCIAL CONDITION

AYTU had cash of roughly $8.7 million as of March 31, 2016. In the beginning of May 2016, AYTU raised about $7.5 million from the sale of 18,750,000 shares of its common stock at an offer price of $0.40 per share. Additionally, AYTU retired $4.1 million of its debt principal from its September 2015 convertible debt offering. Currently, only $1.05 million debt principal remains on the balance sheet.

Aytu's cash burn of roughly $2 million per quarter is likely to continue as the company continues to scale the commercial infrastructure in support of launching Natesto and growing ProstaScint and Primsol sales. With the company putting Zertane's clinical development activities, most resources and cash burn will be directed at commercial operations, with minimal expense associated with gaining FDA regulatory clearance for the MiOXSYS device. We estimate that the cash balance of ~$15 million as of May 2016 is sufficient to continue the company's operations into 2017. Since the company's regional sales representatives are responsible for a large territory, we think the company may need additional funds to expand sales force in the U.S. for continuing the growth of their current products and for Natesto's launch in July 2016.

LEADERSHIP TEAM

Josh Disbrow
Chief Executive Officer
Josh Disbrow has been in the life sciences industry for over eighteen years across pharmaceuticals, diagnostics, and medical devices. Prior to forming Aytu BioScience, Josh was the Chief Operating Officer of Ampio Pharmaceuticals (NYSE MKT: AMPE) and led the Luoxis Diagnostics subsidiary. Luoxis was merged into Aytu in April 2015. Prior to joining Ampio in 2012, he served as Vice President of Commercial Operations at Arbor Pharmaceuticals. Josh began as Arbor's second employee and oversaw the commercialization of the company's first product, scaling the commercial organization to over 150 people across sales, marketing, payer markets, distribution, commercial operations, and national accounts. In less than four years, Arbor grew from a company without any product revenues to a company with net sales in excess of $127 million. When Arbor was sold to a private investment group in 2010, Josh maintained his position and continued to build the company's commercial infrastructure and capabilities. Prior to joining Arbor, he was the Director of Marketing at LipoScience (NASDAQ: LPDX), a cardiovascular in vitro diagnostic company with CLIA-certified laboratory operations. Josh also served as Regional Sales Manager for Cyberonics (NASDAQ: CYBX), a medical device company commercializing implantable neuromodulation devices. Josh started his career at Glaxo Wellcome (now GlaxoSmithKline), holding positions in both sales and marketing. He has a Master of Business Administration from Wake Forest University and Bachelor of Science in Management from North Carolina State University.

Jarrett Disbrow
Chief Operating Officer
Jarrett Disbrow previously served as President & CEO of Vyrix Pharmaceuticals since November 2013 until the merger to form Aytu BioScience in April 2015. Mr. Disbrow has over eighteen years of experience in the pharmaceutical industry with "Big Pharma" and specialty pharmaceutical companies. Mr. Disbrow was the Founder, President and Chief Executive Officer of Arbor Pharmaceuticals – a specialty pharmaceutical company focused initially on pediatrics. As the sole founder of Arbor he was responsible for all aspects of the company's start-up and growth phases including fundraising, business and product development, commercial strategy, product marketing and partnering. Mr. Disbrow was also responsible for negotiating the acquisition of the company to a private investor group in 2010 and remained with the company post-acquisition as Vice President of Commercial Development. In less than five years Arbor grew from a company with no product revenues to net sales in excess of $127 million. Prior to founding Arbor Pharmaceuticals, he was head of marketing for Accentia Biopharmaceuticals, Inc. Mr. Disbrow began his career with GlaxoWellcome, Inc. (now GlaxoSmithKline plc) where he held positions of increasing responsibility in sales and marketing. Mr. Disbrow received a BS in Business Management from North Carolina State University in Raleigh, NC.

Gregory Gould, CPA
Chief Financial Officer, Treasurer, and Secretary
Greg Gould has held senior management positions in the life sciences industry for over 20 years. Prior to the formation of Aytu BioScience, he provided financial and operational consulting services to the biotech industry through his consulting company, Gould LLC from April 2012 until June 2014. Mr. Gould was Chief Financial Officer, Treasurer and Secretary of SeraCare from November 2006 until the company was sold to Linden Capital Partners in April 2012. During the period from July 2011 until April 2012 Mr. Gould also served as the Interim President and Chief Executive Officer of SeraCare Life Sciences. Mr. Gould has held several other executive positions at publicly traded life sciences companies including the Chief Financial Officer role at Atrix Laboratories, Inc., an emerging specialty pharmaceutical company focused on advanced drug delivery. During Mr. Gould's tenure at Atrix he was instrumental in the negotiation and sale of the company to QLT, Inc. for over $855M. He also played a critical role in the management of several licensing agreements including the global licensing agreement with Sanofi-Synthelabo of the Eligard® products. Mr. Gould was the Chief Financial Officer at Colorado MedTech, Inc., a publicly traded medical device design and manufacturing company where he negotiated the transaction to sell the company to KRG Capital Partners. Mr. Gould began his career as an auditor with Arthur Andersen, LLP. He currently serves on the board of directors of CytoDyn, Inc., a publicly traded drug development company pursuing ant-viral agents for the treatment of HIV. Mr. Gould graduated from the University of Colorado with a BS in Business Administration and is a Certified Public Accountant. Greg also serves as the Chief Financial Officer, Treasurer, and Secretary of publicly traded Ampio Pharmaceuticals (NYSE MKT: AMPE).

Jonathan Heath McGrael, MS
Vice President of Commercial Operations
Jon McGrael has spent 17 years in the pharmaceutical industry and has held positions of increasing responsibility in

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sales, sales training, marketing, sales management, and leadership development. Most recently, he was Director of Sales at Arbor Pharmaceuticals, which he joined in 2010 as the Company's 14th employee. Under his leadership the sales organization grew from 10 sales representatives to over 400 and achieved significant, consistent revenue growth throughout his leadership tenure. Mr. McGrael also designed comprehensive leadership development and training programs for sales leaders, as well as a marketing structure that ensured "plug-and-play" incorporation of new products. Mr. McGrael began his career at TAP Pharmaceuticals (now Takeda) where he held positions within the sales and marketing divisions. He received an MS in Public Health from Missouri State University and a BS in Human Bio-Dynamics also from Missouri State University.

Douglas Miller, PhD
Vice President of Technical Operations
Doug has over 20 years' experience across biologics, medical devices, and diagnostics, primarily in Class II and Class III medical devices. He has worked extensively in research and development, the establishment and validation of manufacturing processes, and quality and regulatory affairs related to medical devices. He spent nearly 10 years leading clinical research at Washington University School of Medicine where he directed the development of an electronic implantable medical device, prior to helping found Otologics LLC to commercialize the device. Following his time at Otologics, Doug joined Cochlear Ltd., the world's leading cochlear implant manufacturer, and later directed all external research for the North American division. Since joining Aytu (through one of Aytu's predecessor companies Luoxis), Doug has led the effort of obtaining ISO 13485 and ISO 9001 certifications for the company and has established the manufacturing processes and systems for the company's initial product line. Doug received a Bachelor of Science in Engineering from University of Missouri, and Master of Science and Ph.D. degrees in Engineering from University of Denver, where his focus was on electronic medical devices and electrophysiology.

VALUATION AND RECOMMENDATION

Our price target on AYTU is $8.20/share. We break our valuation into two parts. The first piece of the valuation comes from existing products including ProstaScint, Primsol and MioXSYS. The second piece comes from probability weighted projected cash flows for Zertane, which is still in late stage development.

The company recently commenced marketing of ProstaScint and Primsol. This revenue stream, albeit small, provides Aytu with meaningful cash flow to continue promotional efforts for all of their products. We have included the revenue from ProstaScint, Primsol and MioXSYS system in our valuation. We model increase in revenue throughout 2016 from the sale of ProstaScint, Primsol, and MioXSYS. Although there might be volatility in revenue between quarters, we think that this might be offset over the long term as Aytu expands its global commercialization efforts.

The company is currently getting ready to initiate Phase 3 clinical trials for Zertane. If results are successfully replicated as in the Phase 3 European trials, we believe there is potential opportunity for Zertane given that currently there are no FDA-approved therapies for PE in the market. We look forward to hearing an update from management as Aytu plans the Phase 3 trials and eventual U.S. launch. We will update our assumptions when we think there is enough clarity on the progress of product development.

DCF MODEL: We have built a financial model using a discounted cash flow (DCF) analysis to derive a fair value for Aytu Bioscience. We have the following inputs to the model:

Revenue from marketed products:

- About 24% of men between the ages of 45 and 65 in the U.S. experience low testosterone levels due to several factors. Based on these statistics our target population comes to around 13 million. We project peak revenue of more than $80 million annually from Natesto sales.

- Approximately 30% of the 2.9 million adult population in the U.S. have a recurrent episode of prostate cancer. Of the 220,000 new cases diagnosed each year, 15% of cases are classified as high-risk. Based on these statistics our estimated total target population aggregates to around 0.9 million. We forecast that ProstaScint will reach a market penetration of about 2% by year 2026.

- Primsol is being promoted as a secondary product and promotion is purely resource dependent. We expect peak revenue of $2M annually for the indication otitis media and close to 0.5 million for UTI.

- Since MioXSYS will be sold as a razor-razor-blade model, the instrument will be leased and the disposables will be sold at $25-$40 per unit. We expect the company to achieve 2% market penetration in the global infertility market as well as in the U.S.

- We are using a 15% discount rate in our model that reflects the uncertainty associated with obtaining regulatory approval for marketing products in global markets as well as being able to ramp up sales of urology products in the U.S.

- The terminal growth rate of 2.0% is reasonable in our assumption given the fact that Aytu has shown considerable progress in the urology market as the company matured within one year of forming.

We believe the existing commercial stage product revenue amounts to $50 million in value, or $6.30 per share. We arrive at this value by calculating the NPV of our forecasted revenues.

Revenue from pipeline product: Our forecasted revenue is based on the assumption that Aytu markets Zertane on their own. We incorporate a probability weighted cash flow to capture the potential that Zertane fails in clinical trial and/or fails to gain U.S. regulatory approval. We expect Aytu to price Zertane at the time of launch in 2019 in the range of Priligy, which sells for approximately $30-$35 per unit. Although other drugs are available for individuals with PE, there are no drugs currently in the market that have clinical evidence demonstrating the capability to increase IELT as well as improve ejaculatory control and personal satisfaction. Several clinical studies that have been conducted have confirmed that 25-100 mg treatment with Zertane results in a 2.4-12.6-fold increase in IELT from baseline[28]. Further, patients prefer medications that are convenient to administer, do not have adverse side effects as well as offers a rapid onset of effect. Therefore, we feel this offers an opportunity for Zertane to gain substantial market share by displacing current drugs on the market.

- Given that Priligy has a sales growth of about 40%, and yielded close to $90 million in peak sales in 2012 globally, we assume that Zertane can achieve peak sales of ~$70 million by 2026.

- At this time we remain cautiously optimistic that Zertane could be launched sometime in the 2018 – 2019 timeframe. We remain speculative on the potential success of the trials. If and when Zertane is launched it could prompt an upward revision to our revenue forecast.

We consider two possible scenarios for valuing Aytu; if the company were to sell Zertane outright to a large pharma company or out-license the marketing rights alone.

If Aytu markets Zertane: Since the manufacturing costs associated with Zertane are less, it allows the opportunity to be marketed at a lower price than Priligy. We use forecasted revenues from the sales of Zertane to derive an estimated value for AYTU. This can be used as a guide for what price an acquiring company would reasonably pay for Zertane. AYTU has partnerships to market Zertane in South Korea, Brazil, Canada, the Republic of South Africa, certain countries in Sub-Saharan Africa, Colombia and Latin America.

We include Aytu's current cash balance and an estimated $40 million in CapEx in our valuation. Using an 18% discount rate, FCF amounting to 60% of revenues and 7.9 million shares outstanding (on a fully diluted basis) we arrive at an NPV of $15 million ($1.90/share) for Zertane.

If Aytu out-licenses Zertane: We believe that if Phase 3 data yields strong results, Zertane could also draw takeover interest from firms that have drugs addressing complementary issues such as ED. We think a post-Phase3 partnership deal for Zertane could result in an upfront payment, regulatory approval and milestone payments, as well as an ongoing royalty stream to AYTU. The deal could be similar to the one between Furiex Pharma and J&J. Furiex Pharma partnered with Johnson & Johnson to market Priligy for which Furiex was offered $15 million for achieving development and regulatory milestones, $50 million for commercial milestone and ~ 20% of net sales in royalties.

Sum of the parts values Aytu at $65 million or approximately $8.20/share. This valuation provides an upside to the current trading price which is undervalued. Our model and assumptions are subject to change as news regarding

[28] Çayan, Selahittin, and E. C. Serefoğlu. "Advances in treating premature ejaculation." F1000Prime Rep 6 (2014): 55.

product development and commercialization outflows and certain risks pertaining to clinical trial and regulatory approval abate. This will consequently impact our valuation.

CONCLUDING THOUGHTS

Within a year of formation, the company qualified for and was uplisted to trade on OTCQX. We feel this is a significant accomplishment for a nascent company. Management has a strategic plan in place to build their business in 2016 by prudently utilizing the capital resources at hand. We are listing the highlights below:

Beefed-up sales team: Management has launched urology-focused U.S. sales force in seven regions throughout the country. The company is now focused on building awareness about ProstaScint and Primsol to urologists and has initiated marketing ProstaScint to urologists in the U.S. Currently, AYTU is preparing to market Primsol that was acquired in October 2015.

Investor conferences and meetings: Aytu has given several presentations at investor conferences in an effort to build awareness. As per management, this will be an ongoing process.

Zertane clinical trial: The clinical success and regulatory approval that was obtained for Zertane in Europe was a positive step for Aytu. Management believes that PE represents a large market that has remained untapped.

Other partnerships: Aytu is actively negotiating additional urology asset purchases and expects to acquire other complementary products in urology. Aytu is also focused on expanding their footprint by signing additional distribution agreements in various global regions focusing on the urology market. Aytu's business model has been to find and develop new uses for already approved drugs and new molecular entities and find a market to commercialize them.

Soon after obtaining CE Mark for the MiOXSYS diagnostic platform for male infertility in January 2016, the company announced the first commercial sales of this system in Europe and the Middle East. While the company is seeking FDA clearance in the U.S., widespread commercial use in ex-U.S. markets may help Aytu in generating revenues and additionally build awareness of this system.

RISKS

- ***Insufficient interest from urologists and/or patients:*** Aytu's business model focuses on marketing already approved drugs or molecular entities that can be potentially employed for multiple indications. Further, the efficacy and cost benefits, if any, of the formulation may take some time to bear out after introduction to the medical community. This could lead to reduced revenues and low margins for an extended period of time leading to high cash burn.

- ***Shareholder Dilution:*** AYTU may require funding for several years to run their operations, which could be dilutive to current shareholders.

- ***Zertane fails to obtain regulatory approval:*** Unexpected delays in the clinical trials related to the approval will result in a lengthier development and commercialization timeline. Our revenue estimates are contingent on if and when Zertane obtains regulatory approval. While we expect the FDA approval to come through in a timely fashion, it is possible that it could be delayed due to unforeseeable reasons.

- ***Zertane does not gain widespread market adoption:*** Since perception of benefit varies widely among different patients it is entirely possible that Zertane may not be broadly adopted by the market.

- ***AYTU is unable to obtain a reasonable price for Zertane:*** Although we have forecasted revenue from Zertane, the price the potential acquiring company would be willing to pay for a licensing deal or acquisition could be quite variable depending on the M&A activity in the healthcare space during that time.

- ***Model-based assumptions are prone to large variations:*** Our projected revenue growth from the sales of AYTU's products from the current year and beyond is largely best-guesses based on urologists prescribing the medication as well as growth in the customer base. Revenue could underperform relative to our model if the customer base does not grow at our assumed forecast or is less correlated to revenue growth than what we are assuming. Achieving our price objective includes regulatory, competitive, reimbursement and financial risks.

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PROJECTED INCOME STATEMENT

Aytu Biosciences	Jun-15	Sep-15	Dec-15	Mar-16	Jun-16	Jun-16	Jun-17	Jun-18	Jun-19
AYTU	2015A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E	2019 E
Revenue	$0.3	$0.5	$0.5	$0.7	$0.7	$2.3	$3.9	$6.9	$11.2
YOY Growth	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*781.5%*	*707.0%*	*75.6%*	*61.7%*
Cost of Goods Sold	$0.1	$0.04	$0.24	$0.34	$0.30	$0.92	$2.36	$2.1	$3.4
Gross Profit	$0.2	$0.5	$0.2	$0.3	$0.4	$1.4	$1.6	$4.8	$7.8
Gross Margin	*66.6%*	*92.3%*	*48.0%*	*49.0%*	*57.1%*	*60.3%*	*40.0%*	*70.0%*	*70.0%*
SG&A	$4.4	$1.7	$1.8	$2.2	$2.0	$7.7	$7.0	$9.0	$11.0
%SG&A	*1661.5%*	*350.7%*	*378.1%*	*335.8%*	*285.7%*	*332.4%*	*178.0%*	*130.3%*	*98.5%*
R&D	$3.4	$0.9	$1.4	$1.2	$1.2	$4.7	$4.50	$4.80	$5.00
% R&D	*1297.8%*	*185.5%*	*289.1%*	*178.2%*	*171.4%*	*200.1%*	*114.4%*	*69.5%*	*44.8%*
Amortization	*0.0%*	$0.0	$0.1	$0.1	$0.1	$0.3	$0.0	$0.0	$0.0
Operating Income	($7.6)	($2.2)	($3.0)	($3.2)	($2.9)	($11.3)	($9.9)	($9.0)	($8.2)
Operating Margin	-	-	-	-	-	-	-	-	-
Interest Loss (Gain)	($0.1)	($0.1)	($0.3)	($4.05)	$0.00	($4.48)	$0.00	$0.00	$0.00
Pre-Tax Income	($7.7)	($2.3)	($3.3)	($7.3)	($2.9)	($15.8)	($9.9)	($9.0)	($8.2)
Taxes (benefit)	($0.0)	($0.0)	($0.0)	$0.0	$0.0	($0.0)	$0.00	$0.00	$0.00
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income	($7.7)	($2.3)	($3.3)	($7.3)	($2.9)	($15.7)	($9.9)	($9.0)	($8.2)
Net Margin	-	-	-	-	-	-	-	-	-
EPS	($0.84)	($0.16)	($0.23)	($0.39)	($0.78)	($1.23)	($1.10)	($0.69)	($0.48)
Shares Outstanding	9	14	14	19	4	13	9	13	17

Source: Zacks Investment Research *Anita Dushyant, PhD*

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