SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2016

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number 333-146542

AYTU BIOSCIENCE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**47-0883144** **(I.R.S. Employer Identification Number)**
373 Inverness Parkway **Suite 206** **Englewood, Colorado** **(Address of principal executive offices)**	**80112** **(Zip Code)**

(720) 437-6580
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act

Common Stock, par value $.0001 per share

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ¨ No x

Indicate by a check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K ¨

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer	¨	Accelerated filer	¨
Non-accelerated filer	¨ (Do not check if a smaller reporting company)	Smaller reporting company	☑

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of common stock held by non-affiliates of the Registrant as of December 31, 2015 was $9.9 million based on the closing price of $45.00 as of that date.

Indicate the number of shares outstanding of each of the Registrant's classes of common stock, as of the latest practicable date:

As of August 15, 2016, there are 5,070,591 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2016 Annual Meeting of Stockholders are incorporated herein by reference, as indicated in Part III.

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This Annual Report on Form 10-K refers to trademarks, such as Aytu, Natesto, ProstaScint, Primsol, MiOXSYS, RedoxSYS, Luoxis Vyrix and Zertane which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This Form 10-K also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

Unless otherwise indicated or unless the context otherwise requires, references in this Form 10-K to the "Company," "Aytu," "we," "us," or "our" are to Aytu BioScience, Inc.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

Forward Looking Statements

This Annual Report on Form 10-K, or Annual Report, 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 Annual Report, 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. Such forward-looking statements include, without limitation, statements regarding the markets for our approved products and our plans for our approved products, 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, the potential future commercialization of our product candidates, our anticipated future cash position and future events under our current and potential future collaborations. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including without limitation the risks described in “Risk Factors” in Part I, Item 1A of this Annual Report. These risks are not exhaustive. Other sections of this Annual Report include additional factors that could adversely impact our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We assume no obligation to update or supplement forward-looking statements.

We obtained statistical data, market and product data, and forecasts used throughout this Form 10-K from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

PART I

Item 1. Business

Overview

We are a commercial-stage specialty healthcare company focused on acquiring, developing and commercializing novel products in the field of urology. We have multiple urology-focused products on the market, and we seek to build a portfolio of novel therapeutics that serve large medical needs in the field of urology. We are initially concentrating on hypogonadism, prostate cancer, urinary tract infections, and male infertility and plan to expand into other urological indications for which there are significant medical needs.

We recently acquired exclusive U.S. rights to Natesto™ (testosterone), a novel formulation of testosterone delivered via a discreet, easy-to-use nasal gel, and we launched Natesto in the United States with our direct sales force in July 2016. Natesto is approved by the U.S. Food and Drug Administration, or FDA, for the treatment of hypogonadism (low testosterone) in men and is the only testosterone replacement therapy, or TRT, delivered via a nasal gel. Natesto offers multiple advantages over currently available TRTs and competes in a $2.4 billion market. Importantly, as Natesto is delivered via the nasal mucosa and not the skin, there is no risk of testosterone transference to others, a known potential side effect and black box warning associated with all other topically applied TRTs, including the market leader AndroGel®.

We currently market ProstaScint® (capromab pendetide), the only radioimaging agent indicated to detect the prostate specific membrane antigen, or PSMA, in the assessment and staging of prostate cancer. ProstaScint is approved by the FDA for use in both newly diagnosed, high-risk prostate cancer patients and patients with recurrent prostate cancer. We also market Primsol® (trimethoprim hydrochloride) — the only FDA-approved trimethoprim-only oral solution for urinary tract infections.

We have a focused pipeline, including MiOXSYS, a novel in vitro diagnostic device that is currently CE marked (which generally enables it to be sold within the European Economic Area (see “Business — Foreign Regulatory Approval”)) and for which we intend to initiate a final clinical study to enable FDA clearance in the U.S.

Our MiOXSYS™ system is a novel, point-of-care semen analysis system with the potential to become a standard of care in the diagnosis and management of male infertility. Male infertility is a prevalent and underserved condition and oxidative stress is widely implicated in its pathophysiology. MiOXSYS was developed from our core oxidation-reduction potential research platform known as RedoxSYS®. We are advancing MiOXSYS toward FDA clearance and, as of the date of the Annual Report, we will need to raise additional funding to complete the required clinical study.

In the future we will look to acquire additional urology products, including existing products we believe can offer distinct commercial advantages. Our management team’s prior experience has involved identifying clinical assets that can be re-launched to increase value, with a focused commercial infrastructure specializing in urology.

Natesto™ (testosterone). On April 22, 2016, we entered into an agreement to acquire the exclusive U.S. rights to Natesto ™ (testosterone) nasal gel from Acerus Pharmaceuticals Corporation, or Acerus, which rights we acquired on July 1, 2016. Natesto is a patented, FDA-approved testosterone replacement therapy, or TRT, and is the only nasally-administered formulation of testosterone available in the United States. Natesto is a discreet, easy-to-administer nasal gel that may be appropriate for men with active lifestyles as Natesto is small, portable, Transportation Security Administration, or TSA-compliant, and easy to use. Importantly, Natesto is not applied directly to the patient’s skin as other topically applied TRTs are. Rather, it is delivered directly into the nasal mucosa via a proprietary nasal applicator. Thus, Natesto does not carry a black box warning related to testosterone transference to a man’s female partner or children — as other topically (primarily gels and solutions) administered TRTs do by virtue of their delivery directly onto the skin. We launched Natesto in the U.S. in July 2016 with our direct sales force, and we are positioning Natesto as the ideal treatment solution for men with active, busy lifestyles who suffer from hypogonadism.

ProstaScint® (capromab pendetide). We became a commercial stage company by virtue of our acquisition of ProstaScint in May 2015 and are generating sales of this FDA-approved prostate cancer imaging agent. As prostate cancer is a condition commonly diagnosed and treated by urologists, ProstaScint complements our urology-focused product portfolio and pipeline. Prostate cancer is the most common cancer among men in the United States, with an estimated 241,000 annual cases (as of 2012). Further, more than 2,200,000 men were alive in 2006 with some history of prostate cancer, and over 30,000 U.S. men die each year from the disease. The effect of prostate cancer on healthcare economics is substantial, which makes the need for accurate disease staging critical for treatment and management strategies. The U.S. market for the diagnosis and screening of prostate cancer is expected to total $17.4 billion by 2017, a compound annual growth rate, or CAGR, of 7.5% since 2012.

Primsol® (trimethoprim solution). On October 5, 2015, we purchased Primsol from FSC Laboratories, Inc. Primsol is the only FDA-approved liquid formulation of trimethoprim, an antibiotic that is well established in current guidelines for treating uncomplicated urinary tract infections, or UTIs. This differentiated product is appropriate for UTI patients that have difficulty swallowing tablets, such as the elderly, and particularly for patients that experience adverse reactions to sulfamethoxazole ("sulfa"). It is estimated that 150 million cases of urinary tract infections occur annually worldwide, and the annual estimated incidence is 0.5 – 0.7/persons per year. Importantly, there are more than 1 million catheter-associated UTIs in the U.S. alone. As many of these patients are elderly and unable to swallow pills, an oral liquid formulation represents a convenient formulation for easier administration. The acquisition of Primsol added a second established brand to our product portfolio. We expect to benefit from and continue to grow Primsol's established base of prescribers, which already includes a significant proportion of urologists despite the fact that it has not been previously marketed to these specialists. We can thus utilize the same sales channel as ProstaScint, leading to potential commercial synergies and product growth.

MiOXSYS. MiOXSYS™ is a rapid in vitro diagnostic semen analysis test used in the quantitative measurement of static oxidation reduction potential, or sORP, in human semen. MiOXSYS is a recently CE marked system and is an accurate, easy to use, and fast infertility assessment tool. It is estimated that 72.4 million couples worldwide experience infertility problems. In the United States, approximately 10% of couples are defined as infertile. Male infertility is responsible for between 40 – 50% of all infertility cases and affects approximately 7% of all men. Male infertility is often unexplained (idiopathic), and this idiopathic infertility is frequently associated with levels of oxidative stress in the semen. As such, having a rapid, easy-to-use diagnostic platform to measure oxidative stress should provide a practical way for male infertility specialists to improve semen analysis and infertility assessments without having to refer patients to outside clinical laboratories.

Male infertility is prevalent and underserved, and oxidative stress is widely implicated in its pathophysiology. The global male infertility market is expected to grow to over $300 million by 2020 with a CAGR of nearly 5% from 2014 to 2020. Oxidative stress is broadly implicated in the pathophysiology of male infertility, yet very few diagnostic tools exist to effectively measure oxidative stress levels in men. However, antioxidants are widely available and recommended to infertile men. With the introduction of the MiOXSYS System, we believe for the first time there will be an easy and effective diagnostic tool to assess the degree of oxidative stress, sperm motility and morphology, and potentially enable the monitoring of patients' responses to antioxidant therapy as a treatment regimen for infertility. The MiOXSYS System received CE marking in Europe in January 2016 and obtained Health Canada Class II Medical Device approval in March 2016. We expect to advance MiOXSYS into clinical trials in the United States in order to enable 510(k) clearance.

In addition to the MiOXSYS system, we are continuing to develop the global market for the RedoxSYS System across a range of applications. Specifically, we have begun initial commercializing of the RedoxSYS System for research use through distribution partners, primarily outside the U.S. In 2014, we received ISO 13485 certification, demonstrating our compliance with global quality standards in medical device manufacturing.

The technology underpinning the RedoxSYS and MiOXSYS systems was developed by Luoxis Diagnostics, Inc. in the two years immediately preceding the merger between Luoxis, Vyrix Pharmaceuticals, Inc., and us (under our former name of Rosewind Corporation) in April 2015. Upon the consummation of the merger, the RedoxSYS System and MiOXSYS System became our assets.

Key elements of our business strategy include:

- Launch Natesto in the U.S. for the treatment of hypogonadism with our direct sales force. We launched Natesto in July 2016 and are targeting high-prescribing TRT prescribers with a primary emphasis on urologists and male health practitioners.
- Expand the commercialization of FDA-approved ProstaScint for the staging of both newly diagnosed high-risk and recurrent prostate cancer patients. We have begun commercializing ProstaScint in the U.S. and in key markets around the world.
- Expand the commercialization of FDA-approved Primsol for the treatment of uncomplicated urinary tract infections. We are re-launching Primsol to urologists in the U.S. and in key markets around the world where appropriate.
- Establish MiOXSYS as a leading in vitro diagnostic device in the assessment of male infertility.
- Acquire additional marketed products and late-stage development assets within our core urology focus that can be efficiently marketed through our growing commercial organization.

- Develop a pipeline of urology therapeutics, with a focus on identifying novel products with sufficient clinical proof of concept that require modest internal R&D expense.

We plan to augment our core in-development and commercial assets through efficient identification of complementary therapeutics, devices, and diagnostics related to urological disorders. We intend to seek assets that are near commercial stage or already generating revenues. Further, we intend to seek to acquire products through asset purchases, licensing, co-development, or collaborative commercial arrangements (co-promotions, co-marketing, etc.).

Our management team has extensive experience across a wide range of business development activities and have in-licensed or acquired products from large, mid-sized, and small enterprises in the United States and abroad. Through an assertive product and business development approach, we expect that we will build a substantial portfolio of complementary urology products.

We previously were developing Zertane for the treatment of premature ejaculation, or PE. However, we determined to direct our resources to our commercial-stage products. As a result, at the end of fiscal 2016, we determined that the Zertane asset has no value as we do not have the resources to complete the necessary clinical trials and bring it to market before the patents expire. We intend to sell or out-license Zertane although there can be no assurance that we will be successful in doing so or, if successful, the value, if any, we receive for the asset.

Corporate History

We were incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado.

Vyrix Pharmaceuticals, Inc., or Vyrix, was incorporated under the laws of the State of Delaware on November 18, 2013 and was wholly owned by Ampio Pharmaceuticals, Inc. (NYSE MKT: AMPE), or Ampio, immediately prior to the completion of the Merger (defined below). Vyrix was previously a carve-out of the sexual dysfunction therapeutics business, including the late-stage men's health product candidates, Zertane and Zertane-ED, from Ampio, which carve out was announced in December 2013. Luoxis Diagnostics, Inc., or Luoxis, was incorporated under the laws of the State of Delaware on January 24, 2013 and was majority owned by Ampio immediately prior to the completion of the Merger. Luoxis was focused on initially developing and advancing the RedoxSYS System. The MiOXSYS System was developed following the completed development of the RedoxSYS System.

On March 20, 2015, Rosewind formed Rosewind Merger Sub V, Inc. and Rosewind Merger Sub L, Inc., each a wholly-owned subsidiary formed for the purpose of the Merger, and on April 16, 2015, Rosewind Merger Sub V, Inc. merged with and into Vyrix and Rosewind Merger Sub L, Inc. merged with and into Luoxis, and Vyrix and Luoxis became subsidiaries of Rosewind. Immediately thereafter, Vyrix and Luoxis merged with and into Rosewind with Rosewind as the surviving corporation (herein referred to as the Merger). Concurrent with the closing of the Merger, Rosewind abandoned its pre-merger business plans, and we now solely pursue the specialty healthcare market, focusing on urological related conditions, including the business of Vyrix and Luoxis.

On June 8, 2015, we (i) reincorporated as a domestic Delaware corporation under Delaware General Corporate Law and changed our name from Rosewind Corporation to Aytu BioScience, Inc., and (ii) effected a reverse stock split in which each common stock holder received one share of common stock for each 12.174 shares outstanding. At our annual meeting of shareholders held on May 24, 2016, our shareholders approved (1) an amendment to our Certificate of Incorporation to reduce the number of authorized shares of common stock from 300.0 million to 100.0 million, which amendment was effective on June 1, 2016, and (2) an amendment to our Certificate of Incorporation to effect a reverse stock split at a ratio of 1-for-12 which became effective on June 30, 2016. All share and per share amounts in this report have been adjusted to reflect the effect of these two reverse stock splits (hereafter referred to collectively as the "Reverse Stock Splits").

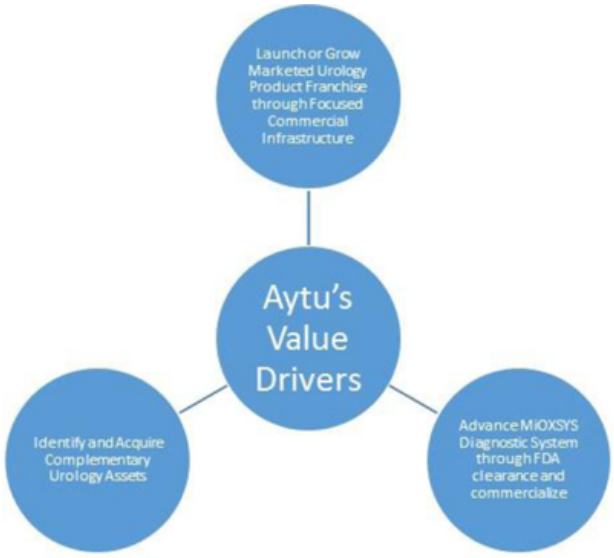
Our Strategy

We expect to create value by implementing a focused, three-pronged strategy. Our primary focus is on launching the recently acquired Natesto in the U.S, growing our current, revenue-generating products, and building a complementary portfolio of aligned urology assets. In just over one year since our merger we have acquired or in-licensed three FDA-approved, marketed assets, launched a specialty urology sales force, initiated ex-U.S. partnering discussions for our commercial products ProstaScint and Primsol, advanced our lead diagnostic asset MiOXSYS to CE marking, engaged in asset purchase and licensing discussions for products aligned to our strategy, and launched Natesto in the U.S. through our own sales force.

We believe the strategy of focusing on commercializing assets prescribed by urologists makes sense for several reasons. First, urology is a large yet concentrated specialty practice area that can be efficiently targeted. There are approximately 10,000 active urologists in the U.S., and we believe that this audience can be efficiently reached with a relatively small, focused sales force. Additionally, 90% of urologists practice in metropolitan areas where concentrated sales targeting can be achieved and "windshield" or sales representative driving time between targets can be minimized. Importantly, 81% of urologists practice in group practices, and over 60% are in practices of four or more physicians. Further, and important in building a balanced yet focused product portfolio, sub-specialization within large urology clinics is common whereby there is frequently individual clinical focus on specific areas within urology including prostate cancer and conditions, infertility, sexual dysfunction, urinary incontinence, hypogonadism, etc. This enables a company to offer multiple products to the various sub-specialties within these focused, concentrated customer targets.

Further, urologists treat a wide range of conditions and are thus appropriate targets across a broad range of clinical assets (Natesto – hypogonadism; ProstaScint – prostate cancer; Primsol – urinary tract infections; MiOXSYS – male infertility). Importantly, in urology, direct physician office purchasing of drugs, devices, and diagnostics is common. Along with this, a significant proportion of urology groups are privately-owned and often own and operate their own outpatient surgery centers and in-office laboratories. Further, large urology group practices have substantial payer influence and can have the ability to negotiate as large groups to achieve better reimbursement and coverage for favored treatments and procedures. Perhaps as important as these other factors, urologists are exposed to relatively limited promotional focus by "Big Pharma" and we believe can therefore be accessed and impacted more readily by an emerging company, such as Aytu, over time.

Aytu BioScience's Strategic Value Drivers



The primary elements of our strategy are:

- *Launching Natesto and expanding commercialization of ProstaScint and Primsol, our revenue-generating, FDA-approved products in the United States via a direct commercial infrastructure. Launching ProstaScint, Primsol, and MiOXSYS outside the United States via a developing distribution network.*

Natesto is a novel, recently FDA-approved testosterone replacement therapy, or TRT, indicated for the treatment of hypogonadism in men. Natesto is the only nasal formulation of testosterone and is delivered via a proprietary nasal gel to enable simple, discreet use of testosterone into the nostrils. By virtue of applying Natesto to the nasal mucosa, and not to the man's skin, there is no risk of transference to others. As such Natesto is the only TRT that does not have a black box warning associated with this potential for transference. Additionally, Natesto is a convenient form of testosterone that does not require application to large areas of the man's body (arms, shoulders, upper torso, under arms) as required with market-leading products AndroGel and Axiron. A convenient form of TRT, applied two-to-three times in the nostrils, may be an appropriate option for men over 45 with hypogonadism who have active lifestyles, travel frequently, and value having a discreet way to treat their hypogonadism.

Low testosterone is a condition affecting approximately 13 million U.S. men, with U.S. revenues estimated at $2.4 billion in 2013. The market is expected to grow to $5.0 billion by 2017, and we believe multiple factors are in place to position Natesto favorably in gaining market share in this large, growing market. By gaining less than a 5% share of the current U.S. market (assuming similar pricing and reimbursement), a novel TRT product could achieve annual revenues in excess of $100.0 million.

ProstaScint has several unique selling features that we believe will enable significant sales growth and regular use by healthcare providers diagnosing and treating prostate cancer. ProstaScint is the only imaging agent that specifically targets prostate cancer cells and demonstrates high sensitivity, specificity, and accuracy. In multiple clinical studies researchers have shown that when SPECT/CT scans were used in patients pre-treated with ProstaScint, ProstaScint imaging was highly sensitive in detecting prostate cancer and significantly predictive of 10-year biochemical disease free survival in prostate cancer patients (86.6% vs. 65.5%; p=0.0014). Additionally, the American Cancer Society specifically recognizes ProstaScint by name in current prostate cancer diagnosis guidelines.

Prostate cancer is the second most common cancer among men in the United States, with an estimated 241,000 annual cases (as of 2012). Further, more than 2.2 million men were alive in 2006 with some history of prostate cancer, and over 30,000 U.S. men die each year from the disease. The effect of prostate cancer on healthcare economics is substantial, which makes the need for accurate disease staging critical for treatment and management strategies. The U.S. market for the diagnosis and screening of prostate cancer is expected to total $17.4 billion in 2017, a CAGR of 7.5% since 2012.

Primsol is an antimicrobial agent that is indicated to treat uncomplicated urinary tract infections (UTIs). Primsol is the only oral solution containing trimethoprim and offers a novel solution for UTI patients who are either allergic to sulfamethoxazole (which is commonly combined with trimethoprim) or have difficulty swallowing pills. Because many prostate cancer patients have temporary urinary catheters placed, they are frequently diagnosed with recurrent urinary tract infections. Primsol offers a solution to those patients and enables us to sell multiple products to a similar base of U.S. prescribing clinicians.

United States. We have launched a commercial infrastructure in the U.S. in order to support increased sales and distribution of Natesto, ProstaScint and Primsol in the U.S. We have a highly experienced sales force that is distinctly focused on impacting the prescribing of urologists, and through this efficient sales channel we are able to increase prescribing of our unique urology assets.

Ex-U.S. As neither ProstaScint nor Primsol have been previously approved and marketed outside the U.S., we believe we can realize commercial opportunities through efficient corporate partnerships in key markets around the world. Also, with MiOXSYS now CE Marked we can develop a distribution network to launch this first-in-class in vitro diagnostic device.

- *Developing a pipeline of novel urological therapeutics through assertive acquisition, licensing, or co-promotion, inclusive of both marketed and late-stage development assets.*

In order to diversify our product portfolio and create more value, we intend to seek to acquire complementary products or product candidates to develop and/or commercialize, including marketed assets. Initially, the focus will be on acquiring products or product candidates for urological conditions but we will opportunistically consider other products or product candidates based on their ability to create value and complement our focus. We plan to pursue product acquisitions, inclusive of therapeutics, diagnostics, and devices, which we will evaluate for their strategic fit and potential for near-term and/or accretive value to us. In a little over a year from the Company's merger in April 2015 we began generating revenue from the acquisition of both ProstaScint and Primsol, and we later launched Natesto in July 2016. We expect to continue to identify and acquire additional, complementary urology assets in the future.

- *Completing U.S. studies in male infertility with the MiOXSYS System to enable 510k de novo clearance by FDA.*

With MiOXSYS now CE marked and available for sale in many markets outside the U.S., we are positioned to initiate our clinical studies in the U.S. to enable 510k de novo clearance. We expect to receive guidance from FDA on clinical study design and patient criteria and implement the required clinical program as soon as possible, subject to additional funding. If approved, MiOXSYS would be the first and only semen analysis diagnostic test for the detection of oxidative stress in infertility.

Male infertility is prevalent and underserved, and oxidative stress is widely implicated in its pathophysiology. As such, we have bolstered our research focus in this area with the MiOXSYS System to complement our focus on urologic conditions. The global male infertility market is expected to grow to over $300 million by 2020 with a CAGR of nearly 5% from 2014 to 2020. Oxidative stress is broadly implicated in the pathophysiology of idiopathic male infertility, yet very few diagnostic tools exist to effectively measure oxidative stress levels in men. However, antioxidants are widely available and recommended to infertile men. With the introduction of the MiOXSYS System, we believe for the first time there will be an easy and effective diagnostic tool to assess degree of oxidative stress and monitor patients' responses to antioxidant therapy and improve diagnosis of male infertility.

Through our extensive network of researchers developed at one of our predecessor companies Luoxis, the RedoxSYS System has demonstrated the potential to have broad clinical applications inclusive of male infertility in semen analysis studies. Studies have been completed at a major U.S. university and major hospital outside the U.S. in the evaluation of male infertility. As such, we developed the MiOXSYS System as a line extension to RedoxSYS to specifically assess oxidative stress in semen as a tool to assess male infertility. In January 2016, the MiOXSYS System received CE Marking and is now available for sale in multiple ex-U.S. markets including Europe, the Middle East, and parts of Asia. In March 2016, the MiOXSYS System obtained Health Canada Class II Medical Device approval. With Health Canada approval in place, the Company expects to begin initial marketing of the product in Canada.

Our FDA – Approved Urology Products

Three of our products have received FDA approval for marketing in the U.S.: Natesto, ProstaScint and Primsol.

Natesto for Testosterone Replacement

On April 22, 2016, we entered into and closed a license and supply agreement to acquire the exclusive U.S. rights to Natesto ® (testosterone) nasal gel from Acerus Pharmaceuticals Corporation, or Acerus, which rights we acquired effective on July 1, 2016. Natesto is a patented, FDA-approved testosterone replacement therapy, or TRT, and is the only nasally-administered formulation of testosterone available in the United States. Natesto is a discreet, easy-to-administer nasal gel that may be appropriate for men with active lifestyles as Natesto is small, portable, TSA-compliant, and easy to use.

Importantly, Natesto is not applied directly to the patient's skin as other topically applied TRTs are. Rather, it is delivered directly into the nasal mucosa via a patented nasal applicator. Thus, Natesto does not carry a black box warning related to testosterone transference to a man's female partner or children — as other topically (primarily gels) administered TRTs do by virtue of their delivery directly onto the skin.

Image of Natesto (testosterone) nasal gel

The unique delivery of Natesto also enables simple, discreet use by a single three times daily application into the nose and may improve compliance over topical forms that are applied to large sections of the arms, shoulders, and other large areas of the man's upper torso. It also offers a more discreet method of TRT administration compared to films/patches (Androderm & Testoderm, which is applied to the scrotum) and doesn't involve the pain, potential for site injection infections, and the administration inconvenience of the injectable TRTs such as Testopel and Aveed.

A concern associated with the use of the currently marketed testosterone gels is the unintentional transfer of testosterone to women (or children) by skin contact with the man's application site. In the event of a female partner receiving inadvertent testosterone exposure due to intimate contact with her male partner, she may develop hyperandrogenism, a condition characterized by excess levels of androgens. This condition may result in women developing acne, scalp hair loss, excessive facial or body hair, breast atrophy, and other symptoms. Natesto, as it is nasally administered, does not present this potential complication of 'transference' and thus does not have a black box warning as is associated with the topically applied testosterone supplements.

Natesto is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone including:

- Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH] and luteinizing hormone [LH]) above the normal range.

- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low serum testosterone concentrations but have gonadotropins in the normal or low range.

The U.S. Testosterone Replacement Therapy Market

We believe we have an opportunity to increase revenue with Natesto in the U.S. Natesto competes in a large, growing market. The U.S. TRT market is large, with annual revenues in the U.S. in 2013 of $2.4 billion. Revenues are expected to increase to $5 billion by 2017. If the TRT market grows as expected, with as little as 5% market penetration, a novel, patent-protected TRT product could achieve sales of $250 million. Even at the current market size of over $2.4 billion, a product with 5% market penetration could achieve sales in excess of $100 million annually, assuming comparatively similar product pricing and reimbursement levels as seen with other TRTs.

The U.S. prescription testosterone market is comprised primarily of topically applied treatments in the form of gels, solutions, and patches. Testopel® and Aveed®, injectable products typically implanted directly under the skin by a physician, are also FDA-approved.

The actively marketed, FDA-approved TRTs include:

Brand Name	Form of Delivery	Company	Year Approved	Black Box Warning
Androderm®	Film/Patch	Actavis	1995	No
AndroGel®	Gel	AbbVie	2000	Yes
Aveed®	Injection	Endo Pharmaceuticals	2014	No
Axiron®	Solution	Eli Lilly & Company	2010	Yes
Fortesta®	Gel	Endo Pharmaceuticals	2010	Yes
Striant®	Extended Release Tablet	Endo Pharmaceuticals	2003	No
Testim®	Gel	Endo Pharmaceuticals	2002	Yes
Testoderm®	Film/Patch	Johnson & Johnson	1993	No
Testopel®	Injection	Endo Pharmaceuticals	1972	No
Vogelxo®	Gel	Upsher-Smith	2014	Yes

AndroGel®, marketed by AbbVie, is the leading TRT and had 2012 revenues of $1.15 billion. AndroGel had over half of the total TRT market across its 1.0% and 1.62% formulations of the product.

Importantly, however, AndroGel is beginning to face generic threats with the expiration of key patents for its 1.0% formulation, and Teva Pharmaceuticals has a competitive generic product in waiting. AbbVie has attempted to block Teva's launch through the filing of a citizen's petition. Products with significant shares of the TRT market and promotional spending include Axiron, Testim, Fortesta, Androderm, and Testopel.

About Hypogonadism

Male hypogonadism is a condition in which the body does not produce enough testosterone — the hormone that plays a key role in masculine growth and development during puberty — or has an impaired ability to produce sperm or both. Men can be born with male hypogonadism, or it can develop later in life from injury or infection.

Hypogonadism is formally defined as deficient or absent male gonadal function that results in insufficient testosterone secretion. Hypogonadism may be caused primarily by testicular failure, or secondarily by hypothalamic-pituitary axis dysfunction, resulting in the production or release of insufficient testosterone to maintain testosterone-dependent functions and systems. It can also result from a combination of testicular failure and hypothalamic-pituitary axis dysfunction.

Hypogonadism affects an estimated 13 million men in the United States, and although it may occur in men at any age, low testosterone levels are especially common in older males. More than 60% of men over age 65 have free testosterone levels below the normal values of men aged 30 to 35. Studies suggest that hypogonadism in adult men is often underdiagnosed and under treated.

Low testosterone, as male hypogonadism is also known, is associated with a number of signs and symptoms, most notably loss of libido and erectile dysfunction (ED). Other signs of low testosterone include depressive symptoms, a decrease in cognitive abilities, irritability and lethargy or loss of energy. Deficient endogenous testosterone also has negative effects on bone mass and is a significant risk factor for osteoporosis in men. Progressive decrease in muscle mass and muscle strength and testicular dysfunction, often resulting in impaired sperm production, are also associated with low testosterone levels.

A younger patient may have pure hypogonadism as a primary event, whereas an older man may have an age-related decline in testosterone production that is a part of his ED profile. However, because both ED and loss of libido are hallmarks of hypogonadism, for a patient who presents with ED it is recommended that he have a basic hormone profile to determine if he has low testosterone. Treatments to normalize testosterone can not only improve libido, energy level and the potential to have normal erections, but can also improve the response to sildenafil, if that is deemed appropriate treatment.

Natesto Clinical Studies Demonstrating Safety and Efficacy

Natesto has been shown to be safe and effective in men with hypogonadism. It was approved by the FDA in May 2014. In its pivotal clinical trial, Natesto was evaluated for efficacy in a 90-day, open-label, multicenter study of 306 hypogonadal men. Eligible patients were 18 years of age and older (mean age 54 years) and had morning serum total testosterone concentrations less than 300 ng/dL. Patients were Caucasian (89%), African-American (6%), Asian (5%), or of other ethnicities (less than 1%).

Patients were instructed to self-administer Natesto (11 mg of testosterone) intranasally either two or three times daily. The primary endpoint was the percentage of patients with an average serum total testosterone concentration (C_{avg}) within the normal range (300 to 1050 ng/dL) on Day 90.

The secondary endpoint was the percentage of patients with a maximum total testosterone concentration (C_{max}) above three predetermined limits: greater than 1500 ng/dL, between 1800 and 2500 ng/dL, and greater than 2500 ng/dL. A total of 78 hypogonadal men received Natesto (11 mg of testosterone) three times daily (33 mg of testosterone daily). Of these, a total of 73 hypogonadal men were included in the statistical evaluation of efficacy (total testosterone pharmacokinetics) on Day 90 based on the intent-to-treat (ITT) population with last observation carried forward (LOCF). Ninety percent of these 73 patients had a C_{avg} within the normal range (300 to 1050 ng/dL) on Day 90. The percentages of patients with C_{avg} below the normal range (less than 300 ng/dL) and above the normal range (greater than 1050 ng/dL) on Day 90 were 10% and 0%, respectively.

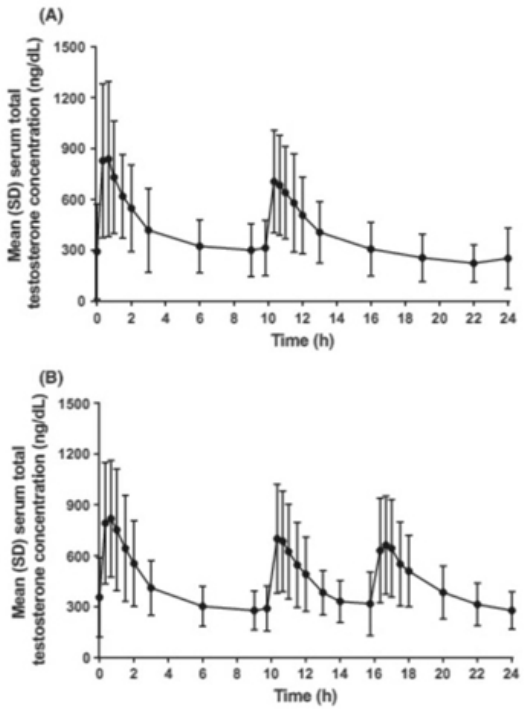
The table below (Table 3 from the Natesto Prescribing Information) summarizes the mean (SD) serum total testosterone concentrations on Day 90 in 69 patients who had a full pharmacokinetic sampling profile and were treated with Natesto (11 mg of testosterone) three times daily for 90 days.

Table 3: Mean (SD) Serum Total Testosterone Concentrations on Day 90 Following Administration of Natesto (11 mg of testosterone) Three Times Daily

	Natesto (11 mg of testosterone) Three Times Daily (N=69)
C_{avg} (ng/dL)	421 (116)
C_{max} (ng/dL)	1044 (378)
C_{min} (ng/dL)	215 (74)

In the same clinical trial studying the safety and efficacy of Natesto, which was conducted at 39 U.S. outpatient sites, it was shown that 70% of the per protocol patients in the twice-daily 'titration arm' (n=141) achieved normal testosterone levels. Ninety-one percent of the per protocol patients in the thrice-daily group (n=77) achieved normal testosterone levels, demonstrating that the majority of men in both treatment groups achieved normalization of testosterone levels while taking Natesto. The efficacy of both B.I.D. (twice daily) and T.I.D. (three times daily) dosing of Natesto is demonstrated in the graphs below:

Figure 3 Plot of 24-h total testosterone concentration-time curves by treatment regimen and time point at Day 90 in the intent-to-treat population. Data are shown for the b.i.d. dosing ($n = 141$) (A), and the t.i.d. dosing ($n = 77$) (B).



Natesto Product Features and Patient Benefits

We believe Natesto has a unique opportunity to gain market share in the more than $2.4 billion U.S. market given the product's novel features and patient benefits including:

- Ease of administration; Appropriate for men with busy, active lives;
- Established efficacy in pivotal FDA trials with a unique, low dose of testosterone; Effective in improving serum testosterone levels while using a proven, lower dose of testosterone;
- Discreet product presentation and ease of transport (TSA compliant); Important for men who travel frequently and desire a simple, portable solution that travels easily with them;
- No risk of secondary exposure to testosterone due to dermal transference, an important consideration when thinking about a hypogonadal man's partner's or child's safety; and
- Safety, with a lower incidence of rising PSA levels than the market leading product AndroGel; Natesto demonstrates a 5.5% rate of rising PSA levels in clinical trials, while AndroGel demonstrated a rising PSA rate of over 11% in clinical trials. This is an important consideration as physicians concerned with understanding and tracking prostate cancer risk frequently monitor PSA levels in men over 50 years of age.

Natesto has proven efficacy and a product profile well suited for men suffering from hypogonadism who have active, busy lifestyles who want a simple, discreet TRT option. We believe Natesto can play an important role in the treatment of hypogonadism, a condition affecting approximately 13 million U.S. men.

Natesto Market Opportunity

Two recent developments have presented a unique opportunity for Natesto that we believe will enable us to effectively compete and be well positioned in the more than $2.4 billion TRT market. As previously indicated, AndroGel's patent expired in 2015 and, unless a citizen's petition filed by AbbVie to delay a Teva Pharmaceuticals generic is successful long-term, we expect a generic entrant to begin eroding AbbVie's market share. As a result, we expect there to be diminished promotional support in the form of fewer physician details and lower overall promotional spending by AbbVie. In conjunction with the market leader's diminished intellectual property position and potential diminished promotional spending, the TRT market has received increased scrutiny from the FDA.

On January 31, 2014 and subsequently on March 3, 2015, the FDA issued Safety Announcements relating to the possible increased risk of non-fatal heart attacks and strokes in patients taking testosterone. While the FDA has not concluded that the FDA-approved testosterone treatment increases the risk of stroke, heart attack, or death, this recent safety consideration has caused patient advocates and consumer groups to ask for increased scrutiny on the direct to consumer advertising associated with the leading testosterone replacement products, most notably AndroGel and Axiron. As a result, we expect decreased advertising spending in the TRT category to enable newer, less established products like Natesto to more effectively infiltrate the market through on-label, physician-directed promotion with a direct selling effort. While the potential safety concerns may cause a decrease in physician prescribing, we expect that physicians will continue to prescribe TRTs for patients for whom TRT treatment is appropriate.

Leading urology groups including the American Urological Association, or AUA, have strongly commented in favor of continued prescribing of TRTs for appropriate patients, and the safety data precipitating the FDA's comments have been called into question. Importantly, the FDA has not called for discontinuation of TRTs. Rather, patients were encouraged to speak with their health care professional and not stop taking TRTs.

In the FDA's initial statement about the potential cardiovascular risks associated with TRT treatment, the agency commented:

> "Patients should not stop taking their prescribed testosterone products without first discussing their questions or concerns with their health care professionals. ... The prescribing information in the drug labels of FDA-approved testosterone products should be followed."

Importantly, following the FDA's statement, the AUA issued a strong response reiterating the clinical importance of low testosterone and maintaining their support for the appropriate use of testosterone replacement therapy:

> "Men with hypogonadism may also experience reduced muscle mass and strength and increased body fat. Hypogonadism may also contribute to reduced bone mineral density and anemia. Testosterone therapy is appropriate treatment for patients with clinically significant hypogonadism, including those with idiopathic clinical hypogonadism that may or may not be age-related, after full discussion of potential adverse effects."

Additional publications publicly refuted the validity of the data that precipitated the FDA's safety concern in a subsequent statement following the 2014 annual meeting of the AUA:

> "During the last several months there has been a firestorm of negative media attention regarding testosterone deficiency and its treatment, precipitated by a study reporting an increased rate of nonfatal myocardial infarction (MI) associated with testosterone prescriptions. This public judgment of T therapy demands a response. As researchers and clinicians with extensive experience with T deficiency and its treatment, we disagree that the recent study published in PLOS (Public Library of Science) One presents any credible evidence that T prescriptions increase health risks, and we find baseless the general assertion that testosterone is prescribed to men "who are simply reluctant to accept the fact that they are getting older." We object to comments questioning whether T deficiency is real, regardless of whether it is called hypogonadism or "low T" as used in advertisements." (Note: The PLOS is an open access online publication venue, and while peer reviewed it is not a published medical journal.)

AbbVie's sales of AndroGel dropped 5% in the first half of 2014, following the FDA's initial Safety Announcement and the subsequent reaction of the AUA and others. In the face of significant new competitive entrants (Aveed, Vogelxo) at that time and the FDA's expressed safety concerns, this represents a relatively insignificant sales decline. We believe this decline speaks to a real, present need in hypogonadism and a substantial opportunity for newly marketed products like Natesto. Natesto has proven safety, a recent FDA approval that speaks to the product's efficacy, and unique product features and patient benefits we believe will set Natesto apart from the topically administered competitive products in the more than $2.4 billion U.S. TRT market.

ProstaScint for the Detection of Prostate Cancer

On May 20, 2015, we acquired ProstaScint® from Jazz Pharmaceuticals. ProstaScint Kit, or capromab pendetide, is a radio-labeled monoclonal antibody, which is a biologic product that targets a specific antigen. ProstaScint targets prostate specific membrane antigen, or PSMA, a protein uniquely expressed by prostate tissue. A radioactive substance called Indium (In 111) is attached to the proprietary, mouse-derived antibody. The radiolabeled antibody is infused into the patient and is taken up by prostate cancer cells which can be detected and visualized with a special nuclear medicine scan (single-photon emission tomography, or SPECT). ProstaScint has been shown to be clinically effective in determining the course of treatment for a patient who has had a prostatectomy and/or has suspected metastasis (spread of the cancer cells beyond the prostate). Further, ProstaScint has demonstrated efficacy in patients classified as high risk or with recurrent prostate cancer. ProstaScint has been approved by the FDA and Health Canada, and significant clinical data exist demonstrating the significant predictive value in prostate cancer staging.

Prostate Cancer Market

According to the American Cancer Society prostate cancer is the most common cancer among men in the United States, with an estimated 241,000 annual cases (as of 2012). Further, more than 2.2 million men were alive in 2006 with some history of prostate cancer, and over 30,000 U.S. men die each year from the disease. The effect of prostate cancer on healthcare economics is substantial, which makes the need for accurate disease staging critical for treatment and management strategies. The U.S. market for the diagnosis and screening of prostate cancer is expected to total $17.4 billion in 2017, a CAGR of 7.5% since 2012. Importantly, ProstaScint is the only FDA-approved radiopharmaceutical (for use in radioimmunoscintigraphy) specifically indicated for prostate cancer screening and is specifically highlighted in the American Cancer Society practice guidelines for prostate cancer screening and staging.

Prostate cancer is classified into four stages based on severity: Stages 1 through 4. Stage 3 is considered “high risk” and Stage 4 is when cancer has become metastatic. Radioimmunoscintigraphy has been established as a diagnostic to stage cancer malignancy and one of the most widespread clinical uses has been for the detection of prostate cancer.

ProstaScint Clinical Data

Multiple clinical studies have been conducted in the United States and published in peer-reviewed publications that consistently demonstrate substantial clinical efficacy of ProstaScint in staging prostate cancer patients and specifically identify whether the cancer is confined to the prostate or has metastasized to other parts of the body. Through more accurate clinical staging and identification of metastatic prostate cancer, clinicians are able to better direct therapeutic interventions and improve outcomes. A brief summary of key clinical findings for ProstaScint from select studies are summarized below.

Principal Investigator(s)/ Primary Authors	**Publication**	**Patient Population**	**Conclusion/Results**
Ellis RJ et al.	Int. J. Radiation Oncology Biol. Phy. (2010)	Patients presenting for primary radiotherapy having a clinical diagnosis of localized primary prostate cancer; Patients evaluated for tumor stage using conventional staging and SPECT/CT (N=239)	SPECT/CT imaging with ProstaScint pre-treatment was significantly predictive of 10-year biochemical disease-free survival (86.6% vs. 65.5%; p=0.0014)
Haseman MK et al.	Urology (2007)	Men with prostate cancer who underwent imaging with ProstaScint pretreatment; Patients were divided according to the presence or absence of central abdominal uptake (CAU) (N=341)	SPECT/CT imaging with ProstaScint pretreatment effectively predicted death rates among patients with central abdominal uptake (CAU), and demonstrated that prostate cancer-specific death rates were 10 times higher in patients identified with ProstaScint as having central abdominal uptake (p=0.005).
Ellis RJ et al.	Brachytherapy (2005)	Men with prostate cancer of all risk categories who underwent imaging with ProstaScint pretreatment; patients were divided into low, intermediate, and high risk and underwent brachytherapy (N=239)	SPECT/CT imaging with ProstaScint pretreatment effectively predicted biochemical disease recurrence regardless of the patient’s risk category; 7-year outcomes data from brachytherapy patients with treatment based on the ProstaScint scan showed a significant difference in biochemical disease-free survival.

Radiation oncology experts have published numerous papers expressing the potential for expanded use of ProstaScint in prostate cancer imaging due to advances in imaging technologies since the product's initial approval. Since the early 2000s, significantly greater image resolution has been enabled due to the advent of dual head cameras (and improved imaging in general) along with the use of co-registered images where radiologists now combine the images of SPECT and computerized tomography, or CT, or magnetic resonance imaging, or MRI. Because of these factors, we believe there is significant commercial opportunity for ProstaScint.

ProstaScint Product Information

ProstaScint is provided as a two-vial kit which contains all of the non-radioactive ingredients necessary to produce a single unit dose for administration by intravenous injection. The ProstaScint vial contains 0.5 mg of capromab pendetide in 1 mL of sodium phosphate buffered saline solution adjusted to pH 6; a sterile, pyrogen-free, clear, colorless solution that may contain some translucent particles. The vial of sodium acetate buffer contains 82 mg of sodium acetate in 2 mL of water for injection adjusted to pH 5 – 7 with glacial acetic acid; it is a sterile, pyrogen-free, clear, and colorless solution. Neither solution contains a preservative.

Each kit also includes one sterile 0.22 µm Millex® GV filter, prescribing information, and two identification labels. The hospital is responsible for addition of Indium (In 111). ProstaScint may also be helpful in conjunction with other scans (CT or MRI) for higher risk patients, by detecting lymph nodes in the abdomen that are involved with prostate cancer cells, but may still appear falsely normal on CT or MRI scans.

The procedure to administer ProstaScint is as follows: the patient is given an intravenous, or IV, infusion of the monoclonal antibody, and 30 minutes later, a scan is performed. A second scan is done between 96 and 120 hours (4 – 5 days) after the infusion. The first scan (on the day of the infusion) takes approximately 1 hour, while the second scan takes approximately 2.5 hours.

ProstaScint Uses

ProstaScint is indicated as a diagnostic imaging agent in newly-diagnosed patients with biopsy-proven prostate cancer, thought to be clinically-localized after standard diagnostic evaluation (e.g. chest x-ray, bone scan, CT scan, or MRI), who are at high-risk for pelvic lymph node metastases. It is not indicated in patients who are not at high risk.

ProstaScint is also indicated as a diagnostic imaging agent in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease. The imaging performance of Indium (In 111) ProstaScint following radiation therapy has not been studied.

The information provided by Indium (In 111) ProstaScint imaging should be considered in conjunction with other diagnostic information. Scans that are positive for metastatic disease should be confirmed histologically in patients who are otherwise candidates for surgery or radiation therapy unless medically contraindicated. Scans that are negative for metastatic disease should not be used in lieu of histological confirmation. ProstaScint is not indicated as a screening tool for carcinoma of the prostate nor for re-administration for the purpose of assessment of response to treatment.

ProstaScint was initially marketed by Cytogen Corporation, which was acquired by EUSA Pharma. Jazz Pharmaceuticals acquired EUSA in June 2012 but significantly reduced promotion of ProstaScint due to a lack of strategic focus. Despite limited commercialization efforts, peak annual unit sales of ProstaScint of 8,216 kits were achieved. At current pricing, this unit sales volume would equate to approximately $14.6 million in annual revenue.

Primsol for the Treatment of Urinary Tract Infections

In October 2015 we acquired Primsol (trimethoprim hydrochloride oral solution) from FSC Laboratories, Inc. Primsol is the only FDA-approved trimethoprim-only oral solution for urinary tract infections and is standard therapy for such infections. Primsol is a sulfa-free, pleasant tasting, dye-free liquid that is appropriate for patients that are sulfa allergic and individuals that have difficulty swallowing pills. Primsol has demonstrated efficacy in eradicating key pathogens implicated in urinary tract infections including *E. coli* and has demonstrated similar efficacy to trimethoprim-sulfamethoxazole combination agents. Primsol addresses a significant issue as many patients experience an allergic reaction to sulfamethoxazole. As the only oral solution containing only trimethoprim, Primsol offers distinct advantages over sulfa-containing antibacterial agents. Primsol was approved by the FDA in 2000 and was originally marketed by Ascent Pediatrics. FSC Laboratories acquired Primsol from Taro Pharmaceutical.

On April 4, 2016, we entered into a co-promotion agreement for Primsol oral solution with Allegis Pharmaceuticals. Under the agreement, the third party will exclusively promote Primsol to pediatricians across the U.S. We retain all other rights in the U.S. and around the world and will continue to market the product in urologic indications. This co-promotion enables us to focus exclusively on the urology channel while monetizing Primsol by virtue of a relationship with a company focused on selling to a non-core non-urology audience than can drive prescription growth of Primsol.

About Primsol

Primsol is a solution of the synthetic antibacterial trimethoprim in water prepared with the aid of hydrochloric acid. Each 5 mL for oral administration contains trimethoprim hydrochloride equivalent to 50 mg trimethoprim and the inactive ingredients bubble gum flavor, fructose, glycerin, methylparaben, monoammonium glycyrrhizinate, povidone, propylparaben, propylene glycol, saccharin sodium, sodium benzoate, sorbitol, water and hydrochloric acid and/or sodium hydroxide to adjust pH to a range of 3.0 – 5.0. Primsol is indicated for the treatment of initial episodes of uncomplicated urinary tract infections in adults due to susceptible strains of the following organisms: *Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Enterobacter* species and coagulase-negative Staphylococcus species, including *S. saprophyticus*.

For the treatment of uncomplicated urinary tract infections the usual oral adult dosage of Primsol is 100 mg (10 mL) every 12 hours or 200 mg (20 mL) every 24 hours, each for 10 days.

Urinary tract infections, or UTIs are among the most common diagnoses in the U.S., where the prevalence is estimated at 8.1 million physician office visits. Additionally, one fourth of women will have recurrent UTIs requiring the repeated use of oral antibiotics. Current UTI treatment recommendations include the use of trimethoprim-containing products given the compound's longstanding, established efficacy profile in effectively eradicating the key pathogens implicated in UTIs. Primsol has demonstrated efficacy in the eradication of the key pathogens implicated in urinary tract infections as demonstrated by a series of quantitative methods and clinical studies.

Quantitative methods are used to determine antimicrobial minimum inhibitory concentrations, or MICs, to eradicate pathogens implicated in urinary tract infections. These MICs provide estimates of the susceptibility of bacteria to antimicrobial compounds. The MICs should be determined using a standardized procedure. Standardized procedures are based on a dilution method (broth or agar) or equivalent with standardized inoculum concentrations and standardized concentrations of trimethoprim powder.

The MIC values should be interpreted according to the following criteria:

For testing aerobic microorganisms isolated from urinary tract infections:

MIC (mcg/mL)	**Interpretation**
≤ 8	Susceptible (S)
≥ 16	Resistant (R)

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of "Intermediate" indicates that the result should be considered equivocal, and, if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone which prevents small uncontrolled technical factors from causing major discrepancies in interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; and other therapy should be selected.

Standardized susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures. Standard trimethoprim powder as contained in Primsol provides the following MIC values against E. coli demonstrating significant susceptibility of this primary causal organism in urinary tract infections:

Microorganism MIC	(mcg/mL)
Escherichia coli	0.5 – 2

Trimethoprim has been shown to be active against the following microbial strains as indicated below and demonstrated through in vitro and clinical studies.

Aerobic gram-positive microorganisms

- *Staphylococcus species* (coagulase-negative strains, including *S. saprophyticus*)
- *Streptococcus pneumoniae* (penicillin-susceptible strains)

Aerobic gram-negative microorganisms

- Enterobacter species
- *Escherichia coli*
- *Haemophilus influenza* (excluding beta-lactamase negative, ampicillin resistant strains)
- *Klebsiella pneumonia*
- *Proteus mirabilis*

Primsol has demonstrated efficacy in the treatment of uncomplicated urinary tract infections without the potential side effects and allergic reactions sometimes attributed to sulfa-containing trimethoprim formulations. Importantly, and despite the fact that FSC Laboratories did not historically promote Primsol to urologists, 26% of Primsol prescriptions over the six-year period of September 2009 through August 2015 were written by urologists. This, we believe, underscores the unmet market opportunity for Primsol in presenting this treatment option more assertively to urologists. As our sales team will already be accessing urologists through their promotion of ProstaScint, Primsol can be positioned as a first-line treatment option for urologists treating uncomplicated UTIs. With two FDA-approved products directed at urologists, we are able to efficiently drive awareness and increase through a focused field effort. ProstaScint and Primsol are commercially complementary and enable us to utilize our field sales force's synergies to affect prescription growth on both products while directing promotional efforts to our urology customers.

Primsol was previously marketed by FSC Laboratories. Due to FSC's strategic refocusing and new product acquisitions to which sales efforts were diverted, Primsol had only limited commercial emphasis in the three to four years preceding our acquisition of the product. Despite FSC's limited commercial focus, annual unit sales of 7,842 units were achieved. At current pricing, this would result in annual revenues of approximately $5.3 million.

MiOXSYS In Vitro Diagnostic System for Male Infertility

Male infertility is a significant medical condition that urologists and infertility specialists treat frequently in the office setting or specialized fertility centers around the world. Of all sexually active couples, 8% to 12% are infertile and male infertility is the sole cause or contributing factor up to 50% of the time. The global male infertility market is large and growing. The market for male infertility diagnosis and treatments is expected to grow to more than $300 million globally by 2020, with a CAGR of nearly 5% from 2014 to 2020. Despite the prevalence of male infertility, difficulties remain in effectively diagnosing root causes. Oxidative stress assessment is considered a standard practice in complex andrology laboratories around the world, but due to various factors oxidative stress testing is not routinely employed in clinicians' offices or standard laboratory settings.

Seminal oxidative stress has been well established throughout the peer-reviewed literature to play a substantial role in unexplained male infertility, and researchers and clinicians actively consider oxidative stress when conducting laboratory infertility assessment. While oxidative stress is well established as a leading contributing factor to male infertility, a significant proportion of male infertility remains unexplained in part because of the lack of standardized tests available to clinicians and researchers to assess oxidative stress in semen and plasma. This lack of standardization has resulted in poor implementation of semen and plasma analysis around the world. Further, current testing platforms are cost-prohibitive for small office settings or local medical laboratories and require extensive training and on-site expertise. Additionally, antioxidant supplementation is frequently recommended to patients by clinicians without an effective method of measuring treatment success. As such, we believe introducing the MiOXSYS System to assess oxidative stress levels in semen and seminal fluid represents a significant commercial opportunity and novel way for clinicians to assess male factor infertility and assess therapeutic responses of patients in a simple, reliable, and cost-effective way.

The MiOXSYS System was CE marked in January 2016, and we expect to initiate early commercialization efforts outside the U.S. by the middle of fiscal 2017.

An attractive aspect of the reproductive health market relates to reimbursement as infertility treatments and the associated diagnostic tests are generally paid directly by patients. The current infertility treatments could cost in excess of $10,000 per treatment cycle, so the addition of a moderately priced oxidative stress test would consume nominal relative costs while providing specific, actionable information needed to improve the oxidative status of infertile patients. The current infertility treatments include antioxidant supplements and lifestyle modifications that lower oxidative stress (e.g., smoking cessation, exercise, dietary changes, etc.), so the measurements reported by the MiOXSYS System could effectively guide treatment in the infertile patients.

The global male infertility market is expected to grow to more than $300 million by 2020. With a substantial base of conditions for which the MiOXSYS System may present utility, we believe there is significant revenue potential from this first-in-class system.

As part of our strategy to develop future clinical applications of the RedoxSYS System (the MiOXSYS System's predecessor product for plasma and whole blood detection), we have conducted initial studies in male reproductive health. Male infertility is a significant medical condition in which oxidative stress is well known to play a substantial role. As such, we believe developing a clinical application to assess oxidative stress levels with the uniquely designed and programmed MiOXSYS System for semen analysis represents a significant commercial opportunity. Oxidative stress is well established as a leading contributing factor to male infertility. Further, a significant proportion of male infertility remains unexplained in part because of the lack of standardized tests available to clinicians and researchers to assess oxidative stress in semen and seminal plasma. This lack of standardization has resulted in poor implementation of semen and plasma analysis around the world. Further, currently available tests are cumbersome, time consuming to perform, and costly.

We conducted initial proof-of-concept clinical studies in male infertility with a leading research center in the United States, which demonstrated that oxidation-reduction potential effectively measures oxidative stress levels in semen and seminal plasma — and that these levels strongly correlate with established markers of infertility. Semen analysis studies are routinely conducted to assess causes of infertility, so we expect clinicians and oxidative stress researchers to readily integrate the MiOXSYS System into routine use upon the completion of more extensive studies and regulatory clearance for this use. Additional studies are now in the late planning stages that will evaluate the MiOXSYS System's performance in the detection of oxidative stress levels and correlations with key semen parameters in both healthy and infertile males. The MiOXSYS System must receive 510(k) de novo clearance from the FDA before we can market it for clinical use in the United States. Of the $300 million male infertility market projected for 2020, the North American, Middle Eastern, and Asia Pacific markets dominate due to prevalence, awareness of treatment, and availability of treatment resources. Thus, it is important that we have already established distribution relationships and direct access to major oxidative stress researchers in many of these important markets.

Following our initial proof of concept studies with a leading center in the United States with the MiOXSYS system, we conducted our CE mark-enabling study with over 300 infertile patients. The two key studies conducted with these leading centers are presented below.

United States-Based Proof-of-Concept Clinical Study

Fifty-one (51) male patients were seen in a national clinic for suspected infertility. In addition to standard semen analyses (WHO 5 th Edition, 2010), samples were measured for oxidative stress using the MiOXSYS System. Raw sORP values were normed to sperm concentration (mv/10^6 sperm/mL) and compared across six semen parameters that are associated with fertility: ejaculate volume, concentration, total sperm number, total motility, progressive motility, and normal morphology. Higher sORP values are associated with a higher state of oxidative stress.

Patients with abnormally low ejaculate volume had similar sORP values as those with a normal volume. Those with an abnormally low sperm concentration or overall total number, have significantly higher sORP values than those in the normal range. Abnormally few motile sperm or few sperm with a progressive motility were also associated with significantly higher sORP values than those in the normal range. Lastly, semen samples that had fewer normal sperm had slightly, but not significantly, higher sORP values. Thus, most abnormal semen parameters appear to be associated with higher measures of oxidative stress.

When samples that achieve all six parameters of associated with fertile semen are compared to samples that fail one or more of the parameters, the samples that meet the parameters have significantly lower sORP values than those that fail one or more. A cutoff value of 1.635 mv/10^6 sperm/mL separated those that met fertility standards from those that did not. In the current study, 85.7% of samples that met standards fell below this cutoff value, whereas 71.8% of those that failed one or more parameters had sORP values above this cutoff. The probability that a semen sample with a measured sORP value higher than the cutoff is abnormal in at least one of the semen parameters, is 96.5%. Lastly, the more parameters that a semen sample falls within the abnormal range, the higher the sORP values, thus those that are abnormal on five or six parameters have higher sORP values than those that are abnormal on one or two.

Data derived from patients of the national clinic confirms the results obtained in an international fertility clinic. Overall, semen that falls into the abnormal range for concentration, total number, motility, and morphology have higher levels of oxidative stress as indicated by higher sORP values. These values are uniquely obtained using the MiOXSYS System for semen analysis.

In April 2016, we observed encouraging data from two prospective studies of the MiOXSYS System that demonstrated its clinical utility as a tool for measuring ORP to assess the degree of oxidative stress levels in human semen.

The first study measured sORP in the semen samples of infertile men that correlated well with the sperm concentration, motility, and morphology. The second study further suggests that sORP is an easy to determine one-step indicator of increased oxidative stress in semen samples of infertile men especially with leukocytospermia. The results are currently being validated in a larger cohort of infertile men.

International Pivotal Clinical Study

Three-hundred sixty-six (366) male partners from couples seeking fertility advisement in an international clinic were recruited. In addition to standard semen analyses (WHO 5th Edition, 2010), samples were measured for oxidative stress using the MiOXSYS System. Raw sORP values were normed to sperm concentration (mv/10^6 sperm/mL) and compared across six semen parameters that are associated with fertility: ejaculate volume, concentration, total sperm number, total motility, progressive motility, and normal morphology. Higher sORP values are associated with a higher state of oxidative stress.

Patients with abnormally low ejaculate volume had similar sORP values as those with a normal volume. Those with an abnormally low sperm concentration or overall total number, have significantly higher sORP values than those in the normal range. Abnormally few motile sperm or few sperm with a progressive motility were also associated with significantly higher sORP values than those in the normal range. Lastly, semen samples that had fewer normal sperm had significantly higher sORP values than those that fell into the range of normal morphology. Thus, most abnormal semen parameters appear to be associated with higher measures of oxidative stress.

When samples that achieve all six parameters associated with fertile semen are compared to samples that fail one or more of the parameters, the samples that meet the parameters have significantly lower sORP values than those that fail one or more. A cutoff value of 1.635 mv/10^6 sperm/mL separated those that met fertility standards from those that did not. In the current study, 91.43% of samples that met fertility standards fell below this cutoff value whereas 59.5% of those that failed one or more had sORP values above this cutoff. The probability that a semen sample with a measured sORP value higher than the cutoff is abnormal in at least one of the semen parameters, is 98.6%. Lastly, the more parameters that a semen samples falls within the abnormal range, the higher the sORP values, thus those that are abnormal on five or six parameters have higher sORP values than those that are abnormal on one or two.

Data derived from patients at this international clinic confirms the results obtained in United States fertility clinic. Overall, semen that falls into the abnormal range for concentration, total number, motility, and morphology have higher levels of oxidative stress as indicated by higher sORP values. These values are obtained uniquely using the MiOXSYS System for semen analysis.

Proof of concept clinical studies have been conducted at the Cleveland Clinic's Department of Urology, and two posters were presented at the 2015 American Society for Reproductive Medicine in November 2015. These abstracts are presented below.

Establishing the Oxidation-Reduction Potential in Semen and Seminal Plasma

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Abstract:

Objective: Oxidation-reduction potential (ORP) is a novel measure of oxidative stress or redox imbalance in biological samples. Static ORP (sORP) provides an integrated measure of the balance between total oxidants and reductants in a biological system, whereas capacity ORP (cORP) equates to the amount of antioxidant reserves. sORP has been shown to correlate well with illness and injury severity that accompanies the state of oxidative stress; cORP correlates with the ability to respond to illness or injury. Our objectives were to evaluate whether 1) ORP can be measured in semen and seminal plasma samples and 2) ORP levels correlate with sperm motility.

Design: Prospective study measuring ORP in both semen and seminal plasma.

Materials and Methods: Semen samples (n=18) from normal control subjects were divided into two fractions and the seminal plasma was isolated from one fraction (300 x g, 7min). Sperm count and motility were assessed manually. sORP (mV/106 sperm) and cORP (µC/106 sperm) were measured in both fractions (RedoxSYS®, Aytu BioScience). Values are reported as Mean ± SEM. Spearman correlation and Receiver Operating Characteristic curves (ROC) were used for statistical analysis.

Results: sORP and cORP levels in semen correlated significantly with the levels in seminal plasma. A significant negative correlation existed between sperm motility and sORP in both semen (r=-0.609; p=0.004) and seminal plasma (r=-0.690; p=0.002). Furthermore, a sORP cutoff of 4.73mV/106 sperm in semen (sensitivity = 100%, specificity = 89.5%, AUC=0.947) and 4.65mV/106 sperm in seminal plasma (sensitivity = 100%, specificity = 93.8%, AUC = 0.969) was highly predictive of abnormal sperm motility.

Conclusions: RedoxSYS® accurately measured sORP and cORP in both semen and seminal plasma samples. Based on high sensitivity as assessed by ROC analysis, sORP levels can be used to screen infertile men with oxidative stress. These results are being validated in a larger cohort of infertile men.

Effect of Time on Oxidation-Reduction Potential in Semen and Seminal Plasma

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Abstract:

Objective: Oxidation-reduction potential (ORP) is a novel measure of oxidative stress or redox imbalance in biological fluids. Reactive oxygen species (ROS) are highly reactive and have a very short half-life. ROS levels in the seminal ejaculate should be measured within an hour after collection to prevent a reduction in ROS levels over time. The traditional methods of measuring seminal ROS are time sensitive and time consuming, making it difficult to use them for diagnostic purposes. It would be highly advantageous to employ a method that is independent of semen age and provides results in real time. The objective was to assess the effect of time on static ORP (sORP), which provides a snapshot of current redox balance, and capacity ORP (cORP) which is indicative of the amount of antioxidant reserves available.

Design: Prospective study measuring ORP in semen and seminal plasma samples at time 0 and 120 minutes. Materials and Methods: The sORP and cORP of both semen (n=18) and seminal plasma (n=15) samples from normal control subjects were measured after liquefaction (time 0) and after 120 minutes of incubation at room temperature (RedoxSYS®, Aytu BioScience). Values are mean ± SEM. Spearman correlation was used for statistical analysis.

Results: A significant correlation was seen between sORP at time 0 and 120 minutes in semen and seminal plasma. Similar correlations were found for cORP values at both time intervals.

Conclusions: ORP values are not affected by the age of semen or seminal plasma for up to 120 minutes, making it easier to employ this new technology for diagnostic use.

RedoxSYS System for Research Use

We completed the development of the RedoxSYS System (MiOXSYS' predecessor product) during the two years preceding the Merger. In 2014, we received ISO 13485 certification, demonstrating our compliance with global quality standards in medical device manufacturing. This enabled the launch of the RedoxSYS System into the research market around the world. We also received a CE marking in Europe in January 2016 and Health Canada clearance in March 2016 to begin the market development of the RedoxSYS System as a clinical diagnostic in Europe, Canada, and elsewhere around the world where CE marking is recognized. We launched sales efforts into the research market in late 2014 and since that time have placed the RedoxSYS System at a number of prominent research centers in the United States, Europe, and Israel. We expect to leverage these research relationships and build numerous applications in areas where researchers are studying oxidative stress. Currently, there are no available research platforms that measure oxidation-reduction potential in biologic fluids (i.e., blood, plasma, serum, semen, seminal fluid, cerebrospinal fluid, tissue, and cells). While oxidative stress is commonly studied in research settings around the world (both academia and industry), the current assessment methods are incomplete, time consuming, and often impractical for assessing oxidative stress completely. To position the RedoxSYS System effectively in the research market, we have placed key personnel in the United States, Europe, and Asia to develop direct research business relationships as well as distribution networks. Through these proof of concept studies and clinical exploratory studies, we identified the application of oxidation-reduction potential in male infertility assessment. As such, MiOXSYS was developed specifically for assessing semen and seminal plasma ORP levels. While we expect additional clinical applications to be developed through these applications, our near-term focus is on completing the development of MiOXSYS for use in semen analysis for male infertility assessment.

Background on the MiOXSYS System

MiOXSYS is a novel, portable device that measures oxidation-reduction potential, or ORP, a global measure of oxidative stress. MiOXSYS is the first and only system that measures ORP in biologic specimens to provide a complete measure of redox balance, which is broadly implicated across a wide range of both acute and chronic conditions.

Potential Role of ORP in Diagnosing Male Infertility

Oxidation-reduction potential is defined in the published literature as follows:

> "ORP in a biological system is an integrated measure of the balance between total oxidants and reductants. In plasma, many constituents contribute to the ORP. Reactive oxygen species (ROS), such as the superoxide ion, hydroxyl radical, hydrogen peroxide, nitric oxide, peroxynitrite, transition metal ions, and hypochlorous acid, contribute to the oxidative potential. Plasma reductants include thiols, vitamin C, tocopherol, β-carotene, lycopene, uric acid, bilirubin, and flavonoids. Enzymes such as superoxide dismutase, or SOD, catalase, and glutathione peroxidase, are involved in the conversion of ROS into less reactive species. ORP monitoring of plasma represents a single measurement that integrates the overall quantitative balance among the oxidants and reductants of the system."

Given that ORP represents a single, global measure of oxidative stress in a biological system, we believe the potential for ORP to serve as a standardized marker in semen analysis and other aspects of infertility assessment is significant. A major limitation of oxidative stress assays relates to the fact that there is poor standardization in testing. As many factors contribute to oxidative stress (e.g., free radical proliferation, antioxidant depletion, DNA damage, etc.), it is important to have an integrated measure that combines all known and unknown oxidants and reductants in the respective system into one measurement. We believe ORP is an integrated measure of oxidative stress that can be easily and quickly measured with the MiOXSYS System.

In the context of infertility, having an integrated value representing all relevant biologic constituents contributing to oxidative stress will enable simple, robust analysis in a two to three minute test. There are various techniques in use to assess semen in cases of male infertility. The most commonly implemented techniques involve DNA fragmentation, oxidative stress analysis, microscopic examination, sperm penetration assays, sperm agglutination, computer assisted semen analysis, and others. The currently available oxidative stress analysis tools are widely considered expensive and cumbersome to use in routine clinical practice. In both developed countries as well as in the developing world, expensive analysis tools and recurring reagent expenses make routine testing nearly impossible to implement with regularity.

The MiOXSYS System Overview

The MiOXSYS System is comprised of two distinct, patented components that enable a system capable of measuring the ORP and antioxidant capacity of a biological fluid: an analyzer and sensor strips. In mechanical terms, ORP is defined as the potential between a working electrode, and a reference electrode at equilibrium. The RedoxSYS System has been specifically studied in human whole blood, serum, semen, seminal plasma, blood plasma, and other biological fluids.

The MiOXSYS System measures two distinct elements to determine a patient's oxidation reduction potential:

- Static ORP — the standard potential between a working electrode and a reference electrode with no driving current (or extremely small current). This is proportional to the balance of redox agents and is what is classically defined as ORP. Low ORP values mean that the biological sample is in the normal range of oxidative stress. Higher than normal ORP values means that the biological sample is in a higher oxidation state.

- Capacity — the measure of antioxidant reserve available in the body's system. High capacity values mean that the biological sample has levels of antioxidant reserves. Lower than normal capacity values means that the biological sample has below normal antioxidant reserves.

The MiOXSYS Analyzer

The MiOXSYS analyzer is a portable, lightweight desktop platform that may be used in a clinical or research laboratory or near a patient care area. The analyzer is a small device that accepts an inserted sensor that has collected a small specimen as obtained by traditional specimen collection procedures. The analyzer is battery powered and equipped with a custom 5 lead strip connector. The reader consists of a Galvanostat analog circuit with greater than 1012 MHz input impedance.

The analyzer contains a 10 MHz external crystal (internal 4X PLL for 40 MHz operation), and a programming/serial header is externally accessible. The device has internal power/heart-beat indicator LED, primary storage of 128Mbit (16Mbyte) SPI Flash (3.3V) (Bulk data storage), and secondary storage of 2Mbit (256Kbyte) SPI FRAM (3.3V) (Hi-Speed Storage).

The MiOXSYS analyzer contains a user-friendly interface that is flexibly designed to accommodate multiple endpoints depending upon the specific clinical condition being considered. The interface is LCD, 16x2, with a white backlight, variable delay auto-off time-out. Two status LED indicators are visible through front panel mounted lenses. Further, the reader contains three DPDT push-button switches (Left, Center, Right), power on button(s) for battery mode operation, switch usage switch, audible alerts, strip detection, and test completion signals.

Further, the MiOXSYS analyzer enables data transfer, has USB serial communication, and is configured for data download to a connected PC.

The MiOXSYS analyzer's power management consists of an external 5VDC power jack with input capacitance and filtering, a boost converter supplied by external 5VDC power or internal Li-Ion battery, and provides main 5VDC digital board supply. The reader functions with or without the battery connected. The battery lasts in excess of 24 hours with continuous operation to enable prolonged use outside of a laboratory setting.

Image of the MiOXSYS Analyzer

The MiOXSYS Sensor Strips

The MiOXSYS sensor strips, via standard biological specimen collection techniques, receive 20 – 40 microliters of a specimen from which the ORP clinical analysis is performed. The ORP sensor strips are small, disposable, and biocompatible and consist of a ceramic substrate and a five-lead configuration. Significant intellectual property surrounds the design, construct, and electrochemical algorithms associated with the sensors.

Image of the MiOXSYS Sensor Strips

Regulatory Pathway

We achieved ISO 13485: 2003 in late 2013 following the successful development of a compliant medical device quality system. Following the issuance of our ISO certification, we obtained CE marking for the RedoxSYS System, which has enabled initial market development in Europe and markets that accept a CE marking. In December 2015, we achieved CE marking for MiOXSYS following technical validation and clinical study completion in male infertility. In March 2016, we obtained Health Canada Class II Medical approvals for MiOXSYS. In the United States, we intend to pursue 510k de novo clearance with the FDA for the MiOXSYS System. We have recent, ongoing correspondence with the FDA and have confirmed that MiOXSYS is appropriate for the 510k de novo pathway, and we are pursuing regulatory clearance through this pathway.

United States Commercial Strategy

If the clinical studies to measure oxidative stress in male infertility are successful, we expect to pursue that intended use for the MiOXSYS System via the FDA 510k de novo pathway. If cleared for the infertility intended use, we intend to seek to commercialize the MiOXSYS System as a new tool for the assessment of oxidative stress in infertility in men. We envision pursuing a direct sales effort to high priority urology/andrology laboratories, infertility clinics and reference centers across the United States. We have identified the primary, influential centers in the United States and believe our commercial deployment will be efficient through a focused sales and marketing effort. We intend to seek to sell the MiOXSYS System into individual centers and laboratories but will focus our revenue model on the repeat ordering of the disposable, single use MiOXSYS sensor strips. We expect to realize a favorable gross margin on the basis of estimated low cost of goods sold on both components of the system. We envision an average selling price for the disposable sensors of approximately $25 – $40. We envision selling the MiOXSYS analyzers for $2,500 – $5,500 but will also pursue an instrument rental agreement model with minimum disposable sensor purchase requirements.

We also intend to leverage our urology commercialization efforts with other products with a focus on urology centers, infertility clinics, and reproductive health laboratories around the United States.

We believe a focused sales force at the onset of commercialization will enable effective representation of our products and penetration of the reproductive health market. Our sales efforts into the research markets will be enabled initially through a full-time business development professional who will focus on collaborative research and research sales to major oxidative stress centers in the United States. We expect to pursue identical pricing in the research market and the clinical diagnostics markets.

ROW Commercial Strategy

We intend to undertake a similar strategy outside the United States for the RedoxSYS and MiOXSYS systems while complementing our efforts in infertility and research with adjunct applications in critical care conditions. To efficiently execute across our strategy, we intend to utilize a network of established distributors in the target markets in Europe and Asia. We have already engaged with distributors in multiple countries, while many other potential distributors are in advanced stages of discussions with us. We anticipate slightly reduced pricing outside the U.S. for the disposable sensors given the anticipated lower pricing observed ex-US for diagnostic and research products.

Our Business Development Strategy — Identifying & Acquiring Complementary Urology Assets

A key growth and value driver for our Company is the ongoing identification and acquisition of novel urology products for commercialization. We seek to identify unique products with urologic indications that may be non-strategic, undervalued or under-resourced by the company that currently markets the product. We believe that we can continue to acquire strategically aligned products at an appropriate valuation and grow those products via our focused sales and marketing efforts. We will also consider acquiring novel, late-stage development products that represent unique commercial opportunities and can be efficiently developed.

We are actively identifying unique product assets to acquire based on specific attributes including but not limited to: therapeutic area/indication; growth potential; intellectual property position (patents, regulatory, manufacturing or development technicalities, etc.), valuation, strategic fit, commercial orientation and other factors. Indications of interest include products to treat conditions such as urinary incontinence, sexual dysfunction, hypogonadism, prostate and other urological cancers, urinary tract infections, and other urological conditions.

Past Product Candidate – Zertane for the Treatment of Premature Ejaculation

Zertane, is a specifically formulated orally disintegrating tablet, or ODT, of tramadol hydrochloride patented for the on-demand treatment of premature ejaculation, or PE. We had been developing Zertane utilizing a regulatory pathway pursuant to Section 505(b)(2) of the FDCA, as the active ingredient is already well characterized for the treatment of pain, and we were relying on the FDA's finding of safety of tramadol hydrochloride to support its use in a new indication, PE, at a lower dose. The FDA accepted the IND for Zertane in late 2015.

While we had partnerships in place to market Zertane in South Korea and Brazil in the event of regulatory approval in those countries, and had entered into an agreement with Endo Ventures Limited, which recently acquired Paladin Labs Inc., or Paladin, a leading Canadian specialty pharmaceutical company, to provide exclusive rights to market, sell and distribute Zertane in Canada, the Republic of South Africa, certain countries in Sub-Saharan Africa, Colombia and Latin America, we decided to cease the development of Zertane as of June 30, 2016 because we are directing our resources towards our commercial-stage products and do not plan to complete the necessary clinical trials and bring Zertane to market ourselves prior to the expiration of the patent covering the product. We intend to attempt to sell or out-license Zertane to one or more third parties to develop independently. We can provide no assurance as to the value, if any, we might receive for Zertane in the event we were to out-license or sell it.

Government Regulation

While we do not have any pharmaceutical product candidates that we are actively developing as of the date of this Annual Report, we may in the future acquire such products. Currently, we are developing two medical device candidates, the RedoxSYS and MiOXSYS Systems, for which regulatory approval must be received before we can market them. Regulatory approval processes for our current and any future product candidates are discussed below.

Approval Process for Pharmaceutical Products

FDA Approval Process for Pharmaceutical Products

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development in the United States typically involves the performance of satisfactory nonclinical, also referred to as pre-clinical, laboratory and animal studies under the FDA's Good Laboratory Practice, or GLP, regulation, the development and demonstration of manufacturing processes, which conform to FDA mandated current good manufacturing requirements, or cGMP, including a quality system regulating manufacturing, the submission and acceptance of an IND application, which must become effective before human clinical trials may begin in the United States, obtaining the approval of Institutional Review Boards, or IRBs, at each site where we plan to conduct a clinical trial to protect the welfare and rights of human subjects in clinical trials, adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought, and the submission to the FDA for review and approval of an NDA. Satisfaction of FDA requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Pre-clinical tests generally include laboratory evaluation of a product candidate, its chemistry, formulation, stability and toxicity, as well as certain animal studies to assess its potential safety and efficacy. Results of these pre-clinical tests, together with chemistry, manufacturing controls and analytical data and the clinical trial protocol, which details the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated, along with other requirements must be submitted to the FDA as part of an IND, which must become effective before human clinical trials can begin. The entire clinical trial and its protocol must be in compliance with what are referred to as good clinical practice, or GCP, requirements. The term, GCP, is used to refer to various FDA laws and regulations, as well as international scientific standards intended to protect the rights, health and safety of patients, define the roles of clinical trial sponsors and assure the integrity of clinical trial data.

An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the intended conduct of the trials and imposes what is referred to as a clinical hold. Pre-clinical studies generally take several years to complete, and there is no guarantee that an IND based on those studies will become effective, allowing clinical testing to begin. In addition to FDA review of an IND, each medical site that desires to participate in a proposed clinical trial must have the protocol reviewed and approved by an independent IRB or Ethics Committee, or EC. The IRB considers, among other things, ethical factors, and the selection and safety of human subjects. Clinical trials must be conducted in accordance with the FDA's GCP requirements. The FDA and/or IRB may order the temporary, or permanent, discontinuation of a clinical trial or that a specific clinical trial site be halted at any time, or impose other sanctions for failure to comply with requirements under the appropriate entity jurisdiction.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1 clinical trials, a product candidate is typically introduced either into healthy human subjects or patients with the medical condition for which the new drug is intended to be used.

The main purpose of the trial is to assess a product candidate's safety and the ability of the human body to tolerate the product candidate. Phase 1 clinical trials generally include less than 50 subjects or patients. During Phase 2 trials, a product candidate is studied in an exploratory trial or trials in a limited number of patients with the disease or medical condition for which it is intended to be used in order to: (i) further identify any possible adverse side effects and safety risks, (ii) assess the preliminary or potential efficacy of the product candidate for specific target diseases or medical conditions, and (iii) assess dosage tolerance and determine the optimal dose for Phase 3 trials. Phase 3 trials are generally undertaken to demonstrate clinical efficacy and to further test for safety in an expanded patient population with the goal of evaluating the overall risk-benefit relationship of the product candidate. Phase 3 trials are generally designed to reach a specific goal or endpoint, the achievement of which is intended to demonstrate the candidate product's clinical efficacy and adequate information for labeling of the approved drug.

There are three main types of NDAs, which are covered by Section 505 of the FDC Act: (1) an application that contains full reports of investigations of safety and efficacy (Section 505(b)(1)); (2) an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the application has not obtained a right of reference (Section 505(b)(2)); and (3) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (Section 505(j)). Section 505(b)(2) expressly permits the FDA to rely, for approval of an NDA, on data not developed by the applicant. In the pre-IND briefing meeting with Ampio and in June 2012, the FDA agreed that our NDA may be submitted under Section 505(b)(2). As such, we intend to rely on studies published in the scientific literature and reference FDA-approved NDAs for tramadol-containing products (NDAs 21-693, 20-281 and 21-692) to support the safety and efficacy demonstrated in our clinical program.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all pre-clinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, currently exceeding $2.3 million and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment user fees, currently approximately $0.1 million per product and $0.6 million per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten months; most applications for priority review drugs are reviewed in six months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer applications for novel drug products, or drug products which present difficult questions of safety or efficacy, to an advisory committee — typically a panel that includes clinicians and other experts — for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks.

REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book that: 1) the required patent information has not been filed; 2) the listed patent has expired; 3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or 4) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent — in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity during which FDA cannot grant effective approval of an ANDA based on the approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use; the approval of which was required to be supported by new clinical trials conducted by, or for, the applicant.

Post-Approval Regulation

Even if a product candidate receives regulatory approval, the approval is typically limited to specific clinical indications. Further, even after regulatory approval is obtained, subsequent discovery of previously unknown problems with a product may result in restrictions on its use or even complete withdrawal of the product from the market. Any FDA-approved products manufactured or distributed by us are subject to continuing regulation by the FDA, including record-keeping requirements and reporting of adverse events or experiences. Further, drug manufacturers and their subcontractors are required to register their establishments with the FDA and state agencies, and are subject to periodic inspections by the FDA and state agencies for compliance with cGMP, which impose rigorous procedural and documentation requirements upon us and our contract manufacturers. We cannot be certain that we or our present or future contract manufacturers or suppliers will be able to comply with cGMP regulations and other FDA regulatory requirements. Failure to comply with these requirements may result in, among other things, total or partial suspension of production activities, failure of the FDA to grant approval for marketing, and withdrawal, suspension, or revocation of marketing approvals.

If the FDA approves one or more of our product candidates, we and the contract manufacturers we use for manufacture of clinical supplies and commercial supplies must provide certain updated safety and efficacy information. Product changes, as well as certain changes in the manufacturing process or facilities where the manufacturing occurs or other post-approval changes may necessitate additional FDA review and approval. The labeling, advertising, promotion, marketing and distribution of a drug or biologic product or medical devices, also must be in compliance with FDA and Federal Trade Commission, or FTC, requirements which include, among others, standards and regulations for direct-to-consumer advertising, off-label promotion, industry sponsored scientific and educational activities, and promotional activities involving the Internet. The FDA and FTC have very broad enforcement authority, and failure to abide by these regulations can result in penalties, including the issuance of a warning letter directing us to correct deviations from regulatory standards and enforcement actions that can include seizures, fines, injunctions and criminal prosecution.

Approval Process for Medical Devices

In the United States, the FDCA, FDA regulations and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. The FDA regulates the design, manufacturing, servicing, sale and distribution of medical devices, including molecular diagnostic test kits and instrumentation systems. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Unless an exemption applies, each medical device we wish to distribute commercially in the United States will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization applicable to a device are premarket notification, also called 510(k) clearance, and premarket approval, also called PMA approval. The type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device's safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification and adherence to the FDA's current Good Manufacturing Practices, or cGMP, known as the Quality System Regulations, or QSR. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or post-market surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls and include life sustaining, life-supporting or implantable devices, devices of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from the FDA. Some Class I devices that have not been so exempted and Class II devices are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III require PMA approval prior to commercial marketing. The PMA approval process is more stringent, time-consuming and expensive than the 510(k) clearance process, however, the 510(k) clearance process has also become increasingly stringent and expensive. The FDA has provided initial guidance to us that the RedoxSYS and MiOXSYS Systems are appropriate for the 510(k) clearance process, likely through the de novo pathway.

510(k) Clearance. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is "substantially equivalent" to a device legally marketed in the United States that is not subject to PMA approval, commonly known as the "predicate device." A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended use, any change or modification that significantly affects its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, may require a new 510(k) clearance or PMA approval and payment of an FDA user fee. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

Before we can submit a medical device for 510(k) clearance, we may have to perform a series of generally short studies over a period of months, including method comparison, reproducibility, interference and stability studies to ensure that users can perform the test successfully. Some of these studies may take place in clinical environments, but are not usually considered clinical trials. For PMA submissions, we would generally be required to conduct a longer clinical trial over a period of years that supports the clinical utility of the device and how the device will be used.

Although clinical investigations of most devices are subject to the investigational device exemption, or IDE, requirements, clinical investigations of diagnostic tests, including our products and products under development, are generally exempt from the IDE requirements. Thus, clinical investigations by intended users for intended uses of our products generally do not require the FDA's prior approval but may require approval of an Institutional Review Board, or IRB, and written informed consent by the patient, provided the clinical evaluation testing is non-invasive, does not require an invasive sampling procedure that presents a significant risk, does not intentionally introduce energy into the subject and is not used as a diagnostic procedure without confirmation by another medically established test or procedure. In addition, our products must be labeled per FDA regulations "for research use only-RUO" or "for investigational use only-IUO," and distribution controls must be established to assure that our products distributed for research, method comparisons or clinical evaluation studies are used only for those purposes.

Regulation after FDA Clearance or Approval

Any devices we manufacture or distribute pursuant to clearance or approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. We are required to adhere to applicable regulations setting forth detailed cGMP requirements, as set forth in the QSR, which include, among other things, testing, control and documentation requirements. Noncompliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to grant 510(k) clearance or PMA approval of devices, withdrawal of marketing approvals and criminal prosecutions, fines and imprisonment. Our contract manufacturers' facilities operate under the FDA's cGMP requirements.

Foreign Regulatory Approval

Outside of the United States, our ability to market our product candidates will be contingent also upon our receiving marketing authorizations from the appropriate foreign regulatory authorities, whether or not FDA approval has been obtained. The foreign regulatory approval process in most industrialized countries generally encompasses risks similar to those we will encounter in the FDA approval process. The requirements governing conduct of clinical trials and marketing authorizations, and the time required to obtain requisite approvals, may vary widely from country to country and differ from those required for FDA approval.

In the European Union, we are required under the European Medical Device Directive (Council Directive 93/42/EEC) to affix the CE mark to certain of our products in order to sell the products in member countries of the European Union. The CE mark is an international symbol that represents adherence to certain essential principles of safety and effectiveness mandated in the European Medical Device Directive, which are referred to as the "essential requirements". Once affixed, the CE mark enables a product to be sold within the European Economic Area, or EEA, which is composed of the 28 member states of the EU plus Norway, Iceland and Liechtenstein as well as other countries that accept the CE mark.

To demonstrate compliance with the essential requirements, we must undergo a conformity assessment procedure which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I with no measuring function and which are not sterile) where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a notified body. Depending on the relevant conformity assessment procedure, the notified body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The notified body issues a CE certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

If we modify our devices, we may need to apply for permission to affix the CE mark to the modified product. Additionally, we may need to apply for a CE mark for any new products that we may develop in the future. Certain products regulated as medical devices according to EC-Directives are subject to vigilance requirements for reporting of adverse events.

We will be subject to additional regulations in other countries in which we market, sell and import our products, including Canada. We or our distributors must receive all necessary approvals or clearance prior to marketing and/or importing our products in those markets.

The International Standards Organization, or ISO, promulgates internationally recognized standards, including those for the requirements of quality systems. To support ISO certifications, surveillance audits are conducted by a notified body yearly and recertification audits every three years that assess continued compliance with the relevant ISO standards.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the Health Care Reform Law, as amended by the Health Care and Education Affordability Reconciliation Act, or ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive recordkeeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines, imprisonment or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

United States Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and other specific aspects of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if any of our NDA's are approved, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond the current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Market exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, or NCE. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. Recently, the FDA stated that it may change its interpretation of 5-year NCE exclusivity determinations to apply to each drug substance in a fixed-combination drug product, not for the drug product as a whole. If this change is implemented, for example, a fixed-combination drug product that contains a drug substance with a single, new active moiety would be eligible for 5 year NCE exclusivity, even if the fixed-combination also contains a drug substance with a previously approved active moiety. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

Reimbursement

Natesto is covered by many commercial insurance providers and pharmacy benefit management companies and is largely dependent upon reimbursement for continued use in the U.S. market. However, Natesto is covered under a Rebate Agreement between us and Centers for Medicare and Medicaid Services. This, in turn, enables states to offer public payer coverage of Natesto through their separate Medicare and public assistance programs. Additionally, privately managed Medicare Part D plans may choose to cover Natesto prescriptions through their plans’ pharmacy benefits. ProstaScint is dependent upon reimbursement for continued use in the U.S. market, and ProstaScint does have a reimbursement code as assigned by the American Medical Association. ProstaScint is currently reimbursed by Medicare, Medicaid, and various private health plans. However, reimbursement is not universally available throughout the United States for ProstaScint. Primsol is also dependent upon reimbursement for continued use in the U.S. market, and Primsol is covered under a Rebate Agreement between us and Centers for Medicare and Medicaid Services. This, in turn, enables states to offer public payer coverage of Primsol through their separate Medicaid and public assistance programs. Primsol is also covered by many private payers who offer coverage benefits to patients for branded, prescription antibiotic treatments. We do not anticipate that the sales of our product candidate, the MiOXSYS System, if approved for sale in the U.S., will be heavily dependent upon reimbursement by third-party payors. Traditionally, sales of pharmaceutical products that are not “life style” indications depend, in part, on the extent to which products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services.

Lack of third-party reimbursement for our product candidate or a decision by a third-party payor to not cover our product candidates could reduce physician usage of the product candidate and have a material adverse effect on our sales, results of operations and financial condition.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

DEA Regulation

Natesto, already approved by the FDA, is a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, because it contains testosterone. As a result, the U.S. Drug Enforcement Agencies, or DEA, regulate Natesto and have listed it as a Schedule III substance.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special permits and notification requirements apply to imports and exports of narcotic drugs.

The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our or our manufacturers' quotas of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our or our manufacturers' quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our manufacturers will be subject to state regulation on distribution of these products, including, for example, state requirements for licensures or registration.

Intellectual Property

Aytu has an exclusive license from Acerus Pharmaceuticals Corporation for the United States to intellectual property related to a nasal gel drug product containing testosterone to treat hypogonadism in males, including the FDA approved product Natesto®, as well as an authorized generic version and OTC versions thereof. The license includes sublicense rights to intellectual property owned by Mattern Pharmaceuticals and exclusively licensed to Acerus by Mattern Pharmaceuticals. The sublicensed intellectual property includes four Orange Book listed patents directed at nasal gel formulations containing testosterone or methods of testosterone replacement therapy by nasal administration of the same. It further includes a pending application, and two patents that are not listed in the Orange Book directed at a method of making a testosterone formulation and a method for reducing physical or chemical interactions between a nasal testosterone formulation and a plastic container.

The Acerus license also grants rights to intellectual property owned by Acerus which includes twelve nonprovisional patent applications, some of which may be abandoned. These patent applications include at least three pending applications directed to testosterone titration methods, intranasal testosterone bio-adhesive gel formulations, and controlled release testosterone formulations.

We have an extensive range of intellectual property for Primsol, MiOXSYS, and RedoxSYS. We have patent protection in the United States and several other large markets worldwide. Specifically, we have numerous patents issued and pending for the RedoxSYS/MiOXSYS systems and their use in the U.S., Europe, Canada, Israel, Japan, and China. Further, we have patent protection in the United States and several other large markets worldwide for the use of tramadol hydrochloride to treat PE.

We have restructured our patent portfolio related to RedoxSYS/MiOXSYS to focus on the United States and core foreign jurisdictions which include Europe, Canada, Israel, Japan and China. In other foreign jurisdictions, patents and pending applications will be allowed to lapse through non-payment of annuities for issued patents and non-response to outstanding actions for pending applications. The portfolio to be supported in the United States and core foreign jurisdictions consists of 16 issued patents and 21 pending applications.

The portfolio primarily consists of four families filed in the United States and in core foreign jurisdictions. The first family includes six issued patents and five pending applications with claims directed to the measurement of the ORP of a patient sample to evaluate various conditions. The standard 20-year expiration for patents in this family is in 2028. The second family includes two pending United States applications, two issued United States patents and four pending applications in core foreign jurisdictions with claims directed to the measurement of the ORP capacity of a patient sample to evaluate various conditions. The standard 20-year expiration for patents in this family is in 2033. The third family includes seven issued patents and four pending applications with claims directed to devices and methods for the measurement of ORP and ORP capacity. The standard 20-year expiration for patents in this family is in 2032. The fourth family includes one pending United States application, one issued United States patent, and five pending applications in core foreign jurisdictions with claims directed to multiple layer gel test strip measurement devices and methods of making for use in measuring ORP and ORP capacity. The standard 20-year expiration for patents in this family is in 2033.

Primsol is protected by a formulation patent and its regulatory designation. By virtue of the fact that Primsol was approved as an NDA and the extremely large backlog of Abbreviated New Drug Applications at the FDA (two to three year review time currently), we do not expect generic competition for Primsol in the next three to four years. There are currently no generic competitors filed with the FDA under Paragraph IV, which is required of potential generic competitors seeking to genericize an on-patent NDA.

ProstaScint is protected by significant trade secrets and manufacturing know-how related to the production of the product and linkage of the base monoclonal antibody and imaging component. The antibody in the ProstaScint product is produced by a proprietary cell line.

We also maintain trade secrets and proprietary know-how that we seek to protect through confidentiality and nondisclosure agreements. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of confidential and proprietary information. If we do not adequately protect our trade secrets and proprietary know-how, our competitive position and business prospects could be materially harmed.

We expect to seek United States and foreign patent protection for drug and diagnostic products we discover, as well as therapeutic and diagnostic products and processes. We expect also to seek patent protection or rely upon trade secret rights to protect certain other technologies which may be used to discover and characterize drugs and diagnostic products and processes, and which may be used to develop novel therapeutic and diagnostic products and processes.

The patent positions of companies such as ours involve complex legal and factual questions and, therefore, their enforceability cannot be predicted with any certainty. Our issued and licensed patents, and those that may be issued to us in the future, may be challenged, invalidated or circumvented, and the rights granted under the patents or licenses may not provide us with meaningful protection or competitive advantages. Our competitors may independently develop similar technologies or duplicate any technology developed by us, which could offset any advantages we might otherwise realize from our intellectual property. Furthermore, even if our product candidates receive regulatory approval, the time required for development, testing, and regulatory review could mean that protection afforded us by our patents may only remain in effect for a short period after commercialization. The expiration of patents or license rights we hold could adversely affect our ability to successfully commercialize our pharmaceutical drugs or diagnostics, thus harming our operating results and financial position.

We will be able to protect our proprietary intellectual property rights from unauthorized use by third parties primarily to the extent that such rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. If we must litigate to protect our intellectual property from infringement, we may incur substantial costs and our officers may be forced to devote significant time to litigation-related matters. The laws of certain foreign countries do not protect intellectual property rights to the same extent as do the laws of the United States. Our pending patent applications, or those we may file or license from third parties in the future, may not result in patents being issued. Until a patent is issued, the claims covered by an application for patent may be narrowed or removed entirely, thus depriving us of adequate protection. As a result, we may face unanticipated competition, or conclude that without patent rights the risk of bringing product candidates to market exceeds the returns we are likely to obtain. We are generally aware of the scientific research being conducted in the areas in which we focus our research and development efforts, but patent applications filed by others are maintained in secrecy for at least 18 months and, in some cases in the United States, until the patent is issued. The publication of discoveries in scientific literature often occurs substantially later than the date on which the underlying discoveries were made. As a result, it is possible that patent applications for products similar to our drug or diagnostic products and product candidates may have already been filed by others without our knowledge.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights, and it is possible that our development of products and product candidates could be challenged by other pharmaceutical or biotechnology companies. If we become involved in litigation concerning the enforceability, scope and validity of the proprietary rights of others, we may incur significant litigation or licensing expenses, be prevented from further developing or commercializing a product or product candidate, be required to seek licenses that may not be available from third parties on commercially acceptable terms, if at all, or subject us to compensatory or punitive damage awards. Any of these consequences could materially harm our business.

Competition

The healthcare industry is highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Significant competitive factors in our industry include product efficacy and safety; quality and breadth of an organization's technology; skill of an organization's employees and its ability to recruit and retain key employees; timing and scope of regulatory approvals; government reimbursement rates for, and the average selling price of, products; the availability of raw materials and qualified manufacturing capacity; manufacturing costs; intellectual property and patent rights and their protection; and sales and marketing capabilities. Market acceptance of our current products and product candidates will depend on a number of factors, including: (i) potential advantages over existing or alternative therapies or tests, (ii) the actual or perceived safety of similar classes of products, (iii) the effectiveness of sales, marketing, and distribution capabilities, and (iv) the scope of any approval provided by the FDA or foreign regulatory authorities.

We are a very small biopharmaceutical company compared to other companies that we are competing against. Our current and potential competitors include large pharmaceutical and biotechnology companies, and specialty pharmaceutical and generic drug companies. Many of our current and potential competitors have substantially greater financial, technical and human resources than we do and significantly more experience in the marketing, commercialization, discovery, development and regulatory approvals of products, which could place us at a significant competitive disadvantage or deny us marketing exclusivity rights. Specifically, our competitors will most likely have larger sales teams and have more capital resources to support their products then we do.

Accordingly, our competitors may be more successful than we may be in achieving widespread market acceptance and obtaining FDA approval for product candidates. We anticipate that we will face intense and increasing competition as new products enter the market, as advanced technologies become available and as generic forms of currently branded products become available. Finally, the development of new treatment methods for the diseases we are targeting could render our products non-competitive or obsolete.

We cannot assure you that any of our products that we acquire or successfully develop will be clinically superior or scientifically preferable to products developed or introduced by our competitors.

Our current approved products compete in highly competitive fields whereby there are numerous options available to clinicians including generics. These generic treatment options are frequently less expensive and more widely available.

Natesto

Natesto competes in a large, growing market. The U.S. TRT market is large, with annual revenues in the U.S. in 2013 of $2.4 billion. If the TRT market grows as expected, with as little as 5% market penetration, a novel, patent-protected TRT product could achieve sales of $250 million. Even at the current market size of approximately $2.4 billion, a product with 5% market penetration could achieve sales of approximately $120 million annually, assuming comparatively similar product pricing and reimbursement levels as seen with other TRTs.

The U.S. prescription testosterone market is comprised primarily of topically applied treatments in the form of gels, solutions, and patches. Testopel® and Aveed®, injectable products typically implanted directly under the skin by a physician, are also FDA-approved. AndroGel is the market-leading TRT and is marketed by AbbVie.

ProstaScint

Currently, there are several FDA approved imaging techniques for cancer in general, however there is only one SPECT-specific agent targeting prostate cancer — ProstaScint. The other imaging methods are F18-fluorodeoxyglucose (F18-FDG), C11-Acetate, and C11-Choline. The primary advantage of these methods is that they all use PET imaging, a technique with better resolution than SPECT. The use of PET is also a disadvantage, however, since it uses radiolabels with short half-lives necessitating the need for a local or on-site cyclotron to generate the labels. The half-life of fluorine-18 (F18) and of carbon-11 (C11) are approximately 110 and 20 minutes, respectively. The radiolabel used by ProstaScint is Indium-11, with a half-life of about 2 – 3 days. This longer time period allows the radiolabel to be made remotely and shipped to the imaging facility; however, it does use SPECT as the imaging modality.

As indicated, ProstaScint is the only radio-imaging marker that is specific for prostate specific membrane antigen (PMSA). ProstaScint is based on radiolabeling the antibody against PSMA, a protein express by prostate cells. This specificity for prostate cells is what allows ProstaScint to detect the metastases of prostate cancer regardless of location. The mechanism of labeling for F18-FDG, C11-Acetate, and C11-Choline is the intracellular accumulation of these markers in cancer cells, due to the fact that cancer cells typically have a higher cellular metabolism than non-cancerous cells. Thus, these markers can accumulate in any type of cancer cell with a high metabolism. Unfortunately for these technologies, prostate cancer cells tend to have a lower cellular metabolism resulting in higher false positives attributed to hyperplasia and prostatitis.

In a meta-analysis of 21 studies evaluating accuracy, sensitivity, specificity, positive/negative predictive values, ProstaScint using combined SPECT/CT imaging was comparable to PET/CT imaging based on F18-FDG and C11-Choline.

Primsol

There are any number of antibiotics available on the market that could compete with Primsol. However, Primsol is the only FDA-approved liquid formulation of trimethoprim, an antibiotic that is well established in current guidelines for treating UTIs. Further, Primsol is the only trimethoprim oral solution on the U.S. market that does not contain sulfamethoxazole, or sulfa. Therefore, Primsol is appropriate for UTI patients that have difficulty swallowing tablets, such as the elderly, and particularly for patients that experience adverse reactions to sulfa.

MiOXSYS/RedoxSYS

With respect to MiOXSYS competitive offerings, there are other oxidative stress diagnostic tests available throughout the world, although none are approved in the United States for clinical use. Diagnostic systems that are marketed for clinical use outside the United States include the FRAS 4 system (H&D srl), FREE Carpe Diem (Diacron International), and the FORM and FORMPlus systems (Callegari srl). These systems are used in both research and clinical settings but do not generate significant sales in the clinical setting. If approved in the United States for clinical use, these systems could present competition to the MiOXSYS System. However, their testing parameters differ significantly from MiOXSYS and would need to demonstrate clinical superiority to MiOXSYS in order to substantially detract from MiOXSYS prescribing and sales. Additionally, to our knowledge these systems have not demonstrated clinical feasibility in human semen or seminal plasma.

Research and Development

Our strategy is to minimize our research and development activities. When we do conduct research and development, we intend to utilize consultants with domain experience for research, development and regulatory guidance.

Our MiOXSYS System has been developed in conjunction with numerous medical device and diagnostic development consultants. Further, we have relationships with regulatory consultants who are actively assisting in the development of our regulatory strategy with the FDA. To complement our internal clinical research efforts with the MiOXSYS System, we have engaged with numerous universities around the world to identify and develop research and clinical applications for the MiOXSYS System. Through these engagements we have access to data and analyses that enable us to develop new uses for the MiOXSYS and RedoxSYS systems. Additionally, we have formal research agreements in place with two prominent U.S.-based universities and one prominent European university for which we are paying a research fee.

Manufacturing

Our business strategy is to use cGMP compliant contract manufacturers for the manufacture of clinical supplies as well as for commercial supplies if required by our commercialization plans, and to transfer manufacturing responsibility to our collaboration partners when possible.

Natesto

On April 22, 2016, we entered into a license and supply agreement with Acerus pursuant to which we will pay Acerus a supply price per unit of the greater of (i) a fixed percentage of Acerus' cost of goods sold for Natesto, not to exceed a fixed ceiling price and (ii) a low double digit percentage of the net selling price for the first year of the agreement, that increases in each of the second and third years and remains constant after that.

ProstaScint

We have acquired a two-year supply of ProstaScint through our asset purchase agreement with Jazz Pharmaceuticals, which we project to last through calendar 2017. Further, we have begun the process of transferring the manufacturing of ProstaScint to a new contract manufacturer as discussed below.

On October 8, 2015, we and Biovest International, Inc., or Biovest, entered into a Master Services Agreement, pursuant to which Biovest is to provide manufacturing services to us for ProstaScint. The agreement provides that we may engage Biovest from time to time to provide services in accordance with mutually agreed upon project addendums and purchase orders for ProstaScint. We expect to use the agreement from time to time for manufacturing services, including without limitation, the manufacturing, processing, quality control testing, release or storage of ProstaScint. The agreement provides customary terms and conditions, including those for performance of services by Biovest in compliance with project addendums, industry standards, regulatory standards and all applicable laws. Biovest will be responsible for obtaining and maintaining all governmental approvals, at our expense, during the term of the agreement. The agreement has a term of four years, provided that either party may terminate the agreement or any project addendum under the agreement on 30 days written notice of a material breach under the agreement.

In addition, we may terminate the agreement or any project addendum under the agreement upon 180 days written notice for any reason. In conjunction with entering into the agreement, we submitted a work order to Biovest to provide us with active pharmaceutical ingredient for ProstaScint over a four-year period at a total cost of $5.3 million, of which we paid $1.0 million upon submission of the work order and $500,000 in each of January and April 2016. In June 2016, we paid $300,000 and in July of 2016, we paid another $500,000 towards this project.

Primsol

We have entered into a supply agreement for Primsol with the same manufacturer used by FSC Laboratories, from whom we purchased Primsol. Pursuant to the agreement, we can order supply as needed at a fixed price for the first two years of the agreement through September 30, 2017; thereafter we will negotiate the price but do not expect the supply price to increase by more than 25%.

MiOXSYS/RedoxSYS

We have completed the technical development of the RedoxSYS System by engaging contract development and manufacturing companies in the United States. We secured supply and quality agreements with manufacturers for both the RedoxSYS and MiOXSYS instruments as well as the RedoxSYS and MiOXSYS sensor strips. Both manufacturers hold long-standing ISO 13485:2003 certifications and are established medical device manufacturers. Both manufacturers have high volume manufacturing capacity such that production volumes can be easily scaled. Both manufacturers have been audited by our quality engineers and are fully compliant.

Employees

As of August 15, 2016, we had 58 full-time employees and utilized the services of a number of consultants on a temporary basis. Overall, we have not experienced any work stoppage and do not anticipate any work stoppage in the foreseeable future. None of our employees is subject to a collective bargaining agreement. Management believes that relations with our employees are good.

Available Information

Our principal executive offices are located at 373 Inverness Parkway, Suite 206, Englewood, Colorado 80112 USA, and our phone number is (720) 437-6580.

We maintain a website on the internet at *http://aytubio.com*. We make available free of charge through our website, by way of a hyperlink to a third-party site that includes filings we make with the SEC website (*www.sec.gov)*, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports electronically filed or furnished pursuant to Section 15(d) of the Exchange Act. The information on our website is not, and shall not be deemed to be, a part of this Annual Report on Form 10-K or incorporated into any other filings we make with the SEC. In addition, the public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C., 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

Code of Ethics

We have adopted a written code of ethics that applies to our officers, directors and employees, including our principal executive officer and principal accounting officer. We intend to disclose any amendments to, or waivers from, our code of ethics that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. This code of ethics and business conduct can be found in the corporate governance section of our website, *http://aytubio.com*.

Item 1A. Risk Factors

Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in this Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our securities to decline and could cause you to lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

Our independent registered public accounting firm has expressed substantial doubt as to our ability to continue as a going concern and may do so again in the future.

In their report accompanying our audited financial statements, our independent registered public accounting firm expressed substantial doubt as to our ability to continue as a going concern. A "going concern" opinion could impair our ability to finance our operations through the sale of debt or equity securities or through bank financing. We believe our entry into the Purchase Agreement with Lincoln Park, pursuant to which, if we meet the conditions, we can require Lincoln Park to purchase up to $10.0 million of our common stock, can provide us with available capital, provided we can meet those conditions, of which there can be no assurance. However, our ability to continue as a going concern will depend on our ability to obtain additional financing. Additional capital may not be available on reasonable terms, or at all. If adequate financing is not available, we would be required to terminate or significantly curtail our operations, or enter into arrangements with collaborative partners or others that may require us to relinquish rights to certain aspects of our products or product candidates, or potential markets that we would not otherwise relinquish. If we are unable to achieve these goals, our business would be jeopardized and we may not be able to continue operations.

We have a limited operating history, have incurred losses, and can give no assurance of profitability.

We are a commercial-stage healthcare company with a limited operating history. Prior to implementing our commercial strategy in the fourth calendar quarter of 2015, we did not have a focus on profitability. As a result, we have not generated substantial revenue to date and are not profitable, and have incurred losses in each year since our inception. Our net loss for the years ended June 30, 2016 and 2015 was $28.2 million and $7.7 million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date, and without significant financing, there is substantial doubt about our ability to continue as a going concern. We expect to incur substantial losses for the foreseeable future. Our ability to generate significant revenue is uncertain, and we may never achieve profitability. We have a very limited operating history on which investors can evaluate our potential for future success. Potential investors should evaluate us in light of the expenses, delays, uncertainties, and complications typically encountered by early-stage healthcare businesses, many of which will be beyond our control. These risks include the following:

- uncertain market acceptance of our products and product candidates;
- U.S. regulatory approval of our products and product candidates;
- foreign regulatory approval of our products and product candidates;
- lack of sufficient capital;
- unanticipated problems, delays, and expense relating to product development and implementation;
- lack of sufficient intellectual property;
- competition; and
- technological changes.

As a result of our limited operating history, and the increasingly competitive nature of the markets in which we compete, our historical financial data, which, prior to April 16, 2015, consists of allocations of expenses from Ampio, is of limited value in anticipating future operating expenses. Our planned expense levels will be based in part on our expectations concerning future operations, which is difficult to forecast accurately based on our limited operating history and the recentness of the acquisition of our products ProstaScint, Primsol and Natesto. We may be unable to adjust spending in a timely manner to compensate for any unexpected budgetary shortfall.

We have not received any substantial revenues from the commercialization of our current products to date and might not receive significant revenues from the commercialization of our current products or our product candidates in the near term. Even though ProstaScint and Primsol are each an approved drug that we are marketing, we only acquired ProstaScint in May 2015 and Primsol in October 2015 and have limited experience on which to base the revenue we could expect to receive from their sales. We acquired Natesto in April 2016 and launched it in July 2016 and consequently have no meaningful experience on which to base expected revenue from Natesto. To obtain revenues from our products and product candidates, we must succeed, either alone or with others, in a range of challenging activities, including expanding markets for our existing products and completing clinical trials of our product candidates, obtaining positive results from those clinical trials, achieving marketing approval for those product candidates, manufacturing, marketing and selling our existing products and those products for which we, or our collaborators, may obtain marketing approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We, and our collaborators, if any, may never succeed in these activities and, even if we do, or one of our collaborators does, we may never generate revenues that are sufficient enough for us to achieve profitability.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our product expansion and development efforts or other operations.

We are expending resources to expand the market for Natesto, ProstaScint and Primsol, none of which might be as successful as we anticipate or at all and all of which might take longer and be more expensive than we anticipate. We also are currently advancing our product candidates through clinical development. Developing product candidates is expensive, lengthy and risky, and we expect to incur research and development expenses in connection with our ongoing clinical development activities with the MiOXSYS System. We also will need additional capital to uplist our common stock to the NYSE MKT or the NASDAQ Capital Market. As of June 30, 2016, our cash and cash equivalents were $8.1 million available to fund our operations offset by an aggregate $8.9 million in accounts payable and accrued liabilities and the Natesto payable. In May 2016, we conducted a public offering of our common stock and warrants from which we received net proceeds of approximately $6.3 million. Our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we will require additional capital to continue the expansion of marketing efforts for Natesto, ProstaScint and Primsol and to obtain regulatory approval for, and to commercialize, our current product candidate, the MiOXSYS System. Raising funds in the current economic environment, as well our lack of operating history, may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. We intend to rely on the purchase agreement (the “Purchase Agreement”) we entered into with Lincoln Park Capital Fund, LLC in July 2016 for our capital needs, including further commercialization of our currently approved products. If we were unable to access a portion or the full amount of the Purchase Agreement, in the absence of any other financing sources, it would have a material adverse impact on our operations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to expand any existing product or develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be unable to expand the market for Natesto, ProstaScint or Primsol and/or be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of our current product candidate, the MiOXSYS system, or any future product candidate or expand our operations generally or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

If we do not obtain the capital necessary to fund our operations, we will be unable to successfully expand the commercialization of Natesto, ProstaScint and Primsol and to develop, obtain regulatory approval of, and commercialize, our current product candidate, the MiOXSYS System.

The expansion of marketing and commercialization activities for our existing products and the development of pharmaceutical products, medical diagnostics and medical devices is capital-intensive. We anticipate we may require additional financing to continue to fund our operations. Our future capital requirements will depend on, and could increase significantly as a result of, many factors including:

- the costs, progress and timing of our efforts to expand the marketing of Natesto, ProstaScint and Primsol;

- progress in, and the costs of, our pre-clinical studies and clinical trials and other research and development programs;
- the costs of securing manufacturing arrangements for commercial production;
- the scope, prioritization and number of our research and development programs;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we obtain;
- the costs of establishing, expanding or contracting for sales and marketing capabilities for any existing products and if we obtain regulatory clearances to market our current product candidate, the MiOXSYS system;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any; and
- the costs involved in filing, prosecuting, enforcing and defending patent claims and other intellectual property rights.

If funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our commercialization efforts or our technologies, research or development programs.

We may not be able to access the full amounts available under the Lincoln Park Purchase Agreement, which could prevent us from accessing the capital we need to continue our operations that could have an adverse effect on our business.

We intend to rely on the purchase agreement (the "Purchase Agreement") we entered into with Lincoln Park Capital Fund, LLC ("Lincoln Park") in July 2016 for our near-term capital needs, including further commercialization of our currently approved products. After selling $500,000 of common stock on the day we executed the Purchase Agreement, pursuant to the terms of the Purchase Agreement, we may now direct Lincoln Park to purchase up to $10,000,000 worth of shares of our common stock over a 36-month period. On any trading day selected by us, we may sell shares of common stock to Lincoln Park in amounts up to 10,000 shares per regular sale (Regular Purchases), which may be increased to up to 20,000 shares depending on certain conditions as set forth in the Purchase Agreement, up to the aggregate commitment of $10,000,000. If the market price of our common stock is not below $7.00 per share on the purchase date, then the Regular Purchase amount may be increased to 15,000 shares. If the market price is not below $9.00 per share on the purchase date, then the Regular Purchase amount may be increased to 20,000 shares. Although there are no upper limits on the per share price Lincoln Park may pay to purchase our common stock, the Company may not sell more than $500,000 in shares of common stock to Lincoln Park per any individual Regular Purchase.

In addition to Regular Purchases, we may in our sole discretion direct Lincoln Park on each purchase date to make "accelerated purchases" on the following business day up to the lesser of (i) two times the number of shares purchased pursuant to such Regular Purchase or (ii) 30% of the trading volume on the accelerated purchase date at a purchase price equal to the lesser of (i) the closing sale price on the accelerated purchase date and (ii) 95% of the accelerated purchase date's volume weighted average price. We cannot submit an accelerated purchase notice if the stock price is below $3.00.

The purchase price of the shares related to the Purchase Agreement will be based on the prevailing market prices of the Company's shares of common stock, which shall be equal to the lesser of the lowest sale price of the common shares during the purchase date and the average of the three lowest closing sale prices of the common shares during the ten business days prior to the purchase date without any fixed discount.

Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $10,000,000 over the term of the Purchase Agreement. Our inability to access a portion or the full amount of the Purchase Agreement, in the absence of any other financing sources, would have a material adverse impact on our operations.

Our investment in Acerus Pharmaceuticals Corporation could decline in value.

On April 28, 2016, we purchased approximately $2.0 million worth of shares of common stock of Acerus Pharmaceutics Corporation as a condition to our licensing of Natesto. The per share purchase price was Cdn.$0.207. Acerus common stock is traded on the Toronto Stock Exchange under the symbol "ASP." On August 15, 2016, the closing price per share was Cdn.$0.09. During the time that we own these shares, there can be no assurance that the value of that stock will not decline and we could lose our entire investment in that stock.

We will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as private companies during the majority of fiscal 2015. In addition, the rules and regulations of the SEC and any national securities exchange to which we may be subject in the future impose numerous requirements on public companies, including requirements relating to our corporate governance practices, with which we will need to comply. Further, we will continue to be required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Based on currently available information and assumptions, we estimate that we will incur approximately $0.5 million in expenses on an annual basis as a direct result of the requirements of being a publicly traded company. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to Section 404 of the Sarbanes-Oxley Act, our management conducted an assessment of the effectiveness of our internal control over financial reporting for the year ended June 30, 2016, and concluded that such control was effective (see Part II, Item 9A).

However, if in the future we were to conclude that our internal control over financial reporting were not effective, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effect on our operations because there is presently no precedent available by which to measure compliance adequacy. As a consequence, we may not be able to complete any necessary remediation process in time to meet our deadline for compliance with Section 404 of the Sarbanes-Oxley Act. Also, there can be no assurance that we will not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. The presence of material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results.

If we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us, when required, with an attestation report on the effectiveness of internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to obtain listing on a securities exchange such as the NYSE MKT or NASDAQ.

Risks Related to Product Development, Regulatory Approval and Commercialization

Natesto, ProstaScint and Primsol may prove to be difficult to effectively commercialize as planned.

Various commercial, regulatory, and manufacturing factors may impact our ability to maintain or grow revenues from sales of Natesto, ProstaScint and Primsol. Specifically, we may encounter difficulty by virtue of:

- our inability to secure continuing prescribing of any of these products by current or previous users of the product;
- our inability to effectively transfer and scale manufacturing as needed to maintain an adequate commercial supply of these products;
- reimbursement and medical policy changes that may adversely affect the pricing, profitability or commercial appeal of Natesto, ProstaScint or Primsol; and
- our inability to effectively identify and align with commercial partners outside the United States, or the inability of those selected partners to gain the required regulatory, reimbursement, and other approvals needed to enable commercial success of ProstaScint or Primsol.

We have limited experience selling our current products as they have been acquired from another company or are newly approved for sale. As a result, we may be unable to successfully commercialize our products and product candidates.

Despite our management's extensive experience in launching and managing commercial-stage healthcare companies, we have limited marketing, sales and distribution experience with our current products. Our ability to achieve profitability depends on attracting and retaining customers for our current products, and building brand loyalty for Natesto, ProstaScint and Primsol. To successfully perform sales, marketing, distribution and customer support functions, we will face a number of risks, including:

- our ability to attract and retain skilled support team, marketing staff and sales force necessary to increase the market for our approved products and to maintain market acceptance for our product candidates;
- the ability of our sales and marketing team to identify and penetrate the potential customer base; and
- the difficulty of establishing brand recognition and loyalty for our products.

In addition, we may seek to enlist one or more third parties to assist with sales, distribution and customer support globally or in certain regions of the world. If we do seek to enter into these arrangements, we may not be successful in attracting desirable sales and distribution partners, or we may not be able to enter into these arrangements on favorable terms, or at all. If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, our currently approved products may not achieve increased market acceptance and our product candidates may not gain market acceptance, which would materially impact our business and operations.

We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, any of our current or future product candidates.

We may not be able to develop our current or any future product candidates. Our product candidates will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence commercialization. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

We are not permitted to market a product in the U.S. until we receive approval of a New Drug Application, or an NDA, for that product from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of any product candidate for many reasons, including, among others:

- we may not be able to demonstrate that a product candidate is safe and effective to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may require that we conduct additional clinical trials;
- the FDA may not approve the formulation, labeling or specifications of any product candidate;
- the clinical research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may find the data from pre-clinical studies and clinical trials insufficient to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks, such as the risk of drug abuse by patients or the public in general;
- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if an NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;
- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the FDA may change its approval policies or adopt new regulations.

These same risks apply to applicable foreign regulatory agencies from which we may seek approval for any of our product candidates.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any product candidate. Moreover, because a substantial portion of our business is or may be dependent upon our product candidates, any such setback in our pursuit of initial or additional regulatory approval would have a material adverse effect on our business and prospects.

If we fail to successfully acquire new products, we may lose market position.

Acquiring new products is an important factor in our planned sales growth, including products that already have been developed and found market acceptance. If we fail to identify existing or emerging consumer markets and trends and to acquire new products, we will not develop a strong revenue source to help pay for our development activities as well as possible acquisitions. This failure would delay implementation of our business plan, which could have a negative adverse effect on our business and prospects.

If we do not secure collaborations with strategic partners to test, commercialize and manufacture product candidates, we may not be able to successfully develop products and generate meaningful revenues.

We may enter into collaborations with third parties to conduct clinical testing, as well as to commercialize and manufacture our products and product candidates. If we are able to identify and reach an agreement with one or more collaborators, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. The current economic environment may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize our products or product candidates. Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals;
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing their own or another party's product candidate; or
- collaborators may decide to terminate or not to renew the collaboration for these or other reasons.

As a result, collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all. For example, our former collaborator that licensed Zertane conducted clinical trials which we believe demonstrated efficacy in treating PE, but the collaborator undertook a merger that we believe altered its strategic focus and thereafter terminated the collaboration agreement. The Merger also created a potential conflict with a principal customer of the acquired company, which sells a product to treat premature ejaculation in certain European markets.

Collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our products or product candidates and may not generate meaningful revenues.

We or our strategic partners may choose not to continue an existing product or choose not to develop a product candidate at any time during development, which would reduce or eliminate our potential return on investment for that product.

At any time and for any reason, we or our strategic partners may decide to discontinue the development or commercialization of a product or product candidate. If we terminate a program in which we have invested significant resources, we will reduce the return, or not receive any return, on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. If one of our strategic partners terminates a program, we will not receive any future milestone payments or royalties relating to that program under our agreement with that party.

Our pre-commercial product candidates are expected to undergo clinical trials that are time-consuming and expensive, the outcomes of which are unpredictable, and for which there is a high risk of failure. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

Pre-clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre-clinical testing and clinical development necessary to commercialize a drug or biologic, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major set-back for that product candidate and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business, prospects and financial condition and on the value of our common stock.

In connection with clinical testing and trials, we face a number of risks, including:

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier testing or trials; and
- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to establish the safety and efficacy of the product candidate.

If we do not successfully complete pre-clinical and clinical development, we will be unable to market and sell products derived from our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Although there are a large number of drugs and biologics in development in the United States and other countries, only a small percentage result in the submission of an NDA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business, prospects and financial condition will be materially harmed.

Delays, suspensions and terminations in any clinical trial we undertake could result in increased costs to us and delay or prevent our ability to generate revenues.

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. Should we undertake the development of a pharmaceutical product candidate, we would expect the necessary clinical trials to take up to 24 months to complete, but the completion of trials for any product candidates may be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;

- obtaining sufficient quantities of the drug substance or device ports;
- manufacturing sufficient quantities of a product candidate;
- obtaining approval of an IND from the FDA;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site;
- determining dosing and clinical design and making related adjustments; and
- patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical trial sites, the availability of effective treatments for the relevant disease and the eligibility criteria for the clinical trial.

The commencement and completion of clinical trials for our product candidates may be delayed, suspended or terminated due to a number of factors, including:

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation or design;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;
- delays in patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war, or a natural disaster; and
- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory agencies.

Many of these factors may also ultimately lead to denial of an NDA for a product candidate. If we experience delay, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, or changes in FDA policy or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn. Delays or failures in obtaining regulatory approvals may result in:

- varying interpretations of data and commitments by the FDA and similar foreign regulatory agencies; and
- diminishment of any competitive advantages that such product candidates may have or attain.

Furthermore, if we fail to comply with applicable FDA and other regulatory requirements at any stage during this regulatory process, we may encounter or be subject to:

- diminishment of any competitive advantages that such product candidates may have or attain;
- delays or termination in clinical trials or commercialization;
- refusal by the FDA or similar foreign regulatory agencies to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties, and criminal prosecutions.

The medical device regulatory clearance or approval process is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from broadly commercializing the MiOXSYS System for clinical use.

The MiOXSYS System is subject to 510(k) clearance by the FDA prior to its marketing for commercial use in the United States, and to regulatory approvals beyond CE marking required by certain foreign governmental entities prior to its marketing outside the United States. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510(k) clearance, pre-market approval, or foreign regulatory approvals. The 510(k) clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510(k) clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510(k) clearance or pre-market approval may never be obtained. We have limited experience in filing FDA applications for 510(k) clearance and pre-market approval. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements even after obtaining clearance or approval. There can be no assurance that we will obtain or maintain any required clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

The approval process for pharmaceutical and medical device products outside the United States varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we, and our collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the United States. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the United States, or we may simultaneously seek regulatory approvals in the United States and other countries. If we or our collaborators seek marketing approval for a product candidate outside the United States, we will be subject to the regulatory requirements of health authorities in each country in which we seek approval. With respect to marketing authorizations in Europe, we will be required to submit a European Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining regulatory approvals from health authorities in countries outside the United States is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

Even if we, or our collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or they market our products, which could materially impair our ability to generate revenue.

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize the product, or may be required to carry a warning in its labeling and on its packaging. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators expect to continue to expend time, money and effort in all areas of regulatory compliance.

Any of our products and product candidates for which we, or our collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such products, among other things, are or will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a REMS to ensure that the benefits of a drug or biological product outweigh its risks.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed.

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the initiation or completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of such milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals from the FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business, prospects and results of operations may be harmed.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.

We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and others to carry out our clinical trials. Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

Even if collaborators with which we contract in the future successfully complete clinical trials of our product candidates, those product candidates may not be commercialized successfully for other reasons.

Even if we contract with collaborators that successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including:

- failure to receive regulatory clearances required to market them as drugs;
- being subject to proprietary rights held by others;

- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable; or
- failing to compete effectively with products or treatments commercialized by competitors.

Any third-party manufacturers we engage are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in, our product commercialization as a result of these regulations.

The manufacturing processes and facilities of third-party manufacturers we have engaged are for our current approved products are, and any future third-party manufacturer will be, required to comply with the federal Quality System Regulation, or QSR, which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of devices. The FDA enforces the QSR through periodic unannounced inspections of manufacturing facilities. Any inspection by the FDA could lead to additional compliance requests that could cause delays in our product commercialization. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with the manufacturing processes and facilities of third-party manufacturers we engage, including the failure to take satisfactory corrective actions in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of the product in question;
- total or partial suspension of production or distribution;
- the FDA's refusal to grant pending future clearance or pre-market approval;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the export of the product in question; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from marketing, distributing or selling our products, and would likely harm our business.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall drugs or devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert our management attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers.

We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us.

We compete with companies that design, manufacture and market already-existing and new urology products. We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and/or our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in product marketing and new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable. Our ability to compete successfully will depend largely on our ability to:

- expand the market for our approved products, especially Natesto ProstaScint and Primsol;
- successfully commercialize our product candidates alone or with commercial partners;
- discover and develop product candidates that are superior to other products in the market;
- obtain required regulatory approvals;
- attract and retain qualified personnel; and
- obtain patent and/or other proprietary protection for our product candidates.

Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our products and product candidates obsolete. Our competitors may obtain patent protection, receive FDA approval, and commercialize medicines before us. Other companies are or may become engaged in the discovery of compounds that may compete with the product candidates we are developing.

Natesto competes in a large, growing market. The U.S. prescription testosterone market is comprised primarily of topically applied treatments in the form of gels, solutions, and patches. Testopel® and Aveed®, injectable products typically implanted directly under the skin by a physician, are also FDA-approved. AndroGel is the market-leading TRT and is marketed by AbbVie.

For the MiOXSYS System and ProstaScint, we compete with companies that design, manufacture and market already existing and new in-vitro diagnostics and diagnostic imaging systems and radio-imaging agents for cancer detection. Additionally, with respect to Primsol, we compete with numerous companies who produce antimicrobial treatments for various pathogens inclusive of products containing trimethoprim as contained in Primsol.

There are any number of antibiotics available on the market that could compete with Primsol. Even though Primsol is the only FDA-approved liquid formulation of trimethoprim, an antibiotic that is well established in current guidelines for treating UTIs, we may not be able to effectively compete with these existing antibiotics.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable.

Any new product we develop or commercialize that competes with a currently-approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to address price competition and be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our or our collaborators' ability to set a price we believe is fair for our approved products;
- our ability to generate revenue from our approved products and achieve profitability; and

- the availability of capital.

The 2010 enactments of the Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act, or the Health Care Reconciliation Act, are expected to significantly impact the provision of, and payment for, health care in the United States. Various provisions of these laws have only recently taken effect or have yet to take effect, and are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. Amendments to the PPACA and/or the Health Care Reconciliation Act, as well as new legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the United States, could influence the purchase of medicines and medical devices and reduce demand and prices for our products and product candidates, if approved. This could harm our or our collaborators' ability to market any approved products and generate revenues. As we expect to receive significant revenues from reimbursement of our Natesto, ProstaScint and Primsol products by commercial third-party payors and government payors, cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of any of our products and product candidates approved in the future, and could cause an increase in our compliance, manufacturing, or other operating expenses. In addition, in certain foreign markets, the pricing of prescription drugs and devices is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell any approved product at a price acceptable to us or any of our future collaborators.

In addition, in some foreign countries, the proposed pricing for a drug or medical device must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. A member state may require that physicians prescribe the generic version of a drug instead of our approved branded product. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products or product candidates. Historically, pharmaceutical products launched in the European Union do not follow price structures of the United States and generally tend to have significantly lower prices.

Our financial results will depend on the acceptance among hospitals, third-party payors and the medical community of our products and product candidates.

Our future success depends on the acceptance by our target customers, third-party payors and the medical community that our products and product candidates are reliable, safe and cost-effective. Many factors may affect the market acceptance and commercial success of our products and product candidates, including:

- our ability to convince our potential customers of the advantages and economic value our products and product candidates over existing technologies and products;
- the relative convenience and ease of our products and product candidates over existing technologies and products;
- the introduction of new technologies and competing products that may make our products and product candidates less attractive for our target customers;
- our success in training medical personnel on the proper use of our products and product candidates;
- the willingness of third-party payors to reimburse our target customers that adopt our products and product candidates;
- the acceptance in the medical community of our products and product candidates;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

If third-party payors do not reimburse our customers for the products we sell or if reimbursement levels are set too low for us to sell one or more of our products at a profit, our ability to sell those products and our results of operations will be harmed.

While Natesto, ProstaScint and Primsol are already FDA-approved and generating revenues in the U.S., they may not receive, or continue to receive, physician, hospital, or laboratory acceptance, or they may not maintain adequate reimbursement from third party payors. Additionally, even if one of our product candidates is approved and reaches the market, the product may not achieve physician, hospital, or laboratory acceptance, or it may not obtain adequate reimbursement from third party payors. We expect to sell our Primsol products and possibly other product candidates to target customers substantially all of whom receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid, other domestic and foreign government programs, private insurance plans and managed care programs. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental.

Obtaining coverage and reimbursement approval for a product from each government or third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our potential product to each government or third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for any product or product candidate, which in turn, could negatively impact pricing. If our customers are not adequately reimbursed for our products, they may reduce or discontinue purchases of our products, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

Manufacturing risks and inefficiencies may adversely affect our ability to produce our products.

As part of the acquisition of ProstaScint from Jazz Pharmaceuticals, we terminated the relationship with the third-party manufacturer of ProstaScint. We have initiated the process of transferring the manufacturing to Biovest International, which we believe is a qualified manufacturer and with whom we have entered into a Master Services Agreement. In the event that this manufacturing transfer does not occur by the time our current inventory expires, we may not be able to supply sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements, such as quality system regulations. In addition, we expect to engage third parties to manufacture components of the MiOXSYS and RedoxSYS systems. We have an agreement for supplies of Natesto with Acerus, from whom we license Natesto, and have entered into a supply agreement for Primsol with the same manufacturer used by FSC Laboratories, from whom we purchased Primsol. For any future product, we expect to use third-party manufacturers because we do not have our own manufacturing capabilities. In determining the required quantities of any product and the manufacturing schedule, we must make significant judgments and estimates based on inventory levels, current market trends and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our current products, there could be significant differences between our estimates and the actual amounts of product we require. If we do not effectively maintain our supply agreements for Natesto and Primsol, we will face difficulty finding replacement suppliers, which could harm sales of those products. If we do not effectively transition sites with our manufacturing and development partners to enable to production scale of ProstaScint, or if we do not secure collaborations with manufacturing and development partners to enable production to scale of the MiOXSYS system, we may not be successful in selling ProstaScint or in commercializing the MiOXSYS system in the event we receive regulatory approval of the MiOXSYS System. If we fail in similar endeavors for future products, we may not be successful in establishing or continuing the commercialization of our products and product candidates.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers; and
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us.

Further, if we are unable to secure the needed financing to fund our internal operations, we may not have adequate resources required to effectively and rapidly transition our third party manufacturing. We may not be able to meet the demand for our products if one or more of any third-party manufacturers is unable to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers for any of our products or product candidates in a timely manner and on terms acceptable to us.

Any third-party manufacturers we engage are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in, our product commercialization as a result of these regulations.

The manufacturing processes and facilities of third-party manufacturers we engage are required to comply with the federal Quality System Regulation, or QSR, which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of devices. The FDA enforces the QSR through periodic unannounced inspections of manufacturing facilities. Any inspection by the FDA could lead to additional compliance requests that could cause delays in our product commercialization. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with the manufacturing processes and facilities of third-party manufacturers we engage, including the failure to take satisfactory corrective actions in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of the product in question;
- total or partial suspension of production or distribution;
- the FDA's refusal to grant pending future clearance or pre-market approval;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the export of the product in question; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from marketing, distributing or selling our products, and would likely harm our business.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall drugs or devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert our management attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our products and product candidates in foreign markets for which we intend to primarily rely on collaboration with third parties. If we commercialize our products or product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to our products;
- foreign currency exchange rate fluctuations;
- our customers' ability to obtain reimbursement for our products in foreign markets; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products or product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to various regulations pertaining to the marketing of our approved products.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products, including inducements to potential patients to request our products and services. Additionally, any product promotion educational activities, support of continuing medical education programs, and other interactions with health-care professionals must be conducted in a manner consistent with the FDA regulations and the Anti-Kickback Statute. The Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Violations of the Anti-Kickback Statute can also carry potential federal False Claims Act liability. Additionally, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. These and any new regulations or requirements may be difficult and expensive for us to comply with, may adversely impact the marketing of our existing products or delay introduction of our product candidates, which may have a material adverse effect on our business, operating results and financial condition.

Our products and product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Further, if a product candidate receives marketing approval and we or others identify undesirable side effects caused by the product after the approval, or if drug abuse is determined to be a significant problem with an approved product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a “Black Box warning” or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing an affected product or product candidates and significantly impact our ability to successfully commercialize or maintain sales of our product or product candidates and generate revenues.

Natesto contains, and future our other product candidates may contain, controlled substances, the manufacture, use, sale, importation, exportation, prescribing and distribution of which are subject to regulation by the DEA.

Natesto, which is approved by the FDA, is regulated by the DEA as a Schedule III controlled substance. Before any commercialization of any product candidate that contains a controlled substance, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. Natesto is, and our other product candidates may, if approved, be regulated as “controlled substances” as defined in the Controlled Substances Act of 1970, or CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our third-party manufacturers and to distributors, prescribers and dispensers of our product candidates. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances.

The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Natesto is regulated by the DEA as a Schedule III controlled substance. Consequently, the manufacturing, shipping, storing, selling and using of the products will be subject to a high degree of regulation. Also, distribution, prescribing and dispensing of these drugs are highly regulated.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

Because of their restrictive nature, these laws and regulations could limit commercialization of our product candidates containing controlled substances. Failure to comply with these laws and regulations could also result in withdrawal of our DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties and state actions, among other consequences.

If testosterone replacement therapies are found, or are perceived, to create health risks, our ability to sell Natesto could be materially adversely affected and our business could be harmed.

Recent publications have suggested potential health risks associated with testosterone replacement therapy, such as increased cardiovascular disease risk, including increased risk of heart attack or stroke, fluid retention, sleep apnea, breast tenderness or enlargement, increased red blood cells, development of clinical prostate disease, including prostate cancer, and the suppression of sperm production. Prompted by these events, the FDA held a T-class Advisory Committee meeting on September 17, 2014 to discuss this topic further. The FDA has also asked health care professionals and patients to report side effects involving prescription testosterone products to the agency.

At the T-class Advisory Committee meeting held on September 17, 2014, the Advisory Committee discussed (i) the identification of the appropriate patient population for whom testosterone replacement therapy should be indicated and (ii) the potential risk of major adverse cardiovascular events, defined as non-fatal stroke, non-fatal myocardial infarction and cardiovascular death associated with testosterone replacement therapy. At the meeting, the Advisory Committee voted that the FDA should require sponsors of testosterone products to conduct a post marketing study (e.g. observational study or controlled clinical trial) to further assess the potential cardiovascular risk.

It is possible that the FDA's evaluation of this topic and further studies on the effects of testosterone replacement therapies could demonstrate the risk of major adverse cardiovascular events or other health risks or could impose requirements that impact the marketing and sale of Natesto, including:

- mandate that certain warnings or precautions be included in our product labeling;
- require that our product carry a "black box warning"; and
- limit use of Natesto to certain populations, such as men without specified conditions.

Demonstrated testosterone replacement therapy safety risks, as well as negative publicity about the risks of hormone replacement therapy, including testosterone replacement, could hurt sales of and impair our ability to successfully relaunch Natesto, which could have a materially adverse impact on our business.

FDA action regarding testosterone replacement therapies could add to the cost of producing and marketing Natesto.

The FDA is requiring post-marketing safety studies for all testosterone replacement therapies approved in the U.S. to assess long-term cardiovascular events related to testosterone use. Depending on the total cost and structure of the FDA's proposed safety studies there may be a substantial cost associated with conducting these studies. Pursuant to our license agreement with Acerus Pharmaceuticals is, Acerus is obligated to reimburse us for the entire cost of any studies required for Natesto by the FDA. However, in the event that Acerus is not able to reimburse us for the cost of any required safety studies, we may be forced to incur this cost, which could have a material adverse impact on our business and results of operations.

Our approved products may not be accepted by physicians, patients, or the medical community in general.

Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing medicines or treatments. We cannot predict the degree of market acceptance of any of our approved products, which will depend on a number of factors, including, but not limited to:

- the efficacy and safety of the product;
- the approved labeling for the product and any required warnings;

- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the reimbursement policies of government and third-party payors pertaining to the product; and
- the market price of our product relative to competing treatments.

We may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean-up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced.

Intellectual Property Risks Related to Our Business

Our ability to compete may decline if we do not adequately protect our proprietary rights or if we are barred by the patent rights of others.

Our commercial success depends on obtaining and maintaining proprietary rights to our products and product candidates as well as successfully defending these rights against third-party challenges. We will only be able to protect our products and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents, or effectively protected trade secrets, cover them. Our ability to obtain patent protection for our products and product candidates is uncertain due to a number of factors, including that:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we may not have been the first to file patent applications for our products and product candidates;
- others may independently develop identical, similar or alternative products, compositions or devices and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions, devices and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art or other bases which could invalidate our patents.

Even if we have or obtain patents covering our products and product candidates, we may still be barred from making, using and selling them because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering products that are similar or identical to ours. There are many issued U.S. and foreign patents relating to chemical compounds, therapeutic products, diagnostic devices, and some of these relate to our products and product candidates. These could materially affect our ability to sell our products and develop our product candidates. Because patent applications can take many years to issue, there may be currently pending applications unknown to us that may later result in issued patents that our products and product candidates may infringe. These patent applications may have priority over patent applications filed by us.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our business, prospects, financial condition and results of operations.

Pharmaceutical and medical device patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of pharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the United States Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to re-examination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products and product candidates without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection of our products and product candidates, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court, other federal courts, the United States Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes the way issued patents are challenged, and changes the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of discovery and development of therapies and medical devices, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific and commercial collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and medical devices. This could make it difficult for us to stop the infringement of some of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have or expect to have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We might employ individuals who were previously employed at universities or other biopharmaceutical or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the pharmaceutical and medical device industries regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our products or product candidates infringe the intellectual property rights of others. If our development and commercialization activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs, compositions or devices. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party’s patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, prospects and financial condition. As a result, we could be prevented from commercializing our products and product candidates.

Risks Related to Our Organization, Structure and Operation

We intend to acquire, through asset purchases or in-licensing, businesses or products, or form strategic alliances, in the future, and we may not realize the intended benefits of such acquisitions or alliances.

We intend to acquire, through asset purchases or in-licensing, additional businesses or products, form strategic alliances and/or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses or assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses or assets if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition or alliance, we will achieve the expected synergies to justify the transaction. These risks apply to our acquisition of ProstaScint in May 2015, Primsol in October 2015 and Natesto in April 2016.

In fiscal 2016 and 2015, the great majority of our net revenue and gross accounts receivable were due to one significant customer, the loss of which could materially and adversely affect our results of operations.

During fiscal 2016 and fiscal 2015, one customer accounted for 86% and 83%, respectively, of our net revenue. At June 30, 2016 and 2015, this same customer accounted for 69% and 99%, respectively, of our gross accounts receivable. Although we have been growing our revenue, particularly in fiscal 2016, and launched Natesto after the close of fiscal 2016, and therefore expect to increase revenue and not be so reliant on this one customer, at least for fiscal 2017, and perhaps beyond, the loss of this customer could have a material adverse effect on our results of operations.

Our ability to operate our business effectively may suffer if we or Ampio terminate our services agreement, or if we are unable to establish on a cost-effective basis our own administrative and other support functions in order to operate as a stand-alone company after the expiration or termination of our services agreement with Ampio.

Prior to the Merger, we relied on administrative and other resources of Ampio to operate our business. We have entered into a services agreement to retain the ability for specified periods to use certain Ampio resources. We may elect to continue this agreement for an indefinite period of time. Any decision by us to terminate this agreement would be approved by disinterested members of our management and board of directors under our procedures regarding related party transactions. After the termination of this agreement, we will need to create our own administrative and other support systems or contract with third parties to replace Ampio's services. These services may not be provided at the same level, and we may not be able to obtain the same benefits that we received prior to the separation. These services may not be sufficient to meet our needs, and if our agreement with Ampio is terminated, we may not be able to replace these services at all or obtain these services at prices and on terms as favorable as we currently have with Ampio. Any failure or significant downtime in our own administrative systems or in Ampio's administrative systems during the transitional period could result in unexpected costs, impact our results or prevent us from paying our suppliers or employees and performing other administrative services on a timely basis.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of August 15, 2016, we had 58 full-time employees, and in connection with being a public company, we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the planned expanded commercialization of our approved products and the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to expand the market for our approved products and develop our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We depend on key personnel and attracting qualified management personnel and our business could be harmed if we lose personnel and cannot attract new personnel.

Our success depends to a significant degree upon the technical and management skills of our officers and key personnel. The loss of the services of any of these individuals would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, marketing, technical, and sales executives and personnel. We do not maintain key person life insurance for any of our officers or key personnel. The loss of any of our key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business.

We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so could have a material adverse effect on our business, prospects, financial condition, and results of operations.

Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our product candidates.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical and medical device products. Side effects of, or manufacturing defects in, products that we develop and commercialized could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products.

We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial condition and operations.

Although we maintain general liability, clinical trial liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit the commercial production and sale of any of our products and product candidates that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully.

In order to satisfy our obligations as a public company, we may need to hire additional qualified accounting and financial personnel with appropriate public company experience in the event that we no longer utilize the finance and administrative functions of Ampio.

As a public company, we must establish and maintain effective disclosure and financial controls. We may need to hire additional accounting and financial personnel with appropriate public company experience and technical accounting knowledge, and it may be difficult to recruit and maintain such personnel. Even if we are able to hire appropriate personnel, our existing operating expenses and operations will be impacted by the direct costs of their employment and the indirect consequences related to the diversion of management resources from product development efforts.

Our internal computer systems, or those of our third-party contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we do not believe that we have experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a loss of clinical trial data for our product candidates which could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed.

We are upgrading our enterprise resource planning system and may experience difficulties with the upgrade or after its full implementation.

As a result of the growth of our business after April 2015, we needed to upgrade our enterprise resource planning, or ERP, system, which upgrade we began in July 2016. Our ERP system is critical to our ability to accurately maintain books and records, keep track of product inventory, marketing and sales, and prepare our financial statements. The implementation of the new ERP system will require additional investment of significant financial and human resources. In addition, we may not be able to successfully complete the full implementation of the ERP system without experiencing difficulties. Any disruptions, delays or deficiencies in the design and implementation of the new ERP system could adversely affect our ability to monitor our business and prepare our financial statements on an accurate and timely basis.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of June 30, 2016, we had federal net operating loss carryforwards of approximately $24.8 million. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2032 and will completely expire in 2035. Under the Internal Revenue Code of 1986, as amended (the "Code") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate changes could limit our ability to use our net operating loss carryforwards and other tax attributes (such as research tax credits) to offset our income. Because Ampio's equity ownership interest in our company fell to below 80% in January 2016, we will be deconsolidated from Ampio's consolidated federal income tax group. As a result, certain of our net operating loss carryforwards may not be available to us and we may not be able to use them to offset our U.S. federal taxable income. As a consequence of the deconsolidation, it is possible that certain other tax attributes and benefits resulting from U.S. federal income tax consolidation may no longer be available to us. Our company and Ampio do not have a tax sharing agreement that could mitigate the loss of net operating losses and other tax attributes resulting from the deconsolidation or our incurrence of liability for the taxes of other members of the consolidated group by reason of the joint and several liability of group members. In addition to the deconsolidation risk, an "ownership change" (generally a 50% change (by value) in equity ownership over a three-year period) under Section 382 of the Code could limit our ability to offset, post-change, our U.S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change net operating loss carryforwards and certain recognized built-in losses. Either the deconsolidation or the ownership change scenario could result in increased future tax liability to us.

Our historical financial information as a business conducted by Ampio may not be representative of our results as an independent public company.

The historical financial information included herein does not necessarily reflect what our financial position, operating results or cash flows would have been had we been an independent entity during the year ended June 30, 2015. The historical costs and expenses reflected in our financial statements include amounts for certain corporate functions historically provided by Ampio, including costs of finance and other administrative services, and income taxes. These expense allocations were developed on the basis of what we and Ampio considered to be reasonable prices for the utilization of services provided or the benefits received by us. The historical financial information in our audited financial statements may not be indicative of what our results of operations, financial position, changes in equity and cash flows would have been had we been a separate stand-alone entity during the periods presented or will be in the future. We have not made adjustments to reflect many significant changes that will occur in our cost structure, funding and operations as a result of our separation from Ampio, including changes in our employee base, changes in our tax structure, potential increased costs associated with reduced economies of scale and increased costs associated with being a publicly traded, stand-alone company, such as compliance costs, nor have we made offsetting adjustments to reflect the benefits of this offering, as these factors are presently difficult to quantify. These same risks will apply to the financial information of any business we acquire when it is included in our financial statements.

Risks Related to Securities Markets and Investment in our Securities

There is not now, and there may never be, an active and orderly trading market for our common stock.

An active trading market for our shares may never develop or be sustained. As a result, investors in our common stock must bear the economic risk of holding those shares for an indefinite period of time. Although our common stock is quoted on the OTCQX, an over-the-counter quotation system, trading of our common stock is extremely limited and sporadic and at very low volumes. We do not now, and may not in the future, meet the initial listing standards of any national securities exchange, and we presently anticipate that our common stock will continue to be quoted on the OTCQX or another over-the-counter quotation system for the foreseeable future. In those venues, our stockholders may find it difficult to obtain accurate quotations as to the market value of their shares of our common stock, and may find few buyers to purchase their stock and few market makers to support its price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the price for which you purchased them, or at all. Further, an inactive market may also impair our ability to raise capital by selling additional equity in the future, and may impair our ability to enter into strategic partnerships or acquire companies or products by using shares of our common stock as consideration.

Our ability to uplist our common stock to the NYSE MKT or the NASDAQ Capital Market is subject to us meeting applicable listing criteria.

We intend to apply for our common stock to be listed on either the NYSE MKT or the NASDAQ Capital Market, each a national securities exchange The NYSE MKT and NASDAQ Capital Market require companies desiring to list their common stock on such exchanges and markets to meet certain listing criteria including total number of stockholders; minimum stock price, total value of public float, and in some cases total shareholders' equity and market capitalization. Our failure to meet such applicable listing criteria could prevent us from listing our common stock on such exchanges or markets. In the event we are unable to uplist our common stock, our common stock will continue to trade on the OTCQX market, which is generally considered less liquid and more volatile than the NYSE MKT and NASDAQ Capital Market. Our failure to uplist our common stock could make it more difficult for you to trade our common stock shares, could prevent our common stock trading on a frequent and liquid basis and could result in the value of our common stock being less than it would be if we were able to uplist.

If we apply and our common stock is accepted for uplisting on the NYSE MKT or the NASDAQ Capital Market, our failure to meet the continued listing requirements of the NYSE MKT or the NASDAQ Capital Market could result in a delisting of our common stock.

If our common stock were to be uplisted on the NYSE MKT or the NASDAQ Capital Market, and thereafter we fail to satisfy the continued listing requirements of the NYSE MKT or the NASDAQ Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, either exchange may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we anticipate that we would take actions to restore our compliance with the applicable exchange's listing requirements, such exchange, stabilize our market price, improve the liquidity of our common stock, prevent our common stock from dropping below such exchange's minimum bid price requirement, or prevent future non-compliance with such exchange's listing requirements.

If we fail to comply with the continued trading standards of the OTCQX U.S. Premier tier, it may result in our common stock moving tiers in the OTC Markets.

Our common stock is currently quoted for trading on the OTCQX U.S. Premier tier, and the continued quotation of our common stock on the OTCQX U.S. Premier tier is subject to our compliance with a number of standards. These standards include the requirement of our common stock to have a minimum bid price of $1.00 per share as of the close of business for at least one of every thirty consecutive calendar days.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

At August 15, 2016, our executive officers, directors and entities affiliated with certain of our directors beneficially owned approximately 38% of our outstanding shares of common stock. Therefore, these stockholders have the ability to influence us through their ownership position. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

The sale of shares of our common stock to Lincoln Park under the Purchase Agreement may cause substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

Under the Purchase Agreement with Lincoln Park, we may sell to Lincoln Park, from time to time and under certain circumstances, up to $10,000,000 of our common stock over approximately 36 months subsequent to the effective date of the registration statement that covers the resale by Lincoln Park of up to 2,500,000 shares of our common stock issuable under the Purchase Agreement. We may be required to file and have declared effective one or more additional registration statements to cover the resale by Lincoln Park of additional shares of our common stock that we may sell and issue to Lincoln Park. Generally, with respect to the Purchase Agreement, we have the right, but no obligation, to direct Lincoln Park to periodically purchase up to $10,000,000 of our common stock in specific amounts under certain conditions, which periodic purchase amounts can be increased under specified circumstances.

Depending upon market liquidity at the time, sales of shares of our common stock to Lincoln Park may cause the trading price of our common stock to decline. Lincoln Park may ultimately purchase all, some or none of the $10,000,000 of common stock under the Purchase Agreement, and after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. The sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales. However, we have the right to control the timing and amount of any sales of our shares to Lincoln Park, and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us.

Future sales and issuances of our equity securities or rights to purchase our equity securities, including pursuant to equity incentive plans, would result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

To the extent we raise additional capital by issuing equity securities, including pursuant to the Purchase Agreement with Lincoln Park, our stockholders may experience substantial dilution. We may, as we have in the past, sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

Pursuant to our 2015 Stock Plan, our Board of Directors is authorized to award up to a total of 833,333 shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. As of June 30, 2016, options to purchase 322,302 shares of common stock issued under our 2015 Stock Plan at a weighted average exercise price of $18.01 per share were outstanding. In addition, at June 30, 2016, there were outstanding warrants to purchase an aggregate of 2,201,627 shares of our common stock at a weighted average exercise price of $6.19. Stockholders will experience dilution in the event that additional shares of common stock are issued under our 2015 Stock Plan, or options issued under our 2015 Stock Plan are exercised, or any warrants are exercised for shares of our common stock.

Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control.

The trading price of our common stock is likely to be highly volatile, and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this prospectus, these factors include:

- the products or product candidates we acquire for commercialization;
- the product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to expand the market for our currently approved products or commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;

- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the healthcare, biotechnology and pharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- our dependence on third parties, including CROs and scientific and medical advisors;
- our ability to uplist our common stock to a national securities exchange;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;

In addition, the stock market in general, and the stocks of small-cap healthcare, biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse impact on the market price of our common stock.

FINRA sales practice requirements may limit a stockholder's ability to buy and sell our stock.

The Financial Industry Regulatory Authority, or FINRA, has adopted rules requiring that, in recommending an investment to a customer, a broker-dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative or low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer's financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA has indicated its belief that there is a high probability that speculative or low-priced securities will not be suitable for at least some customers. Because these FINRA requirements are applicable to our common stock, they may make it more difficult for broker-dealers to recommend that at least some of their customers buy our common stock, which may limit the ability of our stockholders to buy and sell our common stock and could have an adverse effect on the market for and price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on us or our business. If no securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

We have a substantial number of shares of authorized but unissued capital stock, and if we issue additional shares of our capital stock in the future, our existing stockholders will be diluted.

Our Certificate of Incorporation authorize the issuance of up to 100,000,000 shares of our common stock and up to 50,000,000 shares of preferred stock with the rights, preferences and privileges that our Board of Directors may determine from time to time. As of August 15, 2016, we had 5,070,591 shares of our common stock issued and outstanding, which represents approximately 4.9% of our total authorized shares of common stock. In addition to capital raising activities, which we expect to continue to pursue in order to raise the funding we will need in order to continue our operations, other possible business and financial uses for our authorized capital stock include, without limitation, future stock splits, acquiring other companies, businesses or products in exchange for shares of our capital stock, issuing shares of our capital stock to partners or other collaborators in connection with strategic alliances, attracting and retaining employees by the issuance of additional securities under our equity compensation plans, or other transactions and corporate purposes that our Board of Directors deems are in the best interest of our company. Additionally, shares of our capital stock could be used for anti-takeover purposes or to delay or prevent changes in control or our management. Any future issuances of shares of our capital stock may not be made on favorable terms or at all, they may not enhance stockholder value, they may have rights, preferences and privileges that are superior to those of our common stock, and they may have an adverse effect on our business or the trading price of our common stock. The issuance of any additional shares of our common stock will reduce the book value per share and may contribute to a reduction in the market price of the outstanding shares of our common stock. Additionally, any such issuance will reduce the proportionate ownership and voting power of all of our current stockholders.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan or otherwise, could result in dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and applicable Delaware law may discourage an acquisition of us by others, even if the acquisition may be beneficial to some of our stockholders.

Provisions in our Certificate of Incorporation and Amended and Restated Bylaws, as well as certain provisions of Delaware law, could make it more difficult for a third-party to acquire us, even if doing so may benefit some of our stockholders. These provisions include:

- the authorization of 50,000,000 shares of "blank check" preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval;
- limiting the removal of directors by the stockholders;
- allowing for the creation of a staggered board of directors;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by or beneficial to our stockholders.

Any provision of our Certificate of Incorporation or Bylaws or of Delaware law that is applicable to us that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock in the event that a potentially beneficial acquisition is discouraged, and could also affect the price that some investors are willing to pay for our common stock.

The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Certificate of Incorporation and our Bylaws eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Certificate of Incorporation and our Bylaws and individual indemnification agreements we intend to enter with each of our directors and executive officers provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by the Delaware law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any future payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

There is not now and may not be an active liquid trading market for our publicly traded warrants.

There is no established public trading market for our publicly traded warrants issued in May 2016 and that trade on the OTCQX. There is no assurance that an active trading market will develop or if one develops that it will be maintained. Without an active market, the liquidity of the warrants will remain limited.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

On August 19, 2015, Aytu entered into a 37 month non-cancellable operating lease for new office space effective September 1, 2015. The new lease has initial base rent of $8,500 per month beginning in October 2015, with the total base rent over the term of the lease of approximately $318,000 which includes rent abatements. We have also opened a 1,333 square foot office in Raleigh, North Carolina for which the lease runs until July 31, 2018. We believe our current office space is sufficient to meet our current needs.

We recognize rental expense of the facility on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent.

Item 3. Legal Proceedings

We are currently not party to any material legal or administrative proceedings and are not aware of any material pending or threatened legal or administrative proceedings in which we will become involved.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Data

Our common stock is quoted on the OTCQX under the symbol "AYTU." Prior to December 14, 2015, our common stock was quoted on the OTCQB Market. The following table sets forth the range of bid and asked closing quotations for our common stock on the OTCQX or OTCQB, for the periods shown. The quotations represent inter-dealer prices without retail markup, markdown or commission, and may not necessarily represent actual transactions.

Fiscal Year ended June 30, 2015	High	Low
First Quarter (ended September 30, 2014)	$ 29.40	$ 24.12
Second Quarter (ended December 31, 2014)	$ 27.72	$ 27.72
Third Quarter (ended March 31, 2015)	$ 36.48	$ 23.40
Fourth Quarter (ended June 30, 2015)	$ 141.72	$ 29.16

Fiscal Year ended June 30, 2016	High	Low
First Quarter (ended September 30, 2015)	$ 57.00	$ 55.56
Second Quarter (ended December 31, 2015)	$ 57.00	$ 37.68
Third Quarter (ended March 31, 2016)	$ 42.00	$ 6.72
Fourth Quarter (ended June 30, 2016)	$ 7.32	$ 3.60

On August 15, 2016, the closing price as reported on the OTCQX of our common stock was $3.70. As of August 15, 2016, there were 477 holders of record of our common stock.

Equity Compensation Plan Information

In June 2015, our shareholders approved the adoption of a stock and option award plan (the "2015 Plan"), under which 833,334 shares were reserved for future issuance under restricted stock awards, options, and other equity awards. The 2015 Plan permits grants of equity awards to employees, directors and consultants. The following table displays equity compensation plan information as of June 30, 2016.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)		Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders	322,302	$	18.01	511,032
Equity compensation plans not approved by security holders	162,746	$	4.49	-
Total	485,048	$	13.47	511,032

In connection with our private placement of approximately $4.7 million of common stock in 2013, we were obligated to issue to the placement agent warrants to purchase 8,553 shares of our common stock. The placement agent warrants have a term of five years from the date of issuance and an exercise price of $54.36. In connection with our private placement of approximately $5.2 million of convertible notes in July and August 2015, we were obligated to issue to the placement agents warrants for an amount of shares equal to 8% of the number of shares of our common stock issued upon conversion of the notes and any accrued interest. The placement agents' warrants have a term of five years from the date of issuance of the related notes in July and August 2015, an exercise price equal to 100% of the price per share at which equity securities were sold in our next equity financing, and provide for cashless exercise. Those warrants were not approved by our stockholders. In connection with the conversions of the notes in February 2016 and May 2016, which were triggered by an equity financing in January 2016 and our public offering of common stock and warrants in May 2016, respectively, we issued warrants to the placement agents to purchase an aggregate of 22,254 shares of our common stock at an exercise price of $7.80 per share, and an aggregate of 22,564 shares of our common stock at an exercise price of $4.80 per share. In connection with our May 2016 public offering, we issued warrants to purchase an aggregate of 109,375 shares of common stock at an exercise price of $6.00 to the underwriters of the public offering.

Dividend Policy

We have not paid any cash dividends on our common stock and our Board of Directors presently intends to continue a policy of retaining earnings, if any, for use in our operations. The declaration and payment of dividends in the future, of which there can be no assurance, will be determined by the Board of Directors in light of conditions then existing, including earnings, financial condition, capital requirements and other factors. Delaware law prohibits us from declaring dividends where, if after giving effect to the distribution of the dividend:

- we would not be able to pay our debts as they become due in the usual course of business; or
- our total assets would be less than the sum of our total liabilities plus the amount that would be needed to satisfy the rights of stockholders who have preferential rights superior to those receiving the distribution.

Except as set forth above, there are no restrictions that currently materially limit our ability to pay dividends or which we reasonably believe are likely to limit materially the future payment of dividends on common stock.

Our Board of Directors has the right to authorize the issuance of preferred stock, without further stockholder approval, the holders of which may have preferences over the holders of our common stock as to payment of dividends.

Item 6. Selected Financial Data

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage specialty healthcare company concentrating on developing and commercializing products with an initial focus on urological diseases and conditions. We are currently focused on addressing significant medical needs in the areas of hypogonadism, urological cancers, urinary tract infections and male infertility.

Through a multi-step reverse triangular merger, on April 16, 2015, Vyrix Pharmaceuticals, Inc. (''Vyrix'') and Luoxis Diagnostics, Inc. (''Luoxis'') merged with and into our Company (herein referred to as the Merger) and we abandoned our pre-merger business plans to solely pursue the specialty healthcare market, including the business of Vyrix and Luoxis. In the Merger, we acquired the RedoxSYS, MiOXSYS and Zertane products. On June 8, 2015, we reincorporated as a domestic Delaware corporation under Delaware General Corporate Law and changed our name from Rosewind Corporation to Aytu BioScience, Inc., and effected a reverse stock split in which each common stock holder received one share of common stock for every 12.174 shares outstanding. On June 30, 2016, we effected another reverse stock split in which each common stock holder received one share of common stock for each 12 shares. All share and per share amounts in this report have been adjusted to reflect the effect of these two reverse stock splits (herein referred to collectively as the Reverse Stock Splits).

In May 2015, we entered into an asset purchase agreement with Jazz Pharmaceuticals, Inc., pursuant to which we purchased assets related to Jazz Pharmaceuticals' product known as ProstaScint (capromab pendetide), including certain intellectual property and contracts, and the product approvals, inventory and work in progress (together, the ''ProstaScint Business''), and assumed certain of Jazz Pharmaceuticals' liabilities, including those related to product approvals and the sale and marketing of ProstaScint. The purchase price consisted of the upfront payment of $1.0 million. We also paid an additional $500,000 within five days after transfer for the ProstaScint-related product inventory and $227,000 was paid on September 30, 2015 (which represents a portion of certain FDA fees). We also will pay 8% on net sales made after October 31, 2017, payable up to a maximum aggregate payment of an additional $2.5 million.

In October 2015, we entered into an asset purchase agreement with FSC Laboratories, Inc., or FSC. Pursuant to the agreement, we purchased assets related to FSC's product known as Primsol (trimethoprim solution), including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primsol (together, the ''Primsol Business''), and assumed certain of FSC's liabilities, including those related to the sale and marketing of Primsol arising after the closing. We paid $500,000 at closing for the Primsol Business and we paid an additional $142,000, of which $102,000 went to inventory and $40,000 towards the Primsol Business, for the transfer of the Primsol-related product inventory. We also paid $500,000 on April 1, 2016 and $500,000 on July 1, 2016, and must pay $250,000 no later than September 30, 2016 (together, the ''Installment Payments''), for a total purchase price of $1,892,000.

In October 2015, we and Biovest International, Inc., or Biovest, (whose contract manufacturing business is now known as Cell Culture Company, or C3) entered into a Master Services Agreement, pursuant to which Biovest is to provide manufacturing services to us for our product ProstaScint. The agreement provides that we may engage Biovest from time to time to provide services in accordance with mutually agreed upon project addendums and purchase orders for ProstaScint. We expect to use the agreement from time to time for manufacturing services, including without limitation, the manufacturing, processing, quality control testing, release or storage of ProstaScint. The agreement provides customary terms and conditions, including those for performance of services by Biovest in compliance with project addendums, industry standards, regulatory standards and all applicable laws. Biovest will be responsible for obtaining and maintaining all governmental approvals, at our expense, during the term of the agreement. The agreement has a term of four years, provided that either party may terminate the agreement or any project addendum under the agreement on 30 days written notice of a material breach under the agreement. In addition, we may terminate the agreement or any project addendum under the agreement upon 180 days written notice for any reason.

In April 2016, we entered into a license and supply agreement to acquire the exclusive U.S. rights to Natesto nasal gel from Acerus Pharmaceuticals Corporation, or Acerus, which rights we received on July 1, 2016. We paid Acerus an upfront fee of $2.0 million upon execution of the agreement. On September 5, 2016 we will pay an additional $2.0 million. On January 1, 2017, we will pay an additional $4.0 million. We also purchased on April 28, 2016, an aggregate of 12,245,411 shares of Acerus common stock for Cdn. $2,534,800 (approximately US $2.0 million), with a purchase price per share equal to Cdn. $0.207 or approximately US $0.16 per share. We could not dispose of these shares until after August 29, 2016. We also agreed to make various payments up to an aggregate of $37.5 million based on net sales of Natesto. During the term of the agreement, we will purchase all of our Natesto product needs from Acerus at a designated price.

In May 2016, we sold in an underwritten public offering 1,562,500 shares of our common stock, par value $0.0001 per share, and warrants to purchase up to an aggregate 1,562,500 shares of common stock at a combined public offering price of $4.80 per share and related warrant. Each warrant is exercisable for five years from issuance and has an exercise price equal to $6.00. In addition, we granted the underwriters a 45-day option to purchase up to an additional 234,375 shares of common stock and/or 234,375 additional warrants. The underwriters elected a partial exercise their over-allotment option to purchase 170,822 warrants. The net proceeds from the sale of the shares and warrants was approximately $6.3 million, after deducting underwriting discounts and commissions and estimated offering expenses.

In July 2016, we entered into a purchase agreement (the "Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Upon signing the Purchase Agreement, Lincoln Park agreed to purchase 133,690 shares of our common stock for $500,000 as an initial purchase under the agreement. We also issued as a commitment fee to Lincoln Park of 52,500 shares of common stock.

Under the terms and subject to the conditions of the Purchase Agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to an additional $10.0 million in amounts of shares of our common stock , subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which we agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed.

As of the date of this Report, we have financed operations through a combination of private and public debt and equity financings including net proceeds from the private placements of stock and convertible notes. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, as of the date of this Report, we believe we will have sufficient cash to meet our projected operating requirements for only the next 3 months. See "Liquidity and Capital Resources."

We have only begun to generate revenues from the commercialization of our product candidates in the last fiscal year. We have recognized approximately $2.1 million in revenue from ProstaScint, Primsol and RedoxSYS sales during fiscal 2016. We have incurred accumulated net losses since our inception, and at June 30, 2016, we had an accumulated deficit of $46.6 million. Our net loss was $28.2 million for fiscal 2016 and we used $10.7 million in cash from operations during that year.

Significant Accounting Policies and Estimates

Information regarding our Significant Accounting Policies and Estimates is contained in Note 2 to the Financial Statements.

Newly Issued Accounting Pronouncements

Information regarding the recently issued accounting standards (adopted and not adopted as of June 30, 2016) is contained in Note 2 to the Financial Statements.

Results of Operations—June 30, 2016 Compared to June 30, 2015

Results of operations for the year ended June 30, 2016 ("fiscal 2016") and the year ended June 30, 2015 ("fiscal 2015") reflected losses of approximately $28.2 million and $7.7 million, respectively.

Revenue

Product and service revenue

The total product and service revenue recognized during 2016 was $2.1 million, related to the sale of our products ProstaScint and Primsol, as well as the RedoxSYS and MiOXSYS Systems. The product and service revenue in fiscal 2015 was $176,000 which was from the ProstaScint product and the RedoxSYS System. The increase in product revenue of over 1000% from fiscal 2015 to 2016 is due to our acquisitions of those products, which occurred late in fiscal 2015 and early fiscal 2016, respectively, and expanded marketing of those products.

As is customary in the pharmaceutical industry, our gross product sales are subject to a variety of deductions in arriving at reported net product sales. Provisions for these deductions are recorded concurrently with the recognition of gross product sales revenue and include discounts, chargebacks, distributor fees, processing fees, as well as allowances for returns and Medicaid rebates. Provision balances relating to estimated amounts payable to direct customers are netted against accounts receivable and balances relating to indirect customers are included in accounts payable and accrued liabilities. The provisions recorded to reduce gross product sales and net product sales are as follows:

	Year Ended June 30,	
	2016	2015
Gross product and service revenue	$ 2,657,000	$ 178,000
Provisions to reduce gross product sales to net product and service sales	(606,000)	(2,000)
Net product and service revenue	$ 2,051,000	$ 176,000
Percentage of provisions to gross sales	22.8%	1.1%

License revenue

During fiscal 2016 and fiscal 2015, we recognized $512,000 and $86,000, respectively, in license revenue. In 2012, we received a payment of $500,000 for our license agreement of Zertane with a Korean pharmaceutical company. This payment was deferred and was being recognized over 10 years. In 2014, we received a payment of $250,000 for our license agreement of Zertane with a Canadian-based supplier. This payment was deferred and was being recognized over seven years. At June 30, 2016, Aytu determined that the Zertane asset has no value as Aytu does not have the resources to complete the necessary clinical trials and bring it to market before the patents expire. Therefore, the remaining unamortized deferred revenue of $426,000 which was outstanding as of the date it was determined not to proceed with the clinical trials was recognized as of June 30, 2016.

Expenses

Cost of Sales

The cost of sales of $957,000 and $88,000 recognized for fiscal 2016 and fiscal 2015, respectively, are related to the ProstaScint and Primsol products and the RedoxSYS and MiOXSYS Systems. We expect to see cost of sales to continue to increase in the year ending June 30, 2017 (“fiscal 2017”) as we expect our sales to continue to grow.

Research and Development

Research and development costs consist of clinical trials and sponsored research, manufacture transfer expense, labor, stock-based compensation, sponsored research – related party and consultants and other. These costs relate solely to research and development without an allocation of general and administrative expenses and are summarized as follows:

	Year Ended June 30,	
	2016	2015
Manufacturing tech transfer	$ 3,304,000	$ -
Clinical trials and sponsored research	2,278,000	2,244,000
Labor	427,000	411,000
Stock-based compensation	89,000	517,000
Sponsored research - related party	192,000	204,000
Consultants and other	30,000	47,000
	$ 6,320,000	$ 3,423,000

Comparison of Years Ended June 30, 2016 and 2015

Research and development expenses increased $2.9 million, or 84.6%, in fiscal 2016 over fiscal 2015. This was due primarily to switching our manufacturing process for our ProstaScint product to a new manufacturer, which is still in progress as of June 30, 2016 offset by a $428,000 reduction in stock-based compensation. We expect that the research and development expenses will decrease in fiscal 2017 as compared to fiscal 2016 since the transfer of the ProstaScint manufacturing is almost complete and since we should have no more clinical cost related to Zertane.

General and Administrative

General and administrative expenses consist of personnel costs for employees in executive, business development and operational functions and director fees; stock-based compensation; patents and intellectual property; professional fees including legal, auditing, accounting, investor relations, shareholder expense and printing and filing of SEC reports; occupancy, travel and other including rent, governmental and regulatory compliance, insurance, and professional subscriptions. These costs are summarized as follows:

	Year Ended June 30,	
	2016	2015
Labor	$ 3,684,000	$ 979,000
Stock-based compensation	814,000	500,000
Patent costs	303,000	488,000
Professional fees	1,630,000	1,440,000
Occupancy, travel and other	2,086,000	619,000
Management fee - related party	308,000	311,000
	$ 8,825,000	$ 4,337,000

Comparison of Years Ended June 30, 2016 and 2015

General and administrative costs increased $4.5 million, or 103.5%, in fiscal 2016 over fiscal 2015. The increase in labor costs, stock-based compensation, and occupancy, travel and other primarily relates to increased costs related to the increase in professional staffing during fiscal 2016 as compared to fiscal 2015, bonuses earned, increased travel expense and stock options granted as well as the continuing vesting of stock option awards granted in previous years. We expect general and administrative expenses to increase in fiscal 2017 due to the expected overall growth of our company.

Impairment of Intangible Assets

Impairment of intangible assets was $7.5 million for fiscal 2016 related to the impairment of the Zertane in process research and development (IPRD) (see Note 2). We did not recognize any impairment expense in fiscal 2015.

Amortization of Intangible Assets

Amortization of intangible assets was $665,000 and $45,000 for fiscal 2016 and fiscal 2015, respectively. This expense increased due to the acquisition of the ProstaScint and Primsol businesses in late fiscal 2015 and early fiscal 2016, respectively, and the corresponding amortization of their finite-lived intangible assets. As we continue to license and purchase additional assets as part of our business strategy we would expect this non-cash expense to continue to grow.

Net Cash Used in Operating Activities

During fiscal 2016, our operating activities used $10.7 million in cash. The use of cash was approximately $17.5 million lower than the net loss due primarily to non-cash charges for asset impairment, amortization of the beneficial conversion feature, stock-based compensation, depreciation, amortization and accretion, unrecognized loss on investment, noncash interest expense, amortization of prepaid research and development related party, an increase in accounts payable and accrued liabilities and an increase accrued compensation offset by an increase to inventory and a decrease to deferred revenue.

During fiscal 2015, our operating activities used $6.6 million in cash. The use of cash was approximately $1.1 million lower than the net loss due primarily to non-cash charges for stock-based compensation, depreciation and amortization, amortization of prepaid research and development-related party, an increase in accounts payable and an increase in contingent consideration related to the ProstaScint asset purchase. Cash used in operating activities also included a $24,000 deferred tax benefit and a $607,000 decrease in payable to Ampio.

Net Cash Used in Investing Activities

During fiscal 2016, cash was used to acquire Natesto, Primsol, our investment in Acerus, the purchase of fixed assets as well as the refund of a deposit for office space.

During fiscal 2015, cash was used to acquire ProstaScint as well as deposits for office space.

Net Cash from Financing Activities

Net cash of $16.7 million provided by financing activities during fiscal 2016 was primarily related to our registered public offering of $7.5 million of common stock and warrants offset by issuance costs of $905,000, the issuance of convertible promissory notes which reflects gross proceeds of $5.2 million offset by the cash portion of the debt issuance costs of $298,000, as well as the $5.0 million stock subscription payment from Ampio and $200,000 for a sale of stock subscriptions in January 2016 as well as the issuance costs of $30,000 related to the debt conversion.

Net cash provided by financing activities in fiscal 2015 was $12.4 million which reflects a $7.4 million loan from Ampio which was later converted to stock, a $5.0 million stock subscription payment from Ampio, $27,000 paid out to Luoxis option holders pursuant to the Merger and $20,000 paid out for liabilities pursuant to the Merger.

Contractual Obligations and Commitments

Information regarding our Contractual Obligations and Commitments is contained in Note 7 to the Financial Statements.

Liquidity and Capital Resources

We are a relatively young company and we have not yet generated substantial revenue as our primary activities are focused on commercializing our approved products, acquiring products and developing our product candidates, and raising capital. As of June 30, 2016, we had cash and cash equivalents totaling $8.1 million available to fund our operations offset by an aggregate of $8.9 million in accounts payable and accrued liabilities and the Natesto payables. In April 2016, we spent $2.0 million for the Natesto licensing agreement and approximately $2.0 million to purchase 12,245,411 shares of Acerus common stock. We have a remaining commitment of $6.0 million during fiscal year 2017. In May 2016, we completed a registered public offering of common stock and warrants for $6.3 million in proceeds, net of expenses. Based upon our resources at June 30, 2016, and assuming we can access the $10.0 million purchase agreement with Lincoln Park Capital entered into in July 2016, we believe we have adequate capital to continue operations into the second quarter of fiscal 2017. We intend to raise up to an additional $12.5 million in fiscal 2017, which, if successful, we believe would provide adequate capital to continue operations through fiscal 2017 and into 2018. We also intend to seek additional capital within the next 12 months to help acquire new products as well as to support general operations. We will evaluate the capital markets from time to time to determine when to raise additional capital in the form of equity, convertible debt or other financing instruments, depending on market conditions relative to our need for funds at such time. We will seek to raise additional capital at such time as we conclude that such capital is available on terms that we consider to be in the best interests of our Company and our stockholders.

We have prepared a budget for fiscal 2017 which reflects cash requirements from operations of approximately $3.0 million per quarter. Depending on the availability of capital, we may expend additional funds for the purchase of assets and commercialization of products. Accordingly, it may be necessary to raise additional capital and/or enter into licensing or collaboration agreements. At this time, we expect to satisfy our future cash needs through private or public sales of our securities or debt financings. We cannot be certain that financing will be available to us on acceptable terms, or at all. Over the last three years, including recently, volatility in the financial markets has adversely affected the market capitalizations of many bioscience companies and generally made equity and debt financing more difficult to obtain. This volatility, coupled with other factors, may limit our access to additional financing.

If we cannot raise adequate additional capital in the future when we require it, we could be required to delay, reduce the scope of, or eliminate one or more of our commercialization efforts or our research or development programs. We also may be required to relinquish greater or all rights to product candidates at less favorable terms than we would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

Going Concern

The continuation of our business is dependent upon obtaining further financing and achieving a break even or profitable level of operations in our business. The issuance of additional equity securities by us could result in a significant dilution in the equity interests of our current or future stockholders. Obtaining commercial loans, assuming those loans would be available, will increase our liabilities and future cash commitments. There are no assurances that we will be able to obtain additional financing through private placements and/or bank financing or other means necessary to support our working capital requirements. To the extent that funds generated from operations and any private placements, public offerings and/or bank financing are insufficient, we will have to raise additional working capital. No assurance can be given that additional financing will be available, or if available, will be on terms acceptable to us. These conditions raise substantial doubt about our ability to continue as a going concern.

Off Balance Sheet Arrangements

We do not have off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as “variable interest entities.”

Impact of Inflation

In general, we believe that our operating expenses can be negatively impacted by increases in the cost of clinical trials due to inflation and rising health care costs.

Item 7A. Quantitative and Qualitative Disclosures about Market Risks

Not applicable.

Item 8. Financial Statements and Supplementary Data

The financial statements required by this item are identified in Item (a)(1) of Part IV and begin at page F-1 of this Annual Report on Form 10-K and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management is responsible for establishing and maintaining adequate "disclosure controls and procedures," as such term is defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act"), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Our management has concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to provide the reasonable assurance discussed above.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of June 30, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework (2013)*. Our management has concluded that, as of June 30, 2016, our internal control over financial reporting is effective based on these criteria.

EKS&H LLLP, the independent registered public accounting firm that audited our financial statements included in this Annual Report on Form 10-K, was not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

During the fiscal year ended June 30, 2016, we designed and implemented our internal controls over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers, and Corporate Governance

The following table sets forth the names and ages of all of our directors and executive officers as of August 31, 2016. Our Board of Directors is currently comprised of five members, who are elected annually to serve for one year or until their successor is duly elected and qualified, or until their earlier resignation or removal. Executive officers serve at the discretion of the Board of Directors and are appointed by the Board of Directors.

Name	Age	Position
Joshua R. Disbrow	41	Chief Executive Officer and Director
Jarrett T. Disbrow	41	Chief Operating Officer
Gregory A. Gould	50	Chief Financial Officer, Secretary, and Treasurer
Jonathan H. McGrael	46	Vice President of Commercial Operations
Michael Macaluso	64	Director
Carl C. Dockery	53	Director
John A. Donofrio, Jr.	49	Director
Gary V. Cantrell	61	Director

The following is a biographical summary of the experience of our executive officers and directors during the past five years, and an indication of directorships held by the director in other companies subject to the reporting requirements under the federal securities law.

Joshua R. Disbrow – Chairman and Chief Executive Officer

Joshua R. Disbrow has been employed by us since April 16, 2015. Prior to the closing of the Merger, Mr. Disbrow was the Chief Executive Officer of Luoxis since January 2013. Mr. Disbrow was also the Chief Operating Officer of Ampio since December 2012. Prior to joining Ampio, he served as the Vice President of Commercial Operations at Arbor Pharmaceuticals, a specialty pharmaceutical company, from May 2007 through October 2012. He joined Arbor as that company's second full-time employee. Mr. Disbrow led the company's commercial efforts from inception to the company's acquisition in 2010 and growth to over $127 million in net sales in 2011. By the time Mr. Disbrow departed Arbor in late 2012, he had led the growth of the commercial organization to comprise over 150 people in sales, marketing sales training, managed care, national accounts, and other commercial functions. Mr. Disbrow has spent over 17 years in the pharmaceutical, diagnostic and medical device industries and has held positions of increasing responsibility in sales, marketing, sales management, commercial operations and commercial strategy. Prior to joining Arbor, Mr. Disbrow served as Regional Sales Manager with Cyberonics, Inc., a medical device company focused on neuromodulation therapies from June 2005 through April 2007. Prior to joining Cyberonics he was the Director of Marketing at LipoScience, an in vitro diagnostics company. Mr. Disbrow holds an MBA from Wake Forest University and BS in Management from North Carolina State University. Mr. Disbrow's experience in executive management and marketing within the pharmaceutical industry, monetizing company opportunities, and corporate finance led to the conclusion that he should serve as a director of our Company in light of our business and structure.

Gary V. Cantrell – Director

Gary Cantrell joined our Board in July 2016. He has 30 years of experience in the life sciences industry ranging from clinical experience as a respiratory therapist to his current exclusive consulting role with Mayne Pharma (ASX: MYX) as Business Development Executive focused on acquiring branded prescription assets for Mayne's U.S. Specialty Brands Division. Mr. Cantrell served as CEO of Yasoo Health Inc., a global specialty nutritional company from 2007 through June 2016, highlighted by the sale of its majority asset AquADEKs to Actavis in March 2016. Previously, he was President of The Catevo Group, a U.S.-based healthcare consulting firm. Prior to that, he was Executive Vice President, Sales and Marketing for TEAMM Pharmaceuticals, an Accentia Biopharmaceuticals company, where he led all commercial activities for a public specialty pharmaceutical business. His previous 22 years were at GlaxoSmithKline plc where he held progressively senior management positions in sales, marketing and business development. Mr. Cantrell is a graduate of Wichita State University and serves as an advisor to several emerging life science companies. He served as a director for Yasoo Health Inc., Yasoo Health Limited and Flexible Stenting Solutions, Inc., a leading developer of next generation peripheral arterial, venous, neurovascular and biliary stents, which was sold to Cordis, while a Division of Johnson & Johnson in March 2013. Mr. Cantrell served as a director of Vyrix Pharmaceuticals from February 2014 to April 2015.Mr. Cantrell's experience in consulting and executive management within the pharmaceutical industry led to the conclusion that he should serve as a director of our company in light of our business and structure.

Carl C. Dockery – Director

Carl Dockery joined our Board in April 2016. Mr. Dockery is a financial executive with 30 years of experience as an executive in the insurance and reinsurance industry and more recently in 2006 as the founder and president of a registered investment advisory firm, Alpha Advisors, LLC. Mr. Dockery's career as an insurance executive began in 1988 as an officer and director of two related and closely held insurance companies, including serving as secretary of Crossroads Insurance Co. Ltd. of Bermuda and as vice president of Gulf Insurance Co. Ltd. of Grand Cayman. Familiar with the London reinsurance market, in the 1990s, Mr. Dockery worked at Lloyd's and the London Underwriting Centre brokering various types of reinsurance placements. Mr. Dockery serves as a director of CytoDyn Inc. (OTCQB: "CYDY"), a biotechnology company. Mr. Dockery graduated from Southeastern University with a Bachelor of Arts in Humanities. Mr. Dockery's financial expertise and experience, as well as his experience as a director of a publicly traded biopharmaceutical company, led to the conclusion that he should serve as a director of our company in light of our business and structure.

John A. Donofrio, Jr. – Director

John Donofrio joined our Board in July 2016. He is a Senior Finance Executive with 24 years of experience in the pharmaceutical industry across a broad range of areas, including consolidated financial reporting, international accounting and internal controls, financial systems development and implementation, cost accounting, inventory management, supply chain, transfer pricing, budget and forecast planning, integration of mergers and acquisitions and business development. He has served as the Chief Financial Officer and Head of North American Business Development for Merz North America, or Merz, since August 2013. Merz is a specialty healthcare company that develops and commercializes innovative treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. At Merz, Mr. Donofrio is accountable for financial performance, cost management, business development and strategic business planning and analysis for the finance organization in North America. Prior to joining Merz, Mr. Donofrio served as Vice President, Stiefel Global Finance, U.S. Specialty Business and Puerto Rico for Stiefel, a GlaxoSmithKline plc company from July 2009 to July 2013. In that role, Mr. Donofrio was responsible for the financial strategy, management reporting, and overall control framework for the Global Dermatology Business Unit. He was also the Senior Finance Partner accountable for the U.S. Specialty Business Units of GlaxoSmithKline plc. Mr. Donofrio served as a director of Vyrix Pharmaceuticals from February 2014 to April 2015. Mr. Donofrio holds a degree in Accounting from North Carolina State University. Mr. Donofrio's financial expertise and experience in the pharmaceutical industry, led to the conclusion that he should serve as a director of our company in light of our business and structure.

Michael Macaluso – Director

Michael Macaluso has been a member of our Board of Directors since April 2015. Mr. Macaluso is also the Chairman and Chief Executive Officer of Ampio. Mr. Macaluso has been a member of Ampio Pharmaceuticals' Board of Directors since March 2010 and Ampio's Chief Executive Officer since January 2012. Mr. Macaluso served in the roles of president and Chief Executive Officer of Isolagen, Inc. (AMEX: ILE) from June 2001 until September 2004. Mr. Macaluso also served on the board of directors of Isolagen from June 2001 until April 2005. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997, when he sold that business to a private equity firm. Mr. Macaluso's experience in executive management and marketing within the pharmaceutical industry, monetizing company opportunities, and corporate finance led to the conclusion that he should serve as a director of our company in light of our business and structure.

Jarrett T. Disbrow – Chief Operating Officer

Jarrett Disbrow has been employed by us since April 16, 2015. Prior to the closing of the Merger, Mr. Disbrow was the Chief Executive Officer of Vyrix from November 2013. Mr. Disbrow joined Vyrix from Eurus Pharma LLC, or Eurus Pharma, where he held the position of general manager from 2011 to 2013. Prior to joining Eurus Pharma, Mr. Disbrow was the founder, president and chief executive officer of Arbor Pharmaceuticals, Inc., or Arbor Pharmaceuticals from 2006 to 2010. Following Arbor Pharmaceuticals' acquisition in 2010, Mr. Disbrow remained with the company as vice president of commercial development. Prior to founding Arbor Pharmaceuticals in 2006, he was head of marketing for Accentia Biopharmaceuticals, Inc. from 2002 to 2006. Mr. Disbrow began his career with GlaxoWellcome, Inc. (now GlaxoSmithKline plc) from 1997 to 2001, where he held positions of increasing responsibility in sales and later marketing. Mr. Disbrow received a BS in business management from North Carolina State University in Raleigh, NC. Mr. Disbrow served on our Board of Directors from April 2015 to July 2016.

Gregory A. Gould – Chief Financial Officer, Secretary, and Treasurer

Gregory A. Gould has been our Chief Financial Officer since April 16, 2015. Mr. Gould is also the Chief Financial Officer of Ampio where he has been employed since June 2014. Prior to joining Ampio, 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 $855 million. 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 anti-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.

Jonathan H. McGrael – Vice President of Commercial Operations

Jonathan McGrael joined us on September 30, 2015 as Vice President of Sales and in May 2016 became our Vice President of Commercial Operations. Mr. McGrael has spent 17 years in the pharmaceutical industry and has held positions of increasing responsibility in sales, sales training, marketing, sales management, and leadership development. Until September 15, 2015, he was Director of Sales at Arbor Pharmaceuticals, which he joined in 2010 as that 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.

Family Relationships

Jarrett T. Disbrow, our Chief Operating Officer, is the brother of Joshua R. Disbrow, our Chief Executive Officer and a director. There are no other family relationships among or between any of our current or former executive officers and directors.

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any legal proceeding in the past 10 years that would require disclosure under Item 401(f) of Regulation S-K promulgated under the Securities Act.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our officers and directors and persons who own more than 10% of our outstanding common stock to file reports of ownership and changes in ownership with the Securities and Exchange Commission. These officers, directors and stockholders are required by regulations under the Securities Exchange Act to furnish us with copies of all forms they file under Section 16(a).

Based solely on our review of the copies of forms we have received, we believe that all such required reports have been timely filed, except for the following: a Form 4 for each of Joshua Disbrow, Jarrett Disbrow and Carl Dockery to report the purchase of shares of our common stock in our May 2016 public offering, which reports were due on May 10, 2016, and were filed on May 16, 2016.

Code of Ethics

The information required by this Item regarding our Code of Ethics is found in Part I, Item 1, under the caption “Code of Ethics.”

Board Committees

Our Board has established an Audit Committee, Compensation Committee and Nominating and Governance Committee. Our Audit Committee consists of Mr. Donofrio (Chair), Mr. Cantrell and Mr. Dockery. Our Compensation Committee consists of Mr. Cantrell (Chair), Mr. Dockery and Mr. Donofrio. Our Nominating and Governance Committee consists of Mr. Dockery (Chair), Mr. Cantrell and Mr. Donofrio. The independence of our directors is discussed in Part III, Item 13 under the caption “Director Independence.”

Each of the above-referenced committees operates pursuant to a formal written charter. The charters for these committees, which have been adopted by our Board, contain a detailed description of the respective committee’s duties and responsibilities and are available on our website at http://aytubio.com under the “Investor Relations—Corporate Governance” tab.

Our Board has determined Mr. Donofrio qualifies as an audit committee financial expert, as defined in Item 407(d)(5) of Regulation S-K promulgated by the SEC.

Stockholder Proposals

Our bylaws establish procedures for stockholder nominations for elections of directors and bringing business before any annual meeting or special meeting of stockholders. A stockholder entitled to vote in the election of directors may nominate one or more persons for election as directors at a meeting only if written notice of such stockholder’s intent to make such nomination or nominations has been delivered to our Corporate Secretary at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary of the prior year’s annual meeting. In the event that the date of the annual meeting is more than 30 days before or more than 60 days after the anniversary date of the prior year’s annual meeting, the stockholder notice must be given not more than 120 days nor less than the later of 90 days prior to the date of the annual meeting or, if it is later, the 10^{th} day following the date on which the date of the annual meeting is first publicly announced or disclosed by us. These notice deadlines are the same as those required by the SEC’s Rule 14a-8.

Pursuant to the bylaws, a stockholder’s notice must set forth among other things: (a) as to each person whom the stockholder proposes to nominate for election or reelection as a director all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules and regulations thereunder; and (b) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made.

There have been no changes to these nominating procedures since the adoption of the bylaws.

Item 11. Executive Compensation

Executive Compensation

In accordance with Item 402 of Regulation S-K promulgated by the SEC, we are required to disclose certain information regarding the makeup of and compensation for our company's directors and named executive officers. On April 16, 2015, we acquired Luoxis and Vyrix in the Merger. Because for certain periods some of our named executive officers were, prior to the Merger on April 16, 2015, employed by Luoxis and Vyrix, we are providing past compensation information concerning such executive officers with respect to Luoxis and Vyrix.

In establishing executive compensation, our Board is guided by the following goals:

- compensation should consist of a combination of cash and equity awards that are designed to fairly pay the executive officers and directors for work required for a company of our size and scope;
- compensation should align the executive officers' and directors' interests with the long-term interests of stockholders; and
- compensation should assist with attracting and retaining qualified executive officers and directors.

Compensation of Directors

Our current compensation package for non-employee directors, effective July 1, 2017, consists of: an annual cash retainer of $40,000 for the board chair, $25,000 for each other director, $10,000 for each committee chair and $5,000 for each other committee member; a grant of 65,000 restricted shares of stock upon appointment to the board; and an annual stock option grant of 15,000 shares thereafter. In April 2016, we prorated for the last quarter of fiscal 2016 the annual cash retainer (amounting to $6,250) and also made the annual grant of 100,000 stock options to our then two non-employee directors. Prior to April 1, 2016, we paid no cash compensation and made no annual stock option grants. We also reimburse directors for expenses incurred in connection with their service as director.

The following table provides information regarding all compensation paid to non-employee directors of Aytu during the fiscal year ended June 30, 2016.

Name	Fees Earned or Paid in Cash	Stock Option Awards[1]	All Other Compensation	Total
Michael Macaluso[2]	$ 6,250	$ 34,169	$ —	$ 40,419
Carl C. Dockery[2]	$ 6,250	$ 34,169	$ —	$ 40,419
Gary V. Cantrell[2] [3]	$ —	$ —	$ —	$ —
John A. Donofrio Jr[2] [3]	$ —	$ —	$ —	$ —

(1) This column reflects the aggregate grant date fair value computed in accordance with Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASC, Topic 718.

(2) As of June 30, 2016, the number of shares underlying options held by each non-employee director was as follows: 18,750 shares for Mr. Macaluso; 8,334 shares for Mr. Dockery; none for Mr. Cantrell; and none for Mr. Donofrio. The options held by Mr. Macaluso and Mr. Dockery were cancelled on July 7, 2016.

(3) Gary V. Cantrell and John A. Donofrio Jr. were each appointed a director in July 2016 and therefore received no compensation or equity awards from Aytu in the fiscal year ended June 30, 2016.

Executive Officer Compensation

The following table sets forth all cash compensation earned, as well as certain other compensation paid or accrued for the years ended June 30, 2016 and 2015 to each of the following named executive officers.

Name and Principal Position (a)	Year (b)	Salary ($) (c)	Bonus ($) (d)	Stock Award ($) (e)	Option Award ($)(1) (f)	Non-Equity Incentive Plan Compensation ($) (g)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($) (h)	All Other Compensation ($) (i)	Total ($) (j)
Named Exective Officers									
Joshua R. Disbrow (2)									
Chief Executive Officer	2016	250,000	312,500	-	559,000	-	-	-	1,121,500
since December 2012	2015	246,000	202,500	-	198,000	-	-	7,045(3)	653,545
Jarrett T. Disbrow (4)									
Chief Operating Officer, Secretary and Treasurer	2016	250,000	287,500	-	559,000	-	-	-	1,096,500
	2015	218,000	5,000	-	-	-	-	-	223,000
Gregory A. Gould (5)									
Chief Financial Officer	2016	-	250,000	-	-	-	-	-	250,000
since June 2014	2015	-	-	-	66,000	-	-	-	66,000
Jonathan H. McGrael (6)									
VP of Commercial Operations	2016	140,417	237,737	-	186,337	-	-	13,233(7)	577,724
	2015	-	-	-	-	-	-	-	-

(1) Option awards are reported at fair value at the date of grant. See Item 15 of Part IV, “Notes to the Financial Statements — Note 10 — Equity Instruments.” Pre-Merger option awards made in August 2014 to Josh Disbrow and Greg Gould were cancelled in April 2015 and the expenses were reversed.

(2) Joshua R. Disbrow received a salary increase to $250,000 effective April 16, 2015 when he was appointed Chief Executive Officer of Aytu.

(3) This was a cash payout of in-the-money options issued to Mr. Disbrow by Luoxis, which options were cashed out in the Merger.

(4) Jarrett T. Disbrow received a salary increase to $250,000 effective April 16, 2015 when he was appointed Chief Operating Officer of Aytu.

(5) Mr. Gould was appointed to Chief Financial Officer, Secretary and Treasurer effective April 16, 2015. His compensation expense is part of the shared service agreement with Ampio.

(6) Mr. McGrael was hired on September 16, 2015 and his annual salary was increased on May 15, 2016 from $175,000 to $190,000.

(7) Represents reimbursed relocation expenses.

Our executive officers are reimbursed by us for any out-of-pocket expenses incurred in connection with activities conducted on our behalf. Executives are reimbursed for business expenses directly related to Aytu business activities, such as travel, primarily for business development as we grow and expand our product lines. On average, each executive incurs between $1,000 to $3,000 of out-of-pocket business expenses each month. The executive management team meets weekly and determines which activities they will work on based upon what we determine will be the most beneficial to our company and our shareholders. No interest is paid on amounts reimbursed to the executives.

During the fiscal years ended June 30, 2016 and 2015, no compensation was earned by or paid to James B. Wiegand, the former President, Chief Financial Officer and Secretary of Rosewind, who resigned all positions with our company upon the completion of the Merger on April 16, 2015.

Grants of Plan-Based Awards

The following table sets forth certain information regarding grants of plan-based awards to the Named Executive Officers during the year ended June 30, 2016:

Name	Grant Date	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise Price of Option Awards ($/Share)	Grant Date Fair Value of Option Awards ($)(1)
Named Exective Officers				
Joshua R Disbrow	11/11/2015	50,000	$ 18.12	$ 559,000
Jarrett T Disborw	11/11/2015	50,000	$ 18.12	$ 559,000
Gregory A Gould	11/11/2015	20,834	$ 18.12	$ -(2)
Jonathan H McGrael	11/11/2015	16,667	$ 18.12	$ 186,337

(1) The amounts reported in this column represent the aggregate grant date fair value computed in accordance with FASB ASC 718, excluding the effect of any estimated forfeitures and may not correspond to the actual value that will be realized by the named executive officer.

(2) The fair value of this award was recognized by Ampio Pharmaceuticals as at the date of grant, Ampio was the parent company and in accordance with GAAP, since Mr. Gould is still an Ampio employee, it was appropriate for Ampio to recognize the expense.

Outstanding Equity Awards at Fiscal Year-End 2016

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2016.

	Option Awards				
Name (a)	Number of Securities Underlying Unexercised Options Exercisable (#) (b)	Number of Securities Underlying Unexercised Options Unexercisable (#) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#) (d)	Option Exercise Price ($) (e)	Option Expiration Date (f)
Named Exective Officers					
Joshua R. Disbrow	-	50,000	-	$ 18.12	11/11/2025
Jarrett T. Disbrow	-	50,000	-	$ 18.12	11/11/2025
Gregory A. Gould	20,834	-	-	$ 18.12	11/11/2025
Jonathan H. McGrael	-	16,667	-	$ 18.12	11/11/2025

Employment Agreements

We entered into an employment agreement with Joshua Disbrow in connection with his employment as our Chief Executive Officer. The agreement is for a term of 24 months beginning on April 16, 2015, subject to termination by us with or without Cause or as a result of officer's disability, or by the officer with or without Good Reason (as discussed below). Mr. Disbrow is entitled to receive $250,000 in annual salary, plus a discretionary performance bonus with a target of 125% of his base salary. Mr. Disbrow is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans.

We entered into an employment agreement with Jarrett Disbrow, our Chief Operating Officer, in connection with his employment with us. The agreement is for a term of 24 months beginning on April 16, 2015, subject to termination by us with or without Cause or as a result of the officer's disability, or by the officer with or without Good Reason (as discussed below). Mr. Disbrow is entitled to receive $250,000 in annual salary, plus a discretionary performance bonus with a target of 125% of his base salary. Mr. Disbrow is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans.

In September 2015, we entered into an employment agreement with Jonathan McGrael, our Vice President of Sales, in connection with his employment with us. The agreement is at will, subject to termination by us with or without Cause or as a result of the officer's disability, or by the officer with or without Good Reason (as discussed below). Mr. McGrael is entitled to receive $175,000 in annual salary, plus a discretionary performance bonus with a target of 43% of his base salary. Mr. McGrael will also receive up to $20,000 for relocation reimbursement. Mr. McGrael is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans. On May 15, 2016, we amended Mr. McGrael's contract to increase his salary to $190,000 and to name him our Vice President of Commercial Operations.

Payments Provided Upon Termination for Good Reason or Without Cause

Pursuant to the employment agreements, in the event Joshua Disbrow's or Jarrett Disbrow's employment is terminated without Cause by us or either officer terminates his employment with Good Reason, we will be obligated to pay him any accrued compensation and a lump sum payment equal to two times his base salary in effect at the date of termination, as well as continued participation in the health and welfare plans for up to two years. All vested stock options shall remain exercisable from the date of termination until the expiration date of the applicable award. So long as a Change in Control is not in effect, then all options which are unvested at the date of termination Without Cause or for Good Reason shall be accelerated as of the date of termination such that the number of option shares equal to $1/24^{th}$ the number of option shares multiplied by the number of full months of such officer's employment shall be deemed vested and immediately exercisable by the officer. Any unvested options over and above the foregoing shall be cancelled and of no further force or effect, and shall not be exercisable by such officer.

"Good Reason" with respect to the agreements with Joshua Disbrow and Jarrett Disbrow, means, without the officer's written consent, there is:

- a material reduction in the officer's overall responsibilities or authority, or scope of duties (it being understood that the occurrence of a Change in Control shall not, by itself, necessarily constitute a reduction in the officer's responsibilities or authority);
- a material reduction of the level of the officer's compensation (excluding any bonuses) (except where there is a general reduction applicable to the management team generally, provided, however, that in no case may the base salary be reduced below certain specified amounts); or
- a material change in the principal geographic location at which the officer must perform his services.

"Cause" with respect to the agreements with Joshua Disbrow and Jarrett Disbrow, means:

- conviction of, or entry of a plea of guilty to, or entry of a plea of nolo contendere with respect to, any crime, other than a traffic violation which is a misdemeanor;
- willful malfeasance or willful misconduct by the officer in connection with his employment;
- gross negligence in performing any of his duties;
- willful and deliberate violation of any of our policies;
- unintended but material breach of any written policy applicable to all employees adopted by us which is not cured to the reasonable satisfaction of the board;
- unauthorized use or disclosure of any proprietary information or trade secrets of us or any other party as to which the officer owes an obligation of nondisclosure as a result of the officer's relationship with us;
- willful and deliberate breach of his obligations under the employment agreement; or
- any other material breach by officer of any of his obligations which is not cured to the reasonable satisfaction of the board.

In the case of Mr. McGrael's termination without Cause or with Good Reason, we will be obligated to pay him any accrued compensation and continue his salary for six months. In addition, all unvested options will receive accelerated vesting in full.

"Good Reason" with respect to the agreement with Mr. McGrael, means, without the officer's written consent, there is:

- a material reduction in the officer's overall responsibilities or authority, or scope of duties;
- a material reduction of the level of the officer's compensation (excluding any bonuses) (except where there is a general reduction applicable to the management team generally, provided, however, that in no case may the base salary be reduced below certain specified amounts); or
- the Company's material breach of the employment agreement.

"Cause" with respect to the agreement with Mr. McGrael means:

- conviction of, or entry of a plea of guilty to, or entry of a plea of nolo contendere with respect to, a felony or misdemeanor involving moral turpitude;
- willful malfeasance or willful misconduct by the officer in connection with his employment;
- gross negligence in performing any of his duties;
- material failure to comply with our workplace rules, policies or procedures which is not cured within fifteen days of written notice;
- material breach of our Proprietary Information and Inventions Agreement;
- material breach of the employment agreement which is not cured within fifteen days of written notice;
- unauthorized use or disclosure of any proprietary information or trade secrets of us or any other party as to which the officer owes an obligation of nondisclosure as a result of the officer's relationship with us; or
- willful failure or refusal to perform his material duties under the employment agreement or failure to follow any specific lawful instructions of the Chief Executive Officer or his designee which is not cured within fifteen days of written notice.

The severance benefits described above are contingent on each officer executing a general release of claims.

Payments Provided Upon a Change in Control

Pursuant to the employment agreements for Joshua Disbrow and Jarrett Disbrow, in the event of a Change in Control of us, all stock options, restricted stock and other stock-based grants granted or may be granted in the future by us to the officers will immediately vest and become exercisable.

"Change in Control" means: the occurrence of any of the following events:

- the acquisition by any individual, entity, or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (the "Acquiring Person"), other than us, or any of our Subsidiaries, of beneficial ownership (within the meaning of Rule 13d-3- promulgated under the Exchange Act) of 50% or more of the combined voting power or economic interests of the then outstanding voting securities of us entitled to vote generally in the election of directors (excluding any issuance of securities by us in a transaction or series of transactions made principally for bona fide equity financing purposes); or
- the acquisition of us by another entity by means of any transaction or series of related transactions to which we are party (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any issuance of securities by us in a transaction or series of transactions made principally for bona fide equity financing purposes) other than a transaction or series of related transactions in which the holders of the voting securities of us outstanding immediately prior to such transaction or series of related transactions retain, immediately after such transaction or series of related transactions, as a result of shares in us held by such holders prior to such transaction or series of related transactions, at least a majority of the total voting power represented by the outstanding voting securities of us or such other surviving or resulting entity (or if we or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent); or
- the sale or other disposition of all or substantially all of the assets of us in one transaction or series of related transactions.

Our only obligation to Joshua Disbrow and Jarrett Disbrow had a Change in Control occurred as of June 30, 2016, would be the acceleration of the vesting of all options held by them at that date. On June 30, 2016, the closing price of our common stock was below the exercise price for all of the options held by Joshua Disbrow and Jarrett Disbrow and therefore there would have been no economic benefit to them upon the acceleration of vesting of those options.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth information with respect to the beneficial ownership of our common stock as of August 15, 2016 for:

- each beneficial owner of more than 5% of our outstanding common stock;
- each of our director and named executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include common stock that can be acquired within 60 days of August 15, 2016. The percentage ownership information shown in the table is based upon 5,070,591 shares of common stock outstanding as of August 15, 2016.

Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options and warrants held by that person that are immediately exercisable or exercisable within 60 days of August 15, 2016. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The information in the table below is based on information known to us or ascertained by us from public filings made by the stockholders. Except as otherwise indicated in the table below, addresses of the director, executive officers and named beneficial owners are in care of Aytu BioScience, Inc., 373 Inverness Parkway, Suite 206, Englewood, Colorado 80112.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders:		
Alpha Venture Capital Partners, L.P. [1]	837,300	16.5%
Directors and Named Executive Officers:		
Joshua R. Disbrow [2]	296,863	5.8%
Jarrett T. Disbrow [3]	267,673	5.3%
Gregory A. Gould [4]	227,733	4.5%
Jonathan H. McGrael [5]	140,000	2.8%
Michael Macaluso [6]	119,156	2.3%
Carl C. Dockery [7]	912,301	16.6%
John Donofrio [8]	68,750	1.4%
Gary Cantrell [9]	72,500	1.4%
All directors and executive officers as a group (eight persons)	2,104,976	37.6%

* Represents beneficial ownership of less than 1%.

(1) Carl C. Dockery is the President of the general partner of Alpha Venture Capital Partners, L.P. and therefore may be deemed to beneficially own the shares beneficially owned by Alpha Venture Capital Partners, L.P. The address of Alpha Venture Capital Partners, L.P. is 2026 Crystal Wood Drive, Lakeland, Florida 33801. For securities beneficially owned by Alpha Venture Capital Partners, L.P., see footnote 7.

(2) Consists of (i) 86,029 shares, (ii) 190,000 restricted shares and (iii) 20,834 shares issuable upon the exercise warrants. Does not include 46,548 shares held by an irrevocable trust for estate planning in which Mr. Disbrow is a beneficiary. Mr. Disbrow does not have or share investment control over the shares held by the trust, Mr. Disbrow is not the trustee of the trust (nor is any member of Mr. Disbrow's immediate family) and Mr. Disbrow does not have or share the power to revoke the trust. As such, under Rule 16a-8(b) and related rules, Mr. Disbrow does not have beneficial ownership over the shares purchased and held by the trust.

(3) Consists of (i) 81,839 shares, (ii) 190,000 restricted shares and (iii) 20,834 shares issuable upon the exercise warrants. Does not include 46,548 shares held by an irrevocable trust for estate planning in which Mr. Disbrow is a beneficiary. Mr. Disbrow does not have or share investment control over the shares held by the trust, Mr. Disbrow is not the trustee of the trust (nor is any member of Mr. Disbrow's immediate family) and Mr. Disbrow does not have or share the power to revoke the trust. As such, under Rule 16a-8(b) and related rules, Mr. Disbrow does not have beneficial ownership over the shares purchased and held by the trust.

(4) Consists of (i) 41,899 shares, (ii) 165,000 restricted shares, and (iii) vested options to purchase 20,834 shares of common stock.

(5) Consists of 140,000 restricted shares.

(6) Consists of (i) 29,780 shares, (ii) 65,000 restricted shares, and (iii) vested options to purchase 24,376 shares of common stock.

(7) Consists of (i) 65,000 restricted shares, (ii) vested options to purchase 10,001 shares of common stock, (iii) 420,633 shares held by Alpha Venture Capital Partners, L.P and (iv) 416,667 shares issuable upon the exercise warrants held by Alpha Venture Capital Partners, L.P. Mr. Dockery is the President of the general partner of Alpha Venture Capital Partners, L.P. and therefore may be deemed to beneficially own the shares beneficially owned by Alpha Venture Capital Partners, L.P.

(8) Consists of (i) 65,000 restricted shares, and (ii) vested options to purchase 3,750 shares of common stock.

(9) Consists of (i) 65,000 restricted shares, (ii) 3,750 shares issuable upon the exercise of warrants, and (iii) vested options to purchase 3,750 shares of common stock.

Information regarding our equity compensation plans is contained in Part II, Item 5.

Item 13. Certain Relationships, Related Transactions, and Director Independence

Related Party Transactions

We describe below all transactions and series of similar transactions, other than compensation arrangements, during the last three fiscal years, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Merger

On April 16, 2015, pursuant to the Merger Agreement entered into among Rosewind, Luoxis, Vyrix and two subsidiaries of Rosewind created solely for the purposes of the Merger, and which did not survive the Merger, the Merger occurred in two stages.

In the first stage, each of Vyrix and Luoxis merged with one of Rosewind's merger subsidiaries. Vyrix and Luoxis survived these mergers. The outstanding shares of stock of Vyrix and the outstanding shares of stock of Luoxis were converted into the right to receive shares of our common stock. The Vyrix stock and the Luoxis stock were each converted at an exchange factor. The exchange factor for each of them was determined upon the basis of a relative value opinion obtained by Ampio, the parent company of Vyrix and Luoxis. The outstanding shares of Rosewind's merger subsidiary that merged with Vyrix were converted into shares of Vyrix as the surviving corporation. The outstanding shares of Rosewind's merger subsidiary that merged with Luoxis were converted into shares of Luoxis as the surviving corporation. After completion of the first stage, Vyrix and Luoxis became subsidiaries of Rosewind.

In the second stage, which occurred on the same day as the first stage, each of Vyrix and Luoxis merged with Rosewind with Rosewind surviving. The first and second stage mergers are referred to collectively as the "Merger."

Concurrently with the Merger:

- Ampio purchased 4,761,787 shares of our common stock for (i) issuance to Rosewind of a promissory note of Ampio in the principal amount of $10,000,000, maturing on the first anniversary of the Merger; (ii) cancellation of indebtedness of Luoxis to Ampio in the amount of $8,000,000; and (iii) cancellation of indebtedness of Vyrix to Ampio in the amount of $4,000,000.

Rosewind

On March 3, 2015, Rosewind accepted a cash investment from two irrevocable trusts for estate planning of which Joshua Disbrow and Jarrett Disbrow are beneficiaries. None of such persons have or share investment control over our shares held by such trusts. None of such persons, nor members of their respective immediate families, are trustees of such trusts. None of such persons have or share power to revoke such trusts. Accordingly, under Rule 16a-8(b) and related rules, none of such persons has beneficial ownership over our shares purchased and held by such trusts.

Luoxis and Vyrix

Ampio Loan Agreements

In November 2013, Vyrix entered into a loan agreement with Ampio. Pursuant to the loan agreement, Ampio agreed to lend Vyrix up to an aggregate amount of $3,000,000 through cash advances of up to $500,000 each. Unpaid principal amounts under the loan agreement bear simple interest at the "Applicable Federal Rate" for long-term obligations prescribed under Section 1274(d) of the Internal Revenue Code of 1986, as amended (or any successor provision with similar applicability). The initial term of this loan agreement is for one year, subject to automatic extension of successive one-year terms. Vyrix may repay any outstanding balance at any time without penalty. Ampio has an option of converting any balance outstanding under the loan agreement into shares of Vyrix common stock at the fair market value per share of Vyrix common stock, as determined by the Ampio board of directors, as of such conversion date. On April 16, 2015, in connection with the closing of the Merger, Ampio released Vyrix from its then outstanding obligation of $4,000,000 under the loan agreement as consideration of its share purchase, and the loan agreement was terminated.

In March 2014, Luoxis entered into a loan agreement with Ampio. Pursuant to the loan agreement, Ampio agreed to lend Luoxis $3,000,000. Unpaid principal amounts under the loan agreement bear simple interest at the "Applicable Federal Rate" for long-term obligations prescribed under Section 1274(d) of the Internal Revenue Code of 1986, as amended (or any successor provision with similar applicability). The initial term of this loan agreement is for one year, subject to automatic extension of successive one-year terms. Luoxis may repay any outstanding balance at any time without penalty. Ampio has an option of converting any balance outstanding under the loan agreement into shares of Luoxis common stock at the fair market value per share of Luoxis common stock, as determined by the Ampio board of directors, as of such conversion date. On April 16, 2015, in connection with the closing of the Merger, Ampio released Luoxis from its then outstanding obligation of $8,000,000 under the loan agreement as consideration of its share purchase, and the loan agreement was terminated.

On April 16, 2015, Ampio received 396,816 shares of common stock of Aytu for (i) issuance to Aytu of a promissory note from Ampio in the principal amount of $10,000,000, maturing on the first anniversary of the Merger, (ii) cancellation of indebtedness of Luoxis to Ampio in the amount of $8,000,000; and (iii) cancellation of indebtedness of Vyrix to Ampio in the amount of $4,000,000.

Services Agreements

In January 2013, Luoxis entered into a services agreement with Ampio whereby Ampio provides corporate overhead services and a shared facility with Luoxis in exchange for $15,000 per month. The amount can be modified in writing upon the consent of both parties. The agreement may be terminated at any time by either party. In January 2014, Vyrix entered into a services agreement with Ampio whereby Ampio provides corporate overhead services to Vyrix in exchange for $7,000 per month. The amount can be modified in writing upon the consent of both parties. The agreement may be terminated at any time by either party. Both agreements were assigned to us upon the closing of the Merger.

In July 2015, the prior service agreements were canceled and Aytu entered into agreements with Ampio whereby Aytu agreed to pay Ampio $30,000 per month for shared overhead which includes costs related to the shared facility, corporate staff, and other miscellaneous overhead expenses. This agreement will be in effect until it is terminated in writing by both parties. This agreement was amended in April 2016, which reduced the monthly amount to $18,000. This agreement was amended again in July 2016, which reduced the monthly amount to approximately $17,000 per month.

Sponsored Research Agreement

In June 2013, Luoxis entered into a sponsored research agreement with TRLLC, an entity controlled by Ampio's director and Chief Scientific Officer, Dr. Bar-Or. The agreement, which was amended in September 2013 and provides for Luoxis to pay $6,000 per month to TRLLC in consideration for services related to research and development of Luoxis' RedoxSYS System. In March 2014, Luoxis also agreed to pay a sum of $615,000 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet; this amount has been paid in full. This agreement is set to expire March 2019 and cannot be terminated prior to March 2017.

Review, Approval or Ratification of Transactions with Related Persons

Effective upon its adoption in July 2016, pursuant to the Audit Committee Charter, the Audit Committee is responsible for reviewing and approving all related party transactions as defined under Item 404 of Regulation S-K, after reviewing each such transaction for potential conflicts of interests and other improprieties. Our policies and procedures for review and approval of transactions with related persons are in writing in our Code of Conduct and Ethics available on our website at http://aytubio.com under the "Investor Relations—Corporate Governance" tab.

Prior to the adoption of the Audit Committee Charter, and due to the small size of our company, we did not have a formal written policy regarding the review of related party transactions, and relied on our Board of Directors to review, approve or ratify such transactions and identify and prevent conflicts of interest. Our Board of Directors reviewed any such transaction in light of the particular affiliation and interest of any involved director, officer or other employee or stockholder and, if applicable, any such person's affiliates or immediate family members.

Director Independence

Our common stock is not listed on any exchange. Consequently, no exchange rules regarding director independence are applicable to us. Audit Committee members must satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, for listed companies. In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Three of our five directors are independent under the definition of either the NYSE or Nasdaq. The other two directors are not independent under either definition due to (i) being an executive officer of our Company, in the case of Josh Disbrow, and (ii) the payments we make to Ampio under the services agreement with Aytu, in the case of Mr. Macaluso.

Item 14. Principal Accountant Fees and Services

The information required by this Item is incorporated by reference to the information under the section captioned “Audit and Audit Committee Matters” contained our Proxy Statement for the 2016 Annual Meeting of Shareholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

The following documents are filed as part of this Form 10-K, as set forth on the Index to Financial Statements found on page F-1.

- Report of Independent Registered Public Accounting Firm
- Balance Sheets as of June 30, 2016 and 2015
- Statements of Operations for the years ended June 30, 2016 and 2015
- Statements of Stockholders’ Equity (Deficit) for the years ended June 30, 2016 and 2015
- Statements of Cash Flows for the years ended June 30, 2016 and 2015
- Notes to the Financial Statements

(a)(2) Financial Statement Schedules

Not Applicable.

(a)(3) Exhibits

Exhibit No.	Description	Registrant’s Form	Date Filed	Exhibit Number	Filed Herewith
2.1	Agreement and Plan of Merger among Rosewind, Luoxis, Vyrix, two major stockholders of Rosewind and two subsidiaries of Rosewind, dated as of April 16, 2015	8-K	4/22/15	2.1	
2.2	Certificate of Merger	8-K	4/22/15	2.2	
3.1	Certificate of Incorporation	8-K	6/09/15	3.1	
3.2	Certificate of Amendment of Certificate of Incorporation effective June 1, 2016	8-K	6/02/16	3.1	
3.3	Certificate of Amendment of Certificate of Incorporation of Aytu Bioscience, Inc., effective June 30, 2016	8-K	7/01/16	3.1	
3.4	Bylaws	8-K	6/09/15	3.2	
4.1	Form of Convertible Note issued in 2015 Convertible Note Financing	8-K	7/24/15	4.1	
4.2	Form of Placement Agent Warrant issued in 2015 Convertible Note Financing	8-K	7/24/15	4.2	
4.3	Warrant Agent Agreement, dated May 6, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC.	8-K	5/6/16	4.1	
4.4	Form of Underwriter’s Warrant, dated May 6, 2016.	8-K	5/6/16	4.2	
10.1†	Form of Indemnification Agreement, to be entered into between the Registrant and its directors and officers	8-K	4/22/15	10.1	
10.2†	Employment Agreement between the Registrant and Joshua R. Disbrow, dated as of April 16, 2015	8-K	4/22/15	10.2	
10.3†	Employment Agreement between the Registrant and Jarrett Disbrow, dated as of April 16, 2015	8-K	4/22/15	10.3	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.4#	Asset Purchase Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Valeant International (Barbados) SRL, effective as of December 2, 2011	8-K/A	6/08/15	10.4	
10.5#	Manufacturing and Supply Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Ethypharm S.A., dated September 10, 2012	8-K/A	6/08/15	10.5	
10.6	License, Development and Commercialization Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Daewoong Pharmaceuticals Co., Ltd., effective as of August 23, 2011 (incorporated by reference to Exhibit 10.1 of Ampio Pharmaceutical's Form 8-K/A filed October 5, 2011; File No. 001-25182)				
10.7#	Distribution Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and FBM Industria Farmaceutica, Ltda., dated as of March 1, 2012	8-K/A	6/08/15	10.7	
10.8#	Distribution and License Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Endo Ventures Limited, dated April 9, 2014	8-K/A	6/08/15	10.8	
10.9#	Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated September 1, 2009	8-K/A	6/08/15	10.9	
10.10#	Addendum No. 4 to Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated March 17, 2014	8-K	5/27/15	10.14	
10.11	Promissory Note issued by Ampio to the Registrant on April 16, 2015	8-K	4/22/15	10.11	
10.12	Subscription Agreement between the Registrant and Ampio, dated April 16, 2015	8-K	4/22/15	10.12	
10.13	Voting Agreement between the Registrant and Ampio, dated April 21, 2015 (incorporated by reference to Exhibit 10.1 to Ampio's Form 8-K filed April 22, 2015; File No. 001-35182)				
10.14	Asset Purchase Agreement between Jazz Pharmaceuticals, Inc. and Rosewind Corporation, dated May 20, 2015	8-K	5/27/15	10.14	
10.15	Aytu BioScience 2015 Stock Option and Incentive Plan	S-1	7/01/15	10.15	
10.17	Form of Note Purchase Agreement for 2015 Convertible Note Financing	8-K	7/24/15	10.17	
10.18	Asset Purchase Agreement, dated October 5, 2015, between Aytu BioScience, Inc. and FSC Laboratories, Inc.	8-K	10/07/15	10.18	
10.19	Master Services Agreement between Biovest International, Inc. and Aytu BioScience, Inc., entered into on October 8, 2015, and effective October 5, 2015	8-K	10/13/15	10.19	
10.20	Form of Subscription Agreement for January 2016 common stock purchases	8-K	1/20/16	10.1	
10.21	License and Supply Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016	8-K	4/25/16	10.1	
10.22	Subscription Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016	8-K	4/25/16	10.2	
10.23	First Amendment, dated May 15, 2016, to Employment Agreement dated September 16, 2015 between Aytu BioScience, Inc. and Jonathan McGrael	8-K	5/16/16	10.1	
10.24	Purchase Agreement, dated July 27, 2016, by and between Aytu BioScience, Inc. and Lincoln Park Capital Fund, LLC.	8-K	7/28/16	10.1	
10.25	Registration Rights Agreement dated July 27, 2016, by and between Aytu BioScience, Inc. and Lincoln Park Capital Fund, LLC.	8-K	7/28/16	10.2	
16.1	Letter from HJ & Associates, LLC, dated April 22, 2015	8-K	4/22/15	16.1	
23.1	Consent of EKS&H LLLP, Independent Registered Public Accounting Firm.				X
31.1	Certificate of the Chief Executive Officer of Aytu BioScience, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
31.2	Certificate of the Chief Financial Officer of Aytu BioScience, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certificate of the Chief Executive Officer and the Chief Financial Officer of Aytu BioScience, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101*	XBRL (extensible Business Reporting Language). The following materials from Aytu BioScience, Inc.'s Annual Report on Form 10-K for the year ended June 30, 2016 formatted in XBRL: (i) the Balance Sheets, (ii) the Statements of Operations, (iii) the Statements of Stockholders' Equity (Deficit), (iv) the Statements of Cash Flows, and (v) the Notes to the Financial Statements.				X*

† Indicates is a management contract or compensatory plan or arrangement.

The company has received confidential treatment of certain portions of this agreement. These portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

* Due to SEC EDGAR system error, XBRL may not be included herewith, and if it is not, it will be filed as soon as practicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

AYTU BIOSCIENCE, INC.

Date: September 1, 2016

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
Chairman and Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities indicated, on September 1, 2016.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chairman and Chief Executive Officer *(Principal Executive Officer)*
/s/ Gregory A. Gould Gregory A. Gould	Chief Financial Officer *(Principal Financial and Accounting Officer)*
/s/ Michael Macaluso Michael Macaluso	Director
/s/ Carl Dockery Carl Dockery	Director
/s/ John Donofrio John Donofrio	Director
/s/ Gary Cantrell Gary Cantrell	Director

INDEX TO THE FINANCIAL STATEMENTS
AYTU BIOSCIENCE, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Aytu Bioscience, Inc.
Englewood, Colorado

We have audited the accompanying balance sheets of Aytu BioScience, Inc. (the "Company") as of June 30, 2016 and 2015, and the related statements of operations, stockholders' equity, and cash flows for each of the periods then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Aytu BioScience, Inc. as of June 30, 2016 and 2015, and the results of its operations and its cash flows for each of the periods then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EKS&H LLLP

September 1, 2016
Denver, Colorado

AYTU BIOSCIENCE, INC.
Balance Sheets

	June 30, 2016	June 30, 2015
Assets		
Current assets		
Cash and cash equivalents	$ 8,054,190	$ 7,353,061
Accounts receivable, net	162,427	157,058
Inventory, net	524,707	39,442
Prepaid expenses and other	215,558	370,888
Prepaid research and development - related party (Note 11)	121,983	121,983
Investment in Acerus	1,041,362	-
Total current assets	10,120,227	8,042,432
Fixed assets, net	231,430	29,706
Developed technology, net	1,159,736	780,125
Customer contracts, net	1,353,375	711,000
Trade names, net	194,472	79,000
Natesto asset	10,549,797	-
Goodwill	221,000	74,000
In-process research and development	-	7,500,000
Patents, net	296,611	628,776
Long-term portion of prepaid research and development - related party (Note 11)	213,471	335,454
Deposits	2,888	4,886
	14,222,780	10,142,947
Total assets	$ 24,343,007	$ 18,185,379
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and accrued liabilities	$ 3,519,711	$ 1,195,368
Natesto payable	5,379,675	-
Accrued compensation	1,200,930	196,503
Deferred revenue	-	85,714
Deferred rent	4,109	-
Total current liabilities	10,104,425	1,477,585
Contingent consideration	3,869,122	664,000
Long-term deferred revenue	-	425,893
Deferred rent	8,215	1,449
Warrant derivative liability	275,992	-
Total liabilities	14,257,754	2,568,927
Commitments and contingencies (Note 7)		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; none issued	-	-
Common Stock, par value $.0001; 100,000,000 shares authorized; shares issued and outstanding 3,741,944 in 2016 and 1,188,307 in 2015	374	119
Additional paid-in capital	56,646,304	38,997,674
Ampio stock subscription	-	(5,000,000)
Accumulated deficit	(46,561,425)	(18,381,341)
Total stockholders' equity	10,085,253	15,616,452
Total liabilities and stockholders' equity	$ 24,343,007	$ 18,185,379

The accompanying notes are an integral part of these financial statements.

AYTU BIOSCIENCE, INC.
Statements of Operations

	Year Ended June 30, 2016	Year Ended June 30, 2015
Product and service revenue	$ 2,050,838	$ 176,068
License revenue	511,607	85,714
Total revenue	2,562,445	261,782
Operating expenses		
Cost of sales	957,076	88,109
Research and development	6,127,772	3,219,361
Research and development - related party (Note 11)	191,991	203,992
Sales, general and administrative	8,517,592	3,980,974
Sales, general and administrative - related party (Note 11)	307,704	311,004
Impairment of intangible assets	7,500,000	-
Amortization of intangible assets	664,707	90,662
Total operating expenses	24,266,842	7,894,102
Loss from operations	(21,704,397)	(7,632,320)
Other (expense)		
Interest (expense)	(5,491,486)	(114,994)
Unrealized loss on investment	(971,629)	-
Derivative (expense)	(12,572)	-
Total other (expense)	(6,475,687)	(114,994)
Net loss, before income tax	(28,180,084)	(7,747,314)
Deferred income tax benefit	-	23,910
Net loss	$ (28,180,084)	$ (7,723,404)
Weighted average number of Aytu common shares outstanding	1,741,137	767,326
Basic and diluted Aytu net loss per common share	$ (16.18)	$ (10.07)

The accompanying notes are an integral part of these financial statements.

AYTU BIOSCIENCE, INC.
Statements of Stockholders' Equity

	Common Stock		Additional paid-in	Ampio Stock	Accumulated	Total Stockholders'
	Shares	Amount	capital	Subscription	Deficit	Equity
Balance - June 30, 2014	658,452	$ 66	$ 16,027,278	$ -	$ (10,657,937)	$ 5,369,407
Ampio stock subscription payment	180,371	18	9,999,982	(10,000,000)	-	-
Issurance of common stock to Ampio in exchange for Aytu debt	216,445	22	11,999,978	-	-	12,000,000
Ampio stock subscription payment	-	-	-	5,000,000	-	5,000,000
Liabilities paid pursuant to the merger	-	-	(20,013)	-	-	(20,013)
Luoxis options paid-out pursuant to the merger	-	-	(27,476)	-	-	(27,476)
Reverse merger	133,039	13	(13)	-	-	-
Stock-based compensation	-	-	1,017,938	-	-	1,017,938
Net loss	-	-	-	-	(7,723,404)	(7,723,404)
Balance - June 30, 2015	1,188,307	119	38,997,674	(5,000,000)	(18,381,341)	15,616,452
Ampio stock subscription	-	-	-	5,000,000	-	5,000,000
Stock subscription	25,641	3	199,997	-	-	200,000
Conversion of convertible promissory notes and interest to common stock, net of $29,754 conversion costs	962,150	96	10,090,753	-	-	10,090,849
Issuance of warrants related to the convertible promissory notes	-	-	136,828	-	-	136,828
Issuance of common stock, net of $1,202,231 in issuance costs	1,562,500	156	4,237,718	-	-	4,237,874
Warrants issued in connection with equity financing	-	-	2,059,895	-	-	2,059,895
Warrants issued in connection with equity financing to the placement agents for the over-allotment option	-	-	20,493	-	-	20,493
Adjustment for rounding of shares due to stock split	3,346	-	-	-	-	-
Stock-based compensation	-	-	902,946	-	-	902,946
Net loss	-	-	-	-	(28,180,084)	(28,180,084)
Balance - June 30, 2016	3,741,944	$ 374	$ 56,646,304	$ -	$ (46,561,425)	$ 10,085,253

The accompanying notes are an integral part of these financial statements.

AYTU BIOSCIENCE, INC.
Statements of Cash Flows

	Year Ended June 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (28,180,084)	$ (7,723,404)
Stock-based compensation expense	902,946	1,017,938
Depreciation, amortization and accretion	874,789	118,202
Asset impairment	7,500,000	-
Amortization of debt issuance costs	182,759	-
Amortization of beneficial conversion feature	4,943,073	-
Noncash interest expense	221,024	-
Derivative expense	12,572	-
Amortization of prepaid research and development - related party (Note 11)	121,983	121,984
Unrecognized loss on investment	971,629	-
Deferred taxes	-	(23,910)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Increase) in accounts receivable	(5,369)	(157,058)
(Increase) in inventory	(485,265)	(39,442)
Decrease in prepaid expenses and other	155,330	150,434
(Increase) in prepaid research and development - related party (Note 11)	-	(150,000)
Increase in accounts payable and accrued liabilities	1,623,469	547,314
Increase in accrued compensation	1,004,427	196,503
(Decrease) in payable to Ampio	-	(607,061)
Increase in deferred rent	10,875	-
(Decrease) in deferred revenue	(511,607)	(85,714)
Net cash used in operating activities	(10,657,449)	(6,634,214)
Cash flows used in investing activities		
Deposits	1,998	(4,886)
Purchases of fixed assets	(252,932)	-
Purchase of ProstaScint Business	-	(1,000,000)
Purchase of Primsol asset	(1,040,000)	
Purchase of Natesto license	(2,000,000)	
Investment in Acerus	(2,012,991)	
Net cash used in investing activities	(5,303,925)	(1,004,886)
Cash flows from financing activities		
Proceeds from convertible note from Ampio converted to stock	-	7,400,000
Proceeds from convertible promissory notes, net (Note 8)	5,175,000	-
Debt issuance costs (Note 8)	(298,322)	-
Costs related to the conversion of the convertible promissory notes to equity	(29,754)	-
Ampio stock subscription payment	5,000,000	5,000,000
Luoxis option payout pursuant to the merger	-	(27,476)
Liabilities paid out pursuant to the merger	-	(20,013)
Sale of stock subscription	200,000	-
Proceeds from issuance of equity financing	7,520,493	-
Issuance costs related to equity financing	(904,914)	-
Net cash provided by financing activities	16,662,503	12,352,511
Net change in cash and cash equivalents	701,129	4,713,411
Cash and cash equivalents at beginning of period	7,353,061	2,639,650
Cash and cash equivalents at end of period	$ 8,054,190	$ 7,353,061
Non-cash transactions:		
Ampio stock subscription	$ -	$ 5,000,000
Ampio unpaid debt converted to stock, received prior to 2015	$ -	$ 4,600,000
Contingent consideration related to the ProstaScint purchase	$ -	$ 664,000
Warrant derivative liability related to the issuance of the convertible promissory notes (Note 8)	$ 102,931	$ -
Primsol asset purchase included in primsol payable, $1,250,000 less future accretion of $173,000	$ 1,077,000	$ -
Conversion of convertible promissory notes and interest of $221,000 to common stock	$ 5,396,024	$ -
Natesto asset purchase included in Natesto payable, $6,000,000 less future accretion of $620,325	$ 5,379,675	$ -
Warrant derivative liability related to the issuance of the registered offering placement agent warrants (Note 8)	$ 297,317	$ -
Reclassification of liability based warrants to equity presentation related to the convertible promissory notes	$ 136,828	$ -
Beneficial conversion feature related to convertible promissory notes	$ 4,943,073	$ -
Debt issuance costs related to notes that converted to equity	$ (218,494)	$ -

The accompanying notes are an integral part of these financial statements.

Note 1 – Business, Basis of Presentation and Business Combinations

Business

Aytu BioScience, Inc. (“Aytu”, the “Company” or “we”) was incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado. Aytu was re-incorporated in the state of Delaware on June 8, 2015. Aytu is a commercial-stage specialty healthcare company concentrating on developing and commercializing products with an initial focus on urological diseases and conditions. Aytu is currently focused on addressing significant medical needs in the areas of urological cancers, hypogonadism, urinary tract infections, male infertility, and sexual dysfunction.

Basis of Presentation

Through a multi-step reverse triangular merger, on April 16, 2015, Vyrix Pharmaceuticals, Inc. (‘‘Vyrix’’) and Luoxis Diagnostics, Inc. (‘‘Luoxis’’) merged with and into our Company (herein referred to as the Merger) and we abandoned our pre-merger business plans to solely pursue the specialty healthcare market, including the business of Vyrix and Luoxis. In the Merger, we acquired the RedoxSYS, MiOXSYS and Zertane products. On June 8, 2015, we reincorporated as a domestic Delaware corporation under Delaware General Corporate Law and changed our name from Rosewind Corporation to Aytu BioScience, Inc., and effected a reverse stock split in which each common stockholder received one share of common stock for every 12.174 shares outstanding. On June 30, 2016, Aytu effected another reverse stock split in which each common stockholder received one share of common stock for every 12 shares outstanding (herein referred to collectively as the “Reverse Stock Splits”). All share and per share amounts in this report have been adjusted to reflect the effect of these Reverse Stock Splits.

Business Combination—ProstaScint

In May 2015, Aytu entered into and closed on an asset purchase agreement with Jazz Pharmaceuticals, Inc. (“Jazz Pharmaceuticals”). Pursuant to the agreement, Aytu purchased assets related to the Jazz Pharmaceuticals’ product known as ProstaScint® (capromab pendetide), including certain intellectual property and contracts, and the product approvals, inventory and work in progress (together, the ‘‘ProstaScint Business’’), and assumed certain of Jazz Pharmaceuticals’ liabilities, including those related to product approvals and the sale and marketing of ProstaScint. The purchase price consists of the upfront payment of $1.0 million. We also agreed to pay an additional $500,000 which was paid after transfer for the ProstaScint-related product inventory and $227,000 which was paid September 30, 2015 (which represents a portion of certain FDA fees). We also will pay 8% on net sales made after October 31, 2017, payable up to a maximum aggregate payment of an additional $2.5 million. The contingent consideration was initially valued at $664,000 and was revalued as of June 30, 2016 at $699,000 using a discounted cash flow. The total fair value consideration for the purchase was $2.4 million.

The Company’s allocation on consideration transferred for ProstaScint as of the purchase date May 20, 2015 is as follows:

	Estimated Fair Value
Tangible assets	$ 727,000
Intangible assets	1,590,000
Goodwill	74,000
Total assets acquired	$ 2,391,000

Included in the intangible assets is developed technology of $790,000, customer contracts of $720,000 and trade names of $80,000, each of which will be amortized over a ten-year period. Amortization expense of $159,000 was recognized in fiscal 2016. Future amortization from the year ended June 30, 2016 is as follows:

2017	$	159,000
2018		159,000
2019		159,000
2020		159,000
2021		159,000
Thereafter		616,000
	$	1,411,000

Business Combination—Primsol

In October 2015, Aytu entered into and closed on an Asset Purchase Agreement with FSC Laboratories, Inc. ("FSC"). Pursuant to the agreement, Aytu purchased assets related to FSC's product known as Primsol® (trimethoprim solution), including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primsol (together, the "Primsol Business"), and assumed certain of FSC's liabilities, including those related to the sale and marketing of Primsol arising after the closing.

Aytu paid $500,000 at closing for the purchase of the Primsol Business and paid an additional $142,000, of which $102,000 went to inventory and $40,000 towards the Primsol Business, for the transfer of the Primsol-related product inventory. We also agreed to pay an additional (a) $500,000 which was paid on April 1, 2016, (b) $500,000 which was paid on July 1, 2016, and (c) $250,000 payable no later than September 30, 2016 (together, the "Installment Payments").

The Company's allocation on consideration transferred for Primsol as of the purchase date of October 5, 2015 is as follows:

		Fair Value
Tangible assets	$	182,000
Intangible assets		1,470,000
Goodwill		147,000
Total assets acquired	$	1,799,000

Included in tangible assets is $102,000 of inventory and $80,000 of work-in-process inventory. Included in the intangible assets is developed technology of $520,000, customer contracts of $810,000 and trade names of $140,000, each of which will be amortized over a six-year period. Amortization expense of $174,000 was recognized in fiscal 2016.

As of June 30, 2016, the accrued payable adjusted for the present value was $701,000.

Future amortization from the year ended June 30, 2016 is as follows:

2017	$ 245,000
2018	245,000
2019	245,000
2020	245,000
2021	245,000
Thereafter	72,000
	$ 1,297,000

License and Supply Agreement—Natesto

In April, 2016, Aytu entered into and closed a license and supply agreement to acquire the exclusive U.S. rights to Natesto® (testosterone) nasal gel from Acerus Pharmaceuticals Corporation, or Acerus, which rights we will acquire effective upon the expiration of the current licensee's rights, which occurred on June 30, 2016. The licensee's term runs for the greater of eight years or until the expiry of the latest to expire patent including claims covering Natesto and until the entry on the market of at least one AB-rated generic product.

Aytu paid Acerus an upfront fee of $2.0 million upon execution of the agreement. On September 5, 2016 we will pay an additional $2,000,000 (the "Second Upfront"). On January 1, 2017, we will pay an additional $4,000,000 (the "Third Upfront"). We also purchased on April 28, 2016, an aggregate of 12,245,411 shares of Acerus common stock for Cdn. $2,534,800 (approximately US $2.0 million), with a purchase price per share equal to Cdn. $0.207 or approximately US $0.16 per share. Aytu could not dispose of these shares until after August 29, 2016.

In addition to the upfront payments, we must make the following one-time, non-refundable payments to Acerus within 45 days of the occurrence of the following event (provided that, the maximum aggregate amount payable under such milestone payments will be $37,500,000):

- $2,500,000 if net sales during any four consecutive calendar quarter period equal or exceed $25,000,000 (the "First Milestone"); the First Milestone payment is required to be paid even if the threshold is not met in the event that the agreement is terminated for any reason other than material breach by Acerus, bankruptcy of either party, or termination by Acerus because it believes the amounts payable to Aytu for agreed upon trial work would no longer make the agreement economically viable for Acerus
- $5,000,000 if net sales during any four consecutive calendar quarter period equal or exceed $50,000,000;
- $7,500,000 if net sales during any four consecutive calendar quarter period equal or exceed $75,000,000;
- $10,000,000 if net sales during any four consecutive calendar quarter period equal or exceed $100,000,000; and
- $12,500,000 if net sales during any four consecutive calendar quarter period equal or exceed $125,000,000.

The contingent consideration was valued at $3.2 million using a Monte Carlo simulation. The fair values of the net identifiable asset acquired totaled $10.5 million which will be amortized over eight years.

As of June 30, 2016, the accrued payable adjusted for the present value was $5.4 million and the contingent consideration held a value of $3.2 million.

Note 2 – Summary of Significant Accounting Policies

Cash and Cash Equivalents

Aytu considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of money market fund investments. Aytu's investment policy is to preserve principal and maintain liquidity. The Company periodically monitors its positions with, and the credit quality of the financial institutions with which it invests. Periodically, throughout the year, Aytu has maintained balances in excess of federally insured limits.

Revenue Recognition

License Agreements and Royalties

Payments received upon signing of license agreements are for the right to use the license and are deferred and amortized over the lesser of the license term or patent life of the licensed drug. Milestone payments relate to obtaining regulatory approval, cumulative sales targets, and other projected milestones and are recognized at the time the milestones are achieved. Royalties will be recognized as revenue when earned.

Product & Service Sales

Aytu recognizes revenue from product and service sales when there is persuasive evidence that an arrangement exists, delivery has occurred or service has been rendered, the price is fixed or determinable and collectability is reasonably assured.

Estimated Sales Returns and Allowances

Aytu records estimated reductions in revenue for potential returns of products by customers. As a result, management must make estimates of potential future product returns and other allowances related to current period product revenue. In making such estimates, management analyzes historical returns, current economic trends and changes in customer demand and acceptance of our products. If management were to make different judgments or utilize different estimates, material differences in the amount of the Company's reported revenue could result.

Accounts Receivable

Accounts receivable are recorded at their net realized value. Aytu evaluates collectability of accounts receivable on a quarterly basis and records a valuation allowance accordingly. As of June 30, 2016 we had an allowance for doubtful accounts of $41,000, and as of June 30, 2015, no allowance for doubtful accounts had been recorded. The Company had one customer whose revenue individually represented 10% or more of the Company's total revenue, or whose accounts receivable balances individually represented 10% or more of the Company's total accounts receivable, as follows:

For the year ended June 30, 2016, one customer accounted for 86% of net revenue. For the year ended June 30, 2015, one customer accounted for 83% of gross revenue.

At June 30, 2016, one customer accounted for 69% of gross accounts receivable. At June 30, 2015, one customer accounted for 99% of gross accounts receivable.

Inventories

Inventories are recorded at the lower of cost or market, with cost determined on a first-in, first-out basis. Aytu periodically reviews the composition of its inventories in order to identify obsolete, slow-moving or otherwise unsaleable items. If unsaleable items are observed and there are no alternate uses for the inventory, Aytu will record a write-down to net realizable value in the period that the impairment is first recognized.

Trading Securities

Trading securities are carried at fair value with unrealized gains and losses recorded in earnings.

Fixed Assets

Fixed assets are recorded at cost. After being placed in service, the fixed assets are depreciated using the straight-line method over estimated useful lives. Fixed assets consist of the following:

	Estimated Useful Lives in years	June 30, 2016	June 30, 2015
Office equipment and furniture	3 - 5	$ 201,000	$ -
Lab equipment	3 - 5	90,000	90,000
Leasehold improvements	3	45,000	-
Manufacturing equipment	5	7,000	-
Less accumulated depreciation and amortization		(112,000)	(60,000)
Fixed assets, net		$ 231,000	$ 30,000

As of June 30, 2016, Aytu had $24,000 included in Office equipment and furniture for a new phone system and the new enterprise resource system, neither of which had been placed in service nor were being depreciated.

Aytu recorded the following depreciation expense in the respective periods:

	Year Ended June 30, 2016	Year Ended June 30, 2015
Depreciation expense	$ 51,000	$ 27,000

In-Process Research and Development

In-process research and development (“IPRD”) relates to the Company’s Zertane product and clinical trial data acquired in connection with the 2011 acquisition of DMI BioSciences, Inc. (“DMI BioSciences”) by Ampio, the former parent company of Aytu. The $7,500,000 recorded was based on an independent, third party appraisal of the fair value of the assets acquired. IPRD was considered an indefinite-lived intangible asset and its fair value was assessed annually and written down if impaired. At the time the Zertane product obtained regulatory approval and commercial production began, IPRD would have been reclassified to an intangible that will be amortized over its estimated useful life. However, as of June 30, 2016, because we are directing our resources towards our commercial-stage products, the Company determined that this asset has no value as the Company does not have the resources to complete the necessary clinical trials and bring it to market before the patents expire. The IPRD was expensed and is included in impairment of intangible assets in the accompanying statements of operations. The Company will try to market the Zertane asset to other pharmaceutical companies during fiscal year 2017 but there is no guarantee that the Company will be able to monetize this asset.

Patents

Costs of establishing patents, consisting of legal and filing fees paid to third parties, are expensed as incurred. The fair value of the Zertane patents, determined by an independent third party appraisal, was $500,000. The Zertane patents were acquired in connection with the 2011 acquisition of DMI BioSciences and were being amortized over the remaining U.S. patent lives of approximately 11 years, which expires in March 2022. For the fiscal year ended June 30, 2016, because we are directing our resources towards our commercial-stage products, the Company determined that this asset had no value as the Company does not have the resources to complete the necessary clinical trials and bring it to market before the patents expire. The remaining fair value of the Zertane patents have been expensed as of June 30, 2016.

The cost of the Luoxis patents were $380,000 when they were acquired in connection with the 2013 formation of Luoxis and is being amortized over the remaining U.S. patent lives of approximately 15 years, which expires in March 2028. Patents consist of the following:

	June 30, 2016	June 30, 2015
Patents	$ 880,000	$ 880,000
Less accumulated amortization	(583,000)	(251,000)
Patents, net	$ 297,000	$ 629,000

Aytu recorded the following amortization expense in the respective periods:

	Year Ended June 30, 2016	Year Ended June 30, 2015
Amortization expense	$ 332,000	$ 71,000

Future amortization from the year ended June 30, 2016 is as follows:

2017	$ 25,000
2018	25,000
2019	25,000
2020	25,000
2021	25,000
Thereafter	172,000
	$ 297,000

Business Combinations

The Company accounts for its business acquisitions under the acquisition method of accounting as indicated in the Financial Accounting Standards Board's ("FASB") Accounting Standards Codification ("ASC") 805, "Business Combinations", which requires the acquiring entity in a business combination to recognize the fair value of all assets acquired, liabilities assumed, and any non-controlling interest in the acquired business; and establishes the acquisition date as the fair value measurement point. Accordingly, the Company recognizes assets acquired and liabilities assumed in business combinations, including contingent assets and liabilities and non-controlling interest in the acquiree, based on the fair value estimates as of the date of acquisition. In accordance with ASC 805, the Company recognizes and measures goodwill as of the acquisition date, as the excess of the fair value of the consideration paid over the fair value of the identified net assets acquired.

Goodwill

The ProstaScint and Primsol purchase price allocation was based upon an analysis of the fair value of the assets and liabilities acquired. The final purchase price may be adjusted up to one year from the date of the acquisition. Identifying the fair value of the tangible and intangible assets and liabilities acquired required the use of estimates by management, and were based upon currently available data, as noted below.

The Company allocated the excess of purchase price over the identifiable intangible and net tangible assets to goodwill. Such goodwill is not deductible for tax purposes and represents the value placed on entering new markets and expanding market share.

The Company tests its goodwill for impairment annually, or whenever events or changes in circumstances indicate an impairment may have occurred, by comparing the carrying value to its implied fair value. Impairment may result from, among other things, deterioration in the performance of the acquired business, adverse market conditions, adverse changes in applicable laws or regulations and a variety of other circumstances. If the Company determines that an impairment has occurred, it is required to record a write-down of the carrying value and charge the impairment as an operating expense in the period the determination is made. In evaluating the recoverability of the carrying value of goodwill, the Company must make assumptions regarding estimated future cash flows and other factors to determine the fair value of the acquired assets. Changes in strategy or market conditions could significantly impact those judgments in the future and require an adjustment to the recorded balances. The goodwill was recorded as part of the acquisition of ProstaScint that occurred on May 20, 2015 and Primsol that occurred on October 5, 2015. There was no impairment of goodwill for the year ended June 30, 2016.

Use of Estimates

The preparation of financial statements in accordance with Generally Accepted Accounting Principles in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosures of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Significant items subject to such estimates and assumptions include valuation allowances, stock-based compensation, warrant valuation, purchase price allocation, valuation of contingent consideration, sales returns and allowances, useful lives of fixed assets and assumptions in evaluating impairment of definite and indefinite lived assets. Actual results could differ from these estimates.

Income Taxes

Aytu has been included in the consolidated tax returns of Ampio, the former parent company of Aytu, for tax years ended on or before December 31, 2015. As of January 2016, due to the decrease in Ampio's ownership percentage of Aytu stock, Aytu will begin to file tax returns separate from Ampio. For all consolidated tax return periods, Aytu's taxes are computed and reported on a "separate return" basis for these financial statements. Deferred taxes are provided on an asset and liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

The amount of income taxes and related income tax positions taken are subject to audits by federal and state tax authorities. The Company has adopted accounting guidance for uncertain tax positions which provides that in order to recognize an uncertain tax position, the taxpayer must be more likely than not of sustaining the position, and the measurement of the benefit is calculated as the largest amount that is more than 50% likely to be realized upon settlement with the taxing authority. The Company believes that it has no material uncertain tax positions. The Company's policy is to record a liability for the difference between the benefits that are both recognized and measured pursuant to FASB ASC 740-10, "Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109" ("ASC 740-10") and tax position taken or expected to be taken on the tax return. Then, to the extent that the assessment of such tax positions changes, the change in estimate is recorded in the period in which the determination is made. The Company reports tax-related interest and penalties as a component of income tax expense. During the periods reported, management of the Company has concluded that no significant tax position requires recognition under ASC 740-10.

Stock-Based Compensation

Aytu accounts for share based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant. The Company determines the estimated grant fair value using the Black-Scholes option pricing model and recognizes compensation costs ratably over the period of service using the graded method.

Research and Development

Research and development costs are expensed as incurred with expenses recorded in the respective period.

Income (Loss) Per Common Share

Basic income (loss) per common share is calculated by dividing the net income (loss) available to the common shareholders by the weighted average number of common shares outstanding during that period. Diluted net loss per share reflects the potential of securities that could share in the net loss of Aytu. Basic and diluted loss per share was the same in 2016 and 2015. Although there were common stock equivalents of 2,523,929, and 8,553 shares outstanding at June 30, 2016 and 2015, respectively, consisting of stock options and warrants; they were not included in the calculation of the diluted net loss per share because they would have been anti-dilutive.

Fair Value of Financial Instruments

The carrying amounts of financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and other current assets and other liabilities approximate their fair value due to their short maturities. The fair value of acquisition-related contingent consideration is based on estimated discounted future cash flows and assessment of the probability of occurrence of potential future events. The fair values of marketable securities is based on quoted market prices, if available, or estimated discounted future cash flows.

Derivative Liability

Aytu accounts for financial instruments (convertible debt with embedded derivative features – conversion options and conversion provisions) and related warrants by recording the fair value of each instrument in its entirety and recording the fair value of the warrant derivative liability. The fair value of the financial instruments and related warrants was calculated using a Monte Carlo based valuation model. We recorded a derivative expense at the inception of the instrument reflecting the difference between the fair value and cash received. Changes in the fair value in subsequent periods will be recorded as unrealized gain or loss on fair value of debt instruments for the financial instruments and to derivative income or expense for the warrants.

The fair value of the warrants issued to the placement agents in connection with the registered offering were valued using the Black-Scholes valuation methodology. Changes in the fair value in subsequent periods were recorded to derivative income or expense.

Impairment of Long-Lived Assets

Long-lived assets with finite lives are tested for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If indicators of impairment are present, the asset is tested for recoverability by comparing the carrying value of the asset to the related estimated undiscounted future cash flows expected to be derived from the asset. If the expected cash flows are less than the carrying value of the asset, then the asset is considered to be impaired and its carrying value is written down to fair value, based on the related estimated discounted future cash flows.

Indefinite-lived intangible assets, including acquired IPR&D, are tested for impairment annually or more frequently if events or changes in circumstances between annual tests indicate that the asset may be impaired. Impairment losses on indefinite-lived intangible assets are recognized based solely on a comparison of the fair value of the asset to its carrying value, without consideration of any recoverability test.

Based on the Company's evaluation as of June 30, 2016, an impairment existed for IPRD as we do not anticipate any future cash flows from this asset (see In-Process Research and Development). As of June 30, 2015, there had been no impairment for long-lived assets.

Adoption of Newly Issued Accounting Pronouncements

In September 2015, the FASB issued Accounting Standards Update ("ASU") 2015-16, "Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments," which requires that an acquirer recognize adjustments to estimated amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the estimated amounts, calculated as if the accounting had been completed at the acquisition date. The amendments also require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the estimated amounts had been recognized as of the acquisition date. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2015 and early adoption is permitted. As of March 31, 2016, the Company has early adopted this standard, there was no material impact on our financial statements.

In April 2015, the FASB issued ASU 2015-03, "Interest-Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs" to simplify the presentation of debt issuance costs. The amendments in the update require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct reduction of the carrying amount of the debt. Recognition and measurement of debt issuance costs were not affected by this amendment. In August 2015, FASB issued ASU 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements — Amendments to SEC Paragraphs Pursuant to Staff Announcement at June 18, 2015 EITF Meeting" which clarified that the SEC would not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement. The amendments are effective for financial statements issued for fiscal years beginning after December 15, 2015. During the quarter ended September 30, 2015, the Company early adopted this standard and recorded debt issuance costs as a debt discount. There was no impact on the Company's financial statements related to this adoption as the Company did not have any debt issuance costs prior to adoption.

In November 2015, the FASB issued ASU No. 2015-17 regarding ASC Topic 470 "Income Taxes: Balance Sheet Classification of Deferred Taxes." The amendments in ASU 2015-17 eliminate the requirement to bifurcate deferred taxes between current and non-current on the balance sheet and require that deferred tax liabilities and assets be classified as noncurrent on the balance sheet. The amendments for ASU-2015-17 can be applied retrospectively or prospectively and early adoption is permitted. Aytu early adopted ASU 2015-17 and there was no material impact on its financial statements.

Recently Issued Accounting Pronouncements, Not Adopted as of June 30, 2016

In March 2016, the FASB issued ASU 2016-09, "Compensation –Stock Compensation (Topic 718): Improvements to Employee Share Based Payment Accounting". The standard includes multiple provisions intended to simplify various aspects of the accounting for share based payments. The amendments are expected to significantly impact net income, earnings per share, and the statement of cash flows. Implementation and administration may present challenges to companies with significant share based payment activities. The amendments are effective for public entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016. Early adoption is permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. The Company is currently evaluating the impact of this standard on its financial statements however, the Company believes that the

impact will not be material.

In February 2016, the FASB issued ASU 2016-02, “Leases (Topic 842)”. The new standard establishes a right-of-use (ROU) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact of its adoption of this standard on its financial statements.

In January 2016, the FASB issued ASU 2016-01, “Financial Instruments – Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities,” which requires that all equity investments be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under the equity method of accounting or those that result in consolidation of the investee). The amendments in this update also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, the amendments in this update eliminate the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. The amendment is effective for financial statements issued for fiscal years beginning after December 15, 2017. Early adoption is not permitted. The Company is currently evaluating the impact of this standard on its financial statements.

In July 2015, the FASB issued ASU 2015-11, “Simplifying the Measurement of Inventory.” ASU 2015-11 clarifies that inventory should be held at the lower of cost or net realizable value. Net realizable value is defined as the estimated selling price, less the estimated costs to complete, dispose and transport such inventory. ASU 2015-11 will be effective for fiscal years and interim periods beginning after December 15, 2016. ASU 2015-11 is required to be applied prospectively and early adoption is permitted. The adoption of ASU 2015-11 is not expected to have a material impact on the Company’s financial position or results of operations.

In August 2014, the FASB issued ASU 2014-15, “Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”). ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an organization’s ability to continue as a going concern and to provide related footnote disclosures. The amendments in this ASU are effective for reporting periods ending after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact the adoption of ASU 2014-15 will have on its financial statements.

In May 2014, the FASB issuing ASU 2014-09, Topic 606, Revenue from Contracts with Customers (the "New Revenue Standard"). The amendments in this ASU provide a single model for use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance, including industry-specific revenue guidance. The core principle of the new ASU is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. New disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers are also required. In August 2015, the FASB issued ASU 2015-14 which deferred the effective date of the New Revenue Standard. In 2016, the FASB issued ASU 2016-08, ASU 2016-10, ASU 2016-11, and ASU 2016-12 to clarify, among other things, the implementation guidance related to principal versus agent considerations, identifying performance obligations, and accounting for licenses of intellectual property. The New Revenue Standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is not permitted. The amendments in this update are to be applied on a retrospective basis, either to each prior reporting period presented or by presenting the cumulative effect of applying the update recognized at the date of initial application.

The New Revenue Standard will be effective for the Company in fiscal 2019. The Company is evaluating the adoption methodology and the impact of this ASU on its financial statements.

Note 3 – Going Concern

As reflected in the accompanying financial statements, the Company has a net loss of $28.2 million and net cash used in operations of $10.7 million for the year ended June 30, 2016, and stockholders' equity of $10.1 million and an accumulated deficit of $46.6 million at June 30, 2016. In addition, the Company is in the early stage of commercialization and has not yet generated any profits. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company expects that its current cash resources as well as expected lack of operating cash flows will not be sufficient to sustain operations for a period greater than one year. The ability of the Company to continue its operations is dependent on management's plans, which include continuing to raise equity-based financing. There is no assurance that the Company will be successful in accomplishing this objective.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 4 – License Agreement/Revenue Recognition

During 2011, Ampio entered into a license, development and commercialization agreement with a major Korean pharmaceutical company which was assigned to Vyrix when it was formed in 2013. The agreement grants the pharmaceutical company exclusive rights to market Zertane in South Korea for the treatment of premature ejaculation ("PE") and for a combination drug to be developed, utilizing Zertane and an erectile dysfunction drug. Upon signing of the agreement, Ampio received a $500,000 upfront payment, the net proceeds of which were $418,000 after withholding of Korean tax. The upfront payment was deferred and was being recognized as license revenue over a ten-year period. Milestone payments of $3.2 million could have been earned and recognized contingent upon achievement of regulatory approvals and cumulative net sales targets, which could have taken several years. In addition, Aytu could have earned a royalty based on 25% of net sales, as defined, if the royalty exceeded the transfer price of the Zertane product. No royalties have been earned to date.

In April 2014, Vyrix entered into a Distribution and License Agreement (the "Paladin Agreement") with Endo Ventures Limited, which acquired Paladin Labs Inc. ("Paladin"), whereby Paladin has exclusive rights to market, sell and distribute Zertane in Canada, the Republic of South Africa, certain countries in Sub Saharan Africa, Colombia and Latin America. The Paladin Agreement expires on a country by country basis upon the later of 15 years after the first commercial sale of the product in that country or expiration of market exclusivity for Zertane in that country. Paladin paid $250,000 to Vyrix upon signing the Paladin Agreement and is obligated to make milestone payments aggregating up to $3,025,000 based upon achieving Canadian and South African product regulatory approval and achieving specific sales goals. The upfront payment was deferred and was being recognized as license revenue over a seven-year period. In addition, the Paladin Agreement provides that Paladin pay royalties based on sales volume.

At the end of fiscal 2016, Aytu determined that the Zertane asset has no value as Aytu does not have the resources to complete the necessary clinical trials and bring it to market before the patents expire. The remaining deferred revenue of $426,000 was recognized as of June 30, 2016.

Note 5 – Fair Value Considerations

Aytu's financial instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities, convertible promissory notes and warrant derivative liability. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. The fair value of the convertible notes was approximately the face value of the notes (see Note 8 for more information). The valuation policies are determined by the Chief Financial Officer and approved by the Company's Board of Directors.

Authoritative guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of Aytu. Unobservable inputs are inputs that reflect Aytu's assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Aytu for identical assets or liabilities;

Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and

Level 3: Unobservable inputs that are supported by little or no market activity.

Aytu's assets and liabilities which are measured at fair value are classified in their entirety based on the lowest level of input that is significant to their fair value measurement. Aytu's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. Aytu has consistently applied the valuation techniques discussed below in all periods presented.

The following table presents Aytu's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2016, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
June 30, 2016				
ASSETS				
Investment in Acerus	$ 1,041,000	$ -	$ -	$ 1,041,000
LIABILITIES				
Warrant derivative liability	$ -	$ -	$ 276,000	$ 276,000
Contingent consideration	$ -	$ -	$ 3,869,000	$ 3,869,000
June 30, 2015				
ASSETS				
Investment in Acerus	$ -	$ -	$ -	$ -
LIABILITIES				
Warrant derivative liability	$ -	$ -	$ -	$ -
Contingent consideration	$ -	$ -	$ 664,000	$ 664,000

The estimated fair value of the Company's investment, which is classified as Level 1 (quoted price is available), was $1,041,000 as of June 30, 2016. The estimated fair value of the Company's marketable securities is determined using the quoted price in the active market based on the closing price as of the balance sheet date.

As of June 30, 2016	Maturity in Years	Initial Cost	Unrealized Gains	Unrealized Losses	Fair Value
Investment in Acerus	Less than 1 year	$ 2,013,000	$ 0	$ (972,000)	$ 1,041,000

The warrant derivative liability for the warrants was valued using the Black-Scholes valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Significant assumptions in valuing the warrant derivative liability were based on estimates of the value of Aytu common stock, the exercise price of $6.00, the term of 5 years, volatility of 75% and a risk free interest rate of 1.32% at issuance. At June 30, 2016, these warrants were re-valued with an adjusted term of 4.84 years, volatility of 75% and a risk free interest rate of 0.986%.

The following table sets forth a reconciliation of changes in the fair value of financial liabilities classified as Level 3 in the fair valued hierarchy:

	Derivative Instruments
Balance as of June 30, 2015	$ -
Warrant issuances	400,000
Reclassification of warrant liability to equity upon note conversion	(137,000)
Change in fair value included in earnings	13,000
Balance as of June 30, 2016	$ 276,000

Note 6 – Income Taxes

As previously discussed in Note 2 – Summary of Significant Accounting Policies, the Company has been included in the consolidated tax returns of Ampio for tax years ended on or before December 31, 2015. Beginning in January 2016, Aytu will file tax returns separate from Ampio. For all consolidated tax return periods, the Company's taxes have been computed and reported on a "separate return" basis. Ampio and Aytu do not have a tax sharing agreement. Accordingly, certain tax attributes, e.g., net operating loss carryforwards, reflected in these financial statements, may or may not be available to Aytu. In January 2016, Ampio's ownership fell below 80% so that Aytu will no longer be included in the Ampio consolidated income tax return. The deconsolidation resulted in approximately $4.5 million of the net operating loss carryforwards originating prior to the incorporation of Vyrix and Luoxis to no longer be available to Aytu. Upon deconsolidation, the deferred income tax asset and related valuation allowance for these pre-incorporation net operating losses have been removed.

Income tax benefit resulting from applying statutory rates in jurisdictions in which Aytu is taxed (Federal and State of Colorado) differs from the income tax provision (benefit) in the Aytu's financial statements. The following table reflects the reconciliation for the respective periods:

	Year Ended June 30,			
	2016		2015	
Benefit at statutory rate	$ (9,581,229)	(34.00)%	$ (2,634,087)	(34.00)%
State income taxes, net of federal benefit	(853,203)	(3.03)%	(216,183)	(2.79)%
Stock based compensation	7,156	0.03%	426,725	5.51%
Interest on convertible debt	75,148	0.27%	-	0.00%
Change in valuation allowance	8,672,155	30.77%	2,397,527	30.95%
Reduction of net operating losses upon deconsolidation	1,674,110	5.94%	-	0.00%
Other	5,863	0.02%	2,108	0.03%
Net income tax provision (benefit)	$ -	0.00%	$ (23,910)	(0.30)%

Deferred income taxes arise from temporary differences in the recognition of certain items for income tax and financial reporting purposes. The approximate tax effects of significant temporary differences which comprise the deferred tax assets and liabilities are as follows for the respective periods:

	2016	2015
Deferred tax assets (liabilities):		
Deferred revenue	$ -	$ 190,000
Deferred rent	5,000	-
Accrued expenses	445,000	73,000
Net operating loss carry forward	9,202,000	6,337,000
Intangibles	606,000	453,000
Share-based coompensation	327,000	-
Acquired in-process research and development	-	(2,779,000)
Unrealized loss on investment	360,000	-
Warrant liability	153,000	-
Inventory	192,000	-
Allowance for doubtful accounts	15,000	-
Total deferred income tax assets (liabilities)	11,305,000	4,274,000
Less: Valuation allowance	(11,305,000)	(4,274,000)
Total deferred income tax assets (liabilities)	$ -	$ -

Aytu has recorded income tax benefits in its statements of operations since inception, stemming from its operating losses, and is expected to incur operating losses for the foreseeable future. During the year ended June 30, 2015, the net deferred tax liability was reduced to zero based upon the operating losses, thus Aytu established a valuation allowance offsetting any future net deferred tax asset. As such, Aytu would no longer record income tax benefits in its results of operations after the year ended June 30, 2015 because management is currently unable to conclude that it is more likely than not that a benefit will be realized.

In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income, carry back opportunities and tax planning strategies in making the assessment. The Company believes it is more likely than not it will realize the benefits of these deductible differences, net of the valuation allowance provided.

The Company has federal net operating loss carryforwards of approximately $24.8 million and $17.1 million as of June 30, 2016 and June 30, 2015, respectively that, subject to limitation, may be available in future tax years to offset taxable income. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2032 through 2035. Net operating loss carryforwards are subject to examination in the year they are utilized regardless of whether the tax year in which they are generated has been closed by statute. The amount subject to disallowance is limited to the NOL utilized. Accordingly, the Company may be subject to examination for prior NOLs generated as such NOLs are utilized. Under the provisions of the Internal Revenue Code, substantial changes in the Company's ownership may result in limitations on the amount of NOL carryforwards that can be utilized in future years.

As of June 30, 2016 and 2015, the Company has no liability for gross unrecognized tax benefits or related interest and penalties.

Aytu has made its best estimates of certain income tax amounts included in the financial statements. Application of the Company's accounting policies and estimates, however, involves the exercise of judgment and use of assumptions as to future uncertainties and, as a result, could differ from these estimates. In arriving at its estimates, factors the Company considers include how accurate the estimates or assumptions have been in the past, how much the estimates or assumptions have changed and how reasonably likely such changes may have a material impact. Aytu has been historically included in the Ampio consolidated tax return. Under the general statute of limitations, the Company would not be subject to federal or Colorado income tax examinations for years prior to 2012 and 2011, respectively. However, given the net operating losses generated since inception, all tax years since inception are subject to examination.

Note 7 – Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of June 30, 2016:

	Total	2017	2018	2019	2020	2021	Thereafter
Prescription Database	$ 1,902,000	$ 731,000	$ 598,000	$ 573,000	$ -	$ -	$ -
Natesto	8,500,000	6,000,000	-	-	2,500,000	-	-
Manufacturing agreement	3,000,000	2,000,000	500,000	500,000	-	-	-
Service agreement	204,000	204,000	-	-	-	-	-
Primsol	750,000	750,000	-	-	-	-	-
Office Lease	317,000	142,000	145,000	30,000	-	-	-
Sponsored research agreement with related party	70,000	70,000	-	-	-	-	-
	$ 14,743,000	$ 9,897,000	$ 1,243,000	$ 1,103,000	$ 2,500,000	$ -	$ -

Prescription Database

In May 2016, Aytu entered into an agreement with a company that will provide Aytu with prescription database information, whereby Aytu agreed to pay approximately $1,902,000 over three years for access to the database of prescriptions written for Natesto.

Natesto

In April 2016, the Company entered into an agreement with Acerus whereby Aytu agreed to pay $8,000,000 for the exclusive U.S. rights to Natesto of which $6,000,000 is payable in fiscal year 2017. Additionally, Aytu is required to make the first milestone payment even if the milestone is not reached.

Manufacturing Agreement

On October 8, 2015, Aytu and Biovest International, Inc., or Biovest, entered into a Master Services Agreement, pursuant to which Biovest is to provide manufacturing services to us for ProstaScint. In conjunction with entering into the agreement, we submitted a work order to Biovest to provide us with active pharmaceutical ingredient for ProstaScint over a four-year period at a total cost of $5.0 million, of which we paid $1.0 million upon submission of the work order and $500,000 in each of January and April 2016. We will pay an additional $2,000,000 in fiscal 2017, and $500,000 in both fiscal 2018 and 2019.

Service Agreement

In July 2015, Aytu entered into agreements with Ampio whereby Aytu agreed to pay Ampio $30,000 per month for shared overhead which includes costs related to the shared facility, corporate staff, and other miscellaneous overhead expenses. These agreements will be in effect until they are terminated in writing by both parties. This agreement was amended in April 2016, which reduced the monthly amount to $18,000. This agreement was amended again in July 2016, which reduced the monthly amount to approximately $17,000 per month. For the years ended June 30, 2016 and 2015, the Company paid approximately $310,000 for this service agreement.

Primsol

In October 2015, Aytu entered into an asset purchase agreement with FSC Laboratories, Inc., or FSC. Pursuant to the agreement, we purchased assets related to FSC's product known as Primsol (trimethoprim solution), including certain intellectual property and contracts, inventory, work in progress and all marketing and sales assets and materials related solely to Primsol (together, the ''Primsol Business''), and assumed certain of FSC's liabilities, including those related to the sale and marketing of Primsol arising after the closing. We paid $500,000 at closing for the Primsol Business and we paid an additional $142,000, of which $102,000 went to inventory and $40,000 towards the Primsol Business, for the transfer of the Primsol-related product inventory. We also paid $500,000 on April 1, 2016 and $500,000 on July 1, 2016 and must pay $250,000 no later than September 30, 2016 (together, the ''Installment Payments''), for a total purchase price of $1,892,000. This amount is included in accounts payable and accrued liabilities on the balance sheet.

Office Lease

In June 2015, Aytu entered into a 37 month operating lease for a space in Raleigh, North Carolina. This lease has initial base rent of $3,000 a month, with total base rent over the term of the lease of approximately $112,000. In August 2015, the Company entered into a 37 month operating lease in Englewood, Colorado effective September 1, 2015. This lease has an initial base rent of $9,000 a month with a total base rent over the term of the lease of approximately $318,000 which includes rent abatements. The Company recognizes rental expense of the facilities on a straight-line basis over the term of the lease. Differences between the straight-line net expenses on rent payments are classified as liabilities between current deferred rent and long-term deferred rent. Rent expense for the respective periods is as follows:

	Year Ended June 30,	
	2016	2015
Rent expense	$ 120,000	$ 51,000

Sponsored Research Agreement with Related Party

Aytu entered into a Sponsored Research Agreement with Trauma Research LLC ("TRLLC"), a related party, in June 2013. Under the terms of the Sponsored Research Agreement, TRLLC agreed to work collaboratively in advancing the RedoxSYS System diagnostic platform through research and development efforts. The Sponsored Research Agreement may be terminated without cause by either party on 30 days' notice.

Note 8 – Convertible Promissory Notes

Convertible Promissory Notes

During July and August 2015, Aytu closed on note purchase agreements with institutional and high net worth individual investors for the purchase and sale of convertible promissory notes ("Notes") with an aggregate principal amount of $5.2 million. The sale of the Notes was pursuant to a private placement. Debt issuance costs totaled $401,000, which include the $103,000 fair value of the placement agent warrants.

The Notes were an unsecured obligation. Aytu did not have the right to prepay the Notes prior to the maturity date. Interest accrued on the Notes in the following amounts: (i) 8% simple interest per annum for the first six months and (ii) 12% simple interest per annum thereafter if not converted during the first nine months. Interest accrued, was payable with the principal upon maturity, conversion or acceleration of the Notes and could have been paid in kind or in cash, in Aytu's sole discretion.

Placement agents for the offerings sold the institutional portion of the offering of the Notes. Aytu sold the balance of the Notes to individuals and entities with whom Aytu has an established relationship. For Notes sold by the placement agent, Aytu paid the placement agent 8% of the gross proceeds of Notes sold by the placement agents and is obligated to issue warrants for an amount of shares to be equal to 8% of the gross number of shares of the Company stock issuable upon conversion of the Notes issued to investors introduced to the Company by the private placement agents in the private placement, in addition to a previously paid non-refundable retainer fee of $20,000. The placement agent warrants had a term of five years from the date of issuance of the related notes in July and August 2015, an exercise price equal to the conversion price per share at which the Notes are converted into common stock. Change in fair value is recorded in earnings. Fair value at the grant date was recorded as a debt discount and amortized over the term of the debt.

The warrants were recorded at fair value as long-term liabilities on the Balance Sheet (see Note 5).

Upon Aytu's adoption of ASU 2015-3, the issuance costs associated with the Notes were recorded as a long–term liability and were presented in the Balance Sheet as a direct reduction of the carrying amount of the Notes on their inception date.

Pursuant to the terms of the convertible promissory note agreements, if Aytu sold equity securities at any time while the notes were outstanding in a financing transaction that was not a Qualified Financing (a public offering of Aytu stock resulting in gross proceeds of at least $5.0 million (excluding indebtedness converted in such financing) prior to the maturity date of the Notes), the holders of the convertible promissory notes had the option, but not the obligation, to convert the outstanding principal and accrued interest as of the closing of such financings into a number of shares of Aytu capital stock in an amount equal to 120% of the number of such shares calculated by dividing the outstanding principal and accrued interest by the lesser of (a) the lowest cash price per share paid by purchasers of shares in such financing, or (b) $4.63. As a result of Aytu's sale of common stock on January 20, 2016, the Company was obligated to provide notice to the above-referenced noteholders of such stock sales. In accordance with the convertible note terms, for a period of ten business days (which was extended to 15 business days by the Company, or February 10, 2016) following receipt of the notice, noteholders had the option to convert their entire balance (inclusive of accrued but unpaid interest) into a number of shares of Aytu common stock equal to 120% of the number of shares calculated by dividing such note balance by $7.80, which was the per share purchase price paid in the equity financing described above. On February 10, 2015, the date of the conversion, an aggregate of $4,125,000 of principal and $143,000 of accrued interest on the notes converted into an aggregate of 656,591 shares of Aytu's common stock under the original terms of the agreement.

In May 2016, Aytu completed a registered public offering which was considered a Qualified Financing and all outstanding notes were forced to convert into the same arrangement that was given in the offering. At the insistence of the underwriters of the offering, all outstanding noteholders had signed lockup agreements which granted them an extra 10% on the conversion increasing it to 130% of shares calculated by dividing such note balance by $4.80, which was the per share purchase price in the registered offering. On May 6, 2016, the date of conversion, an aggregate of $1,050,000 of principal and $78,000 of accrued interest on the notes converted into an aggregate of 305,559 shares of Aytu's common stock and 305,559 warrants according to the terms of the agreement.

In connection with the conversion of the Aytu notes, Aytu was obligated to issue to the placement agents for the convertible note offering warrants for an amount of shares equal to 8% of the number of shares of Aytu's common stock for the notes sold by the placement agents issued upon conversion of the notes. As a result of the optional note conversion, on February 10, 2016, Aytu issued warrants to the placement agents to purchase an aggregate of 22,254 shares of our common stock at an exercise price of $7.80 per share. As a result of the second note conversion, on May 6, 2016, Aytu issued warrants to the placement agents to purchase an aggregate of 22,564 shares of our common stock at an exercise price of $4.80 per share. These warrants are exercisable for five years from the date of issuance of the related notes in July and August 2015. The warrants have a cashless exercise feature.

Also in connection with the conversion of the notes, Aytu recorded a beneficial conversion feature of $4.9 million which was recorded as a debt discount; this amount represents that carrying amount of the notes at the date of conversion. The beneficial conversion feature was expensed upon conversion of the notes to interest expense.

Note 9 – Common Stock

Capital Stock

At June 30, 2016 and 2015, Aytu had 100 million and 300 million shares, respectively, of common stock authorized with a par value of $0.0001 per share and 50 million shares of preferred stock authorized with a par value of $0.0001 per share. In May 2016, the Aytu shareholders voted to reduce the authorized common stock outstanding from 300 million to 100 million shares.

In May 2016, we raised gross proceeds of approximately $7.5 million through a public offering of 1,562,500 Units, offering costs totaled $1.2 million resulting in net proceeds of $6.3 million. Each Unit consists of one share of Aytu common stock and a warrant to purchase one share of Aytu common stock. The common stock issued had a relative fair value of $4.2 million. The warrants have an exercise price of $6.00 per share and will expire five years from the date of issuance. These warrants have a relative fair value of $2.1 million. We also granted the underwriters a 45-day option (the Over-Allotment Option) to purchase up an additional 234,375 shares of common stock and/or warrants. The underwriters exercised 170,822 of this over-allotment option for the warrants and paid $0.12 per over-allotment warrant. These warrants have the same terms as the warrants offered in the registered offering. These warrants have a relative fair value of $20,000, which was the purchase price per the underwriting agreement.

On June 30, 2016, Aytu effected a reverse stock split in which each common stock holder received one share of common stock for each 12 shares. All share and per share amounts for all periods presented in this report have been adjusted to reflect the effect of this reverse stock split.

Note 10 – Equity Instruments

Options

Prior to the Merger, Aytu had two approved stock option plans (Luoxis 2013 Stock Option Plan and Vyrix 2013 Stock Option Plan), pursuant to which Aytu had reserved a total of 143,236 shares of common stock, both of which were terminated on April 16, 2015 upon the closing of the Merger.

The Luoxis options that were in the money and all outstanding Vyrix options issued under the 2013 Option Plans were accelerated and cancelled in connection with the Merger. Option holders received a cash payment per option share equal to the difference between the consideration payable per share of common stock pursuant to the Merger and the exercise price of the option, if the consideration paid to holders of common stock was less than the exercise price of such options, no amount was paid to the option holder in connection with the cancellation. The cash payment during the period ended June 30, 2015 was $27,000. The Company recognized compensation of $422,000 and $189,000 related to the Luoxis and Vyrix options that had accelerated vesting as of the Merger date.

The Luoxis options that were not paid out were terminated pursuant to the terms of the 2013 Luoxis Option Plan. The Company treated these options as pre-vesting forfeitures and $433,000 of previously recognized compensation was reversed.

On June 1, 2015, Aytu's stockholders approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 833,334 shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2015 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan.

Pursuant to the 2015 Stock Plan, 833,334 shares of its common stock, were reserved for issuance. The fair value of the options was calculated using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. Aytu estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The assumptions are as follows:

	Year Ended June 30,	
	2016	2015
Expected volatility	75%	-
Risk free interest rate	1.16% - 1.90%	-
Expected term (years)	3.75 - 6.25	-
Dividend yield	0%	-
Forfeiture rate	0%	-

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2015	-	$ -	
Granted	326,469	$ 18.01	
Exercised	-	$ -	
Forfeited/Cancelled	(4,167)	$ 18.12	
Outstanding June 30, 2016	322,302	$ 18.01	9.33
Exercisable at June 30, 2016	139,798	$ 16.76	9.42
Available for grant at June 30, 2016	511,032		

The following table details the options outstanding at June 30, 2016 by range of exercise prices:

Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life of Options Outstanding	Number of Options Exercisable	Weighted Average Exercise Price
$ 6.72	16,668	$ 6.72	9.79	16,668	$ 6.72
$ 18.12	301,467	$ 18.12	9.37	123,130	$ 18.12
$ 55.56	4,167	$ 55.56	4.11	-	$ -
	322,302	$ 18.01	9.33	139,798	$ 16.76

Stock-based compensation expense related to the fair value of stock options was included in the statements of operations as research and development expenses and sales, general and administrative expenses as set forth in the table below. Aytu determined the fair value as of the date of grant using the Black-Scholes option pricing model and expenses the fair value ratably over the vesting period. The following table summarizes stock-based compensation expense for the years ended June 30 2016 and 2015:

	Year Ended June 30, 2016	2015
Research and development expenses		
Stock options	$ 89,000	$ 519,000
Selling, general and administrative expenses		
Stock options	814,000	499,000
	$ 903,000	$ 1,018,000
Unrecognized expense at June 30, 2016	$ 1,267,000	
Weighted average remaining years to vest	2.66	

Warrants

A summary of all warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2014	8,553	$ 54.36	3.92
Granted in fiscal 2015	-	-	
Expired in fiscal 2015	-	-	
Outstanding June 30, 2015	8,553	$ 54.36	2.92
Warrants issued to placement agents for convertible promissory notes	22,254	$ 7.80	
Warrants issued to investors in connection with the registered offering	1,733,322	$ 6.00	
Warrants issued to placement agents for convertible promissory notes	22,564	$ 4.80	
Warrants issued to placement agents for the registered offering	109,375	$ 6.00	
Warrants issued to convertible note holders who converted May 5, 2016	305,559	$ 6.00	
Outstanding June 30, 2016	2,201,627	$ 6.19	4.71

In connection with our private placement of approximately $5.2 million of convertible notes in July and August 2015, the Company was obligated to issue to the placement agents' warrants for an amount of shares equal to 8% of the number of shares of our common stock issued upon conversion of the notes and any accrued interest. The placement agents warrants have a term of five years from the date of issuance of the related notes in July and August 2015, an exercise price equal to 100% of the price per share at which equity securities were sold in our next equity financing, and provide for cashless exercise.

In connection with the conversions of the notes in February 2016 and May 2016, which were triggered by an equity financing in January 2016 and our public offering of common stock and warrants in May 2016, respectively, we issued warrants to the placement agents to purchase an aggregate of 22,254 shares of our common stock at an exercise price of $7.80 per share, and an aggregate of 22,564 shares of our common stock at an exercise price of $4.80 per share. These warrants have a fair value of $87,000 and $50,000, respectively. As discussed in Note 5, these amount were reclassified from liability accounting to equity upon the second conversion of the convertible notes in May 2016.

Also in connection with the conversion of the notes in May 2016, the noteholders that converted also received 305,559 warrants (see Note 8). These warrants have a term of five years with an exercise price of $6.00 per share. These warrants are accounted for under equity treatment and have a fair value of $480,000.

In connection with our May 2016 public offering, we issued warrants to purchase an aggregate of 109,375 shares of common stock at an exercise price of $6.00 and a term of five years to the underwriters of the public offering. These warrants are accounted for under liability accounting and are fair valued at each reporting period (see Note 5). At June 30, 2016, these warrants had a fair value of $276,000.

Also in connection with our May 2016 public offering, we issued to investors warrants to purchase an aggregate of 1,733,322 shares of common stock, which includes the over-allotment warrants, at an exercise price of $6.00 with a term of five years. These warrants are accounted for under equity treatment (see Note 9).

The warrants issued in connection with our registered offering are all registered and tradable on the OTCQX under the ticker symbol “AYTUW”.

All warrants were valued using the Black-Scholes option pricing model. In order to calculate the fair value of the warrants, certain assumptions were made regarding components of the model, including the closing price of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and expected life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing a weighted average of comparable published volatilities of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity.

The assumptions are as follows:

	Year Ended June 30,	
	2016	2015
Expected volatility	75%	-
Risk free interest rate	1.07 - 1.76%	-
Contractual term (years)	4.2 - 5.0	-
Dividend yield	0%	-

Note 11 – Related Party Transactions

Ampio Loan Agreements

In November 2013, Vyrix entered into a loan agreement with Ampio. Pursuant to the loan agreement, Ampio agreed to lend Vyrix up to an aggregate amount of $3,000,000 through cash advances of up to $500,000 each. Unpaid principal amounts under the loan agreement bear simple interest at the “Applicable Federal Rate” for long-term obligations prescribed under Section 1274(d) of the Internal Revenue Code of 1986, as amended (or any successor provision with similar applicability). The initial term of this loan agreement is for one year, subject to automatic extension of successive one-year terms. Vyrix may repay any outstanding balance at any time without penalty. Ampio has an option of converting any balance outstanding under the loan agreement into shares of Vyrix common stock at the fair market value per share of Vyrix common stock, as determined by the Ampio board of directors, as of such conversion date. As of June 30, 2014, the amount advanced was $1,600,000 with interest rates from 3.11%-3.32%. On April 16, 2015, in connection with the closing of the Merger, Ampio released Vyrix from its then outstanding obligation of $4,000,000 under the loan agreement as consideration of its share purchase, and the loan agreement was terminated.

In March 2014, Luoxis entered into a loan agreement with Ampio. Pursuant to the loan agreement, Ampio agreed to lend Luoxis $3,000,000. Unpaid principal amounts under the loan agreement bear simple interest at the “Applicable Federal Rate” for long-term obligations prescribed under Section 1274(d) of the Internal Revenue Code of 1986, as amended (or any successor provision with similar applicability). The initial term of this loan agreement is for one year, subject to automatic extension of successive one-year terms. Luoxis may repay any outstanding balance at any time without penalty. Ampio has an option of converting any balance outstanding under the loan agreement into shares of Luoxis common stock at the fair market value per share of Luoxis common stock, as determined by the Ampio board of directors, as of such conversion date. As of June 30, 2014, the amount advanced was $3,000,000 with interest rates from 3.11%—3.32%. On April 16, 2015, in connection with the closing of the Merger, Ampio released Luoxis from its then outstanding obligation of $8,000,000 under the loan agreement as consideration of its share purchase, and the loan agreement was terminated.

On April 16, 2015, Ampio received 396,816 shares of common stock of Aytu for (i) issuance to Aytu of a promissory note from Ampio in the principal amount of $10,000,000, maturing on the first anniversary of the Merger, (ii) cancellation of indebtedness of Luoxis to Ampio in the amount of $8,000,000; and (iii) cancellation of indebtedness of Vyrix to Ampio in the amount of $4,000,000.

Services Agreement

The Company has service agreements with Ampio which are described in Note 7.

Sponsored Research Agreement

In June 2013, Luoxis entered into a sponsored research agreement with TRLLC, an entity controlled by Ampio's director and Chief Scientific Officer, Dr. Bar-Or. The agreement, which was amended in January 2015 and provides for Luoxis (now Aytu) to pay $6,000 per month to TRLLC in consideration for services related to research and development of the Oxidation Reduction Potential platform. In March 2014, Luoxis also agreed to pay a sum of $615,000 which is being amortized over the contractual term of 60.5 months and is divided between current and long-term on the balance sheet; as of September 2014, this amount had been paid in full. This agreement is set to expire in March 2019 but can be terminated earlier but not until after March 2017.

Note 12 – Employee Benefit Plan

Aytu has a 401(k) plan that allows participants to contribute a portion of their salary, subject to eligibility requirements and annual IRS limits. As of June 30, 2016, Aytu does not match employee contributions. Starting in fiscal 2017, the Company will match 50% of the first 6% contributed to the plan by employees.

Note 13 – Subsequent Events

In July 2016, Aytu cancelled and re-issued certain outstanding stock option agreements as well as issued an additional 441,999 stock options to executives, employees, directors and consultants. Aytu also issued 1.0 million shares of restricted stock to executive officers and directors.

On July 27, 2016, we entered into a purchase agreement (the "Purchase Agreement"), together with a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), an Illinois limited liability company. Upon signing the Purchase Agreement, Lincoln Park agreed to purchase 133,690 shares of our common stock for $500,000 as an initial purchase under the agreement.

Under the terms and subject to the conditions of the Purchase Agreement, we have the right to sell to and Lincoln Park is obligated to purchase up to an additional $10.0 million in amounts of shares of our common stock ("Common Stock"), subject to certain limitations, from time to time, over the 36-month period commencing on the date that a registration statement, which we agreed to file with the Securities and Exchange Commission (the "SEC") pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus in connection therewith is filed.

In connection with the Purchase Agreement, we issued as a commitment fee to Lincoln Park 52,500 shares of Common Stock. Joseph Gunnar & Co., LLC ("Joseph Gunnar") and Fordham Financial Management, Inc. ("Fordham") acted as Financial Advisor on our behalf. Upon the execution of the Purchase Agreement, we paid $50,000 to Joseph Gunnar and $50,000 to Fordham. Upon the earlier of six months from the execution of the Purchase Agreement or upon the effectiveness of the resale registration statement to be filed pursuant to the Registration Rights Agreement, we will pay an additional $50,000 to Joseph Gunnar and $50,000 to Fordham.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 No. 333-205462 and Forms S-1 Nos. 333-207421, 333-205414, 333-209874, 333-210144, 333-212100 and related prospectus of Aytu BioScience, Inc. of our report dated September 1, 2016 relating to our audit of the financial statements of Aytu BioScience, Inc., which appears in this Annual Report on Form 10-K as of and for the year ended June 30, 2016.

/s/ EKS&H LLLP

September 1, 2016
Denver, Colorado

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua R. Disbrow, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended June 30, 2016 of Aytu BioScience, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 1, 2016

/s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gregory A. Gould, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended June 30, 2016 of Aytu BioScience, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 1, 2016

/s/ Gregory A. Gould
Gregory A. Gould
Chief Financial Officer (Principal Financial Officer
and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Aytu BioScience, Inc. (the "Company") for the fiscal year ended June 30, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of Joshua R. Disbrow, Chief Executive Officer (Principal Executive Officer), and Gregory A. Gould, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: September 1, 2016

/s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer (Principal Executive Officer)

/s/ Gregory A. Gould
Gregory A. Gould
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)