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, 2017

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13a) of the Exchange Act. ¨

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, 2016 was $10.5 million based on the closing price of $24.00 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, 2017, there are 4,021,822 shares of common stock outstanding and 2,250 shares of Series A preferred stock outstanding.

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This Annual Report on Form 10-K refers to trademarks, such as Aytu, Natesto, ProstaScint, Primsol, MiOXSYS, RedoxSYS, and Fiera 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 concentrating on hypogonadism, prostate cancer, male infertility and, recently, female sexual wellbeing and intimacy and plan to expand into other urological indications for which we believe there are significant medical needs.

We acquired exclusive U.S. rights to Natesto® (testosterone) nasal gel, 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 late summer 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 $2.0 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®.

Outside the U.S. we market MiOXSYS®, a novel in vitro diagnostic device that is currently CE marked (which generally enables it to be sold within the European Economic Area) 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.

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.

On May 5, 2017, we acquired Nuelle, Inc, or Nuelle, a women's sexual health company. This transaction expanded our product portfolio with the addition of the Fiera® personal care device for women. Fiera was recently launched in the U.S. and is a proprietary, revenue-generating product scientifically proven to enhance physical arousal and sexual desire in the millions of adult women around the world impacted by changes in sexual desire. This acquisition adds a novel, commercial-stage product in a complementary adjacency readily accessible by our U.S.-based commercial infrastructure. Nuelle was previously a portfolio company of leading venture capital firm New Enterprise Associates.

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) nasal gel.

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 late summer 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.

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 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 increased 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 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 the degree of oxidative stress 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 510k clearance.

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 2.2 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 by 2017, a compound annual growth rate, or CAGR, of 7.5% since 2012. At June 30, 2017, the ProstaScint asset was impaired based upon sales projections that we intend to only sell this product through mid-fiscal 2019, when this product expires.

Fiera® Personal Care Device

The Fiera Personal Care Device is the first hands-free wearable product for women, specifically designed to increase interest in, and physical readiness for sex, naturally. The product does so by creating a physically aroused state via the genitals. Co-created with healthcare professionals, Fiera is a small, discreet, fast-acting, and hands-free product that is designed to be used in advance of physical intimacy to help women feel ready and in the mood for sex. Fiera uses gentle suction coupled with stimulation to enhance blood flow to the genitals, increase lubrication, and ultimately get a woman ready for partnered intimacy in as little as 5 minutes.

With the acquisition of Nuelle, Inc., Aytu is expanding into the women's sexual health and wellness market. Sexual wellness is inclusive of female sexual dysfunction which is a term that describes various sexual problems, such as low desire or interest, diminished arousal, orgasmic difficulties, and dyspareunia. Female sexual dysfunction is considered common, with an estimated prevalence of 43% from the U.S. National Health and Social Life Survey and similar estimates from other large, population-based surveys in the United States and the United Kingdom. In a study of over 31,000 women in the United States it was determined that 44% of women report a sexual problem. Specifically, the most common sexual problem is low desire, with a prevalence of 39%; followed by low arousal (26%) and orgasm difficulties (21%). Additionally, the incidence of sexual dysfunction is expected to increase through 2020 to effect more than 124 million women worldwide.

Fiera has been well studied and tested by health care professionals, and consumers and is scientifically proven to enhance arousal and interest in women of all ages, including pre and post-menopausal women. Recent consumer study results in women ages 25 – 75 showed that after 4 weeks of using Fiera:

- 97% of women felt physically aroused;
- 96% looked forward to being intimate with their partner;
- 93% felt excited and ready for sex;
- 89% of women felt more "in the mood";
- 87% felt as ready for sex as their partner did;
- 86% of women felt a stronger emotional connection with their partner;
- 85% reported their orgasm felt pleasurable and intense;
- 85% thought about sex more often; and
- 85% engaged in sexual activity more often and felt satisfied in her relationship.

Previous studies also showed that 87% of women felt increased desire and 67% felt increased lubrication.

Key elements of our business strategy include:

- Expand the commercialization of Natesto in the U.S. for the treatment of hypogonadism with our direct sales force. We launched Natesto in late summer 2016 and are targeting high prescribing TRT prescribers with a primary emphasis on urologists and male health practitioners.
- Expand the commercialization in the U.S. of Fiera, through professional promotion using our existing sales force.
- Establish MiOXSYS as a leading in vitro diagnostic device in the assessment of male infertility.
- Continue the commercialization of FDA-approved ProstaScint for the staging of both newly diagnosed high-risk and recurrent prostate cancer patients.
- 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 products, 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.

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 American: 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, that 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 initially focused on 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. When we discuss our business in this Report, we include the pre-Merger business of Luoxis and Vyrix.

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 affect a reverse stock split at a ratio of 1-for-12 which became effective on June 30, 2016. At our special meeting of shareholders held on July 26, 2017, our shareholders approved an amendment to our Certificate of Incorporation to affect a reverse stock split at a ratio of 1-for-20 which became effective on August 25, 2017. All share and per share amounts in this report have been adjusted to reflect the effect of these three reverse stock splits (hereafter referred to collectively as the "Reverse Stock Splits").

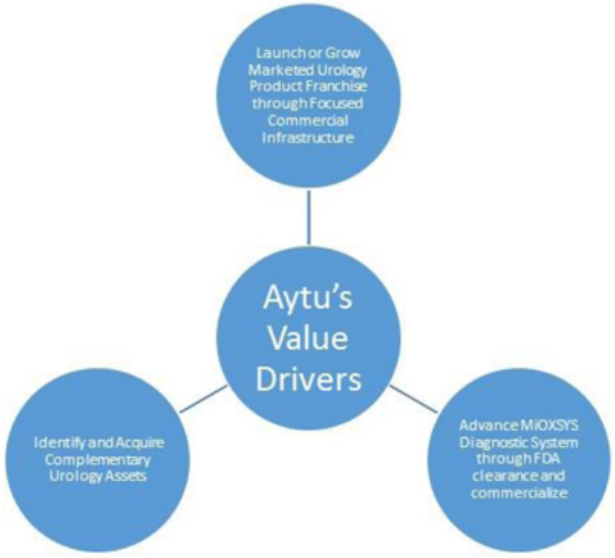
Our Strategy

We expect to create value by implementing a focused, three-pronged strategy. Our primary focus is on expanding Natesto in the U.S, growing our current, revenue-generating products, and building a complementary portfolio of aligned urology assets. In just over two years since our merger we have acquired or in-licensed three FDA-approved, marketed assets (and have since divested one asset – Primsol® Solution), launched a specialty urology sales force, advanced our lead diagnostic asset MiOXSYS to CE marking, engaged in asset purchase and licensing discussions for products aligned to our strategy, launched Natesto in the U.S. through our own sales force and acquired Nuelle Inc., a wholly owned subsidiary focused on the Fiera product.

We believe the strategy of focusing on commercializing assets prescribed by urologists is logical 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 wellness and vitality, 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; MiOXSYS – male infertility; Fiera – female sexual wellness). 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:

- *Expanding the commercialization of Natesto , our revenue-generating, FDA-approved product in the United States via our direct commercial infrastructure. Launching Fiera in the United States via our direct sales force, and commercializing Fiera 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 application 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 a day in the nostrils, may be an appropriate option for men 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 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 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. At June 30, 2017, the ProstaScint asset was impaired based upon sales projections that we intend to only sell this product through mid-fiscal 2019, when this product expires.

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.

The Fiera Personal Care Device is the first hands-free wearable product for women, specifically designed to increase interest in, and physical readiness for sex, naturally. Sexual wellness is inclusive of female sexual dysfunction which is a term that describes various sexual problems, such as low desire or interest, diminished arousal, orgasmic difficulties, and dyspareunia. Female sexual dysfunction is considered common, with an estimated prevalence of 43% from the U.S. National Health and Social Life Survey and similar estimates from other large, population-based surveys in the United States and the United Kingdom. In a study of over 31,000 women in the United States it was determined that 44% of women report a sexual problem. Specifically, the most common sexual problem is low desire, with a prevalence of 39%; followed by low arousal (26%) and orgasm difficulties (21%). Additionally, the incidence of sexual dysfunction is expected to increase through 2020 to effect more than 124 million women worldwide.

United States. We have launched a commercial infrastructure in the U.S. in order to support increased sales and distribution of Natesto, ProstaScint and Fiera 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. Fiera has not been previously marketed outside the U.S., therefore we believe we can realize commercial opportunities through efficient corporate partnerships in key markets around the world. With MiOXSYS now CE Marked we have started developing 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 two years from the Company’s merger in April 2015 we began generating revenue from the acquisition of ProstaScint (which we have since divested), and we later launched Natesto in July 2016 and Fiera in May 2017. 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 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 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. If cleared in the U.S., MiOXSYS would be the first and only semen analysis diagnostic test cleared by the FDA 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 ex-US global male infertility market is estimated at over $800 million in diagnostics, therapeutics, and procedure costs. 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 the Cleveland Clinic, a major U.S. university and Hamad Medical Corporation, major hospital in Doha, Qatar 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 has begun initial marketing of the product in Canada.

Our FDA – Approved Urology Products

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

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 application into each nostril two to three times daily 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 implantable and/or 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 (TRT) 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. At the current market size of over $2.0 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 now facing generic threats with the expiration of key patents for its 1.0% formulation, and is beginning to see generic equivalents to its 1.62% formulation be introduced. Other products with significant shares of the TRT market 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.

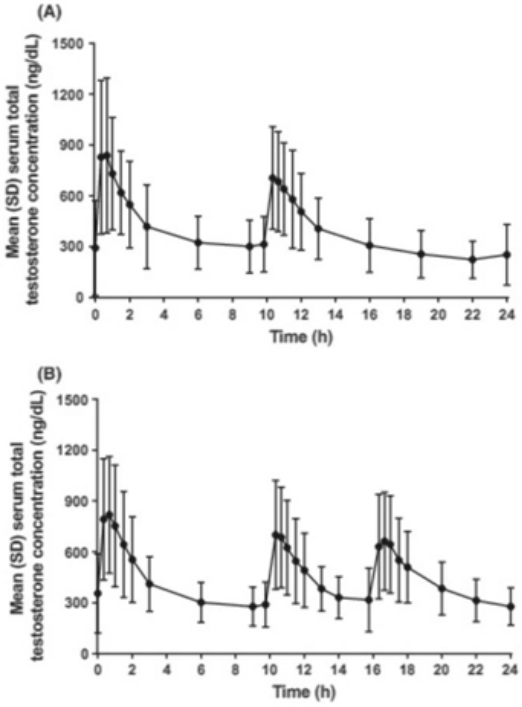
The table below (Table 3 from the Natesto Prescribing Information) summarizes the mean (SD) serum total testosterone concentrations on Day 90 in 69 patients who had a full pharmacokinetic sampling profile and were treated with Natesto (11 mg of testosterone) three times daily for 90 days.

Table 3: Mean (SD) Serum Total Testosterone Concentration 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).



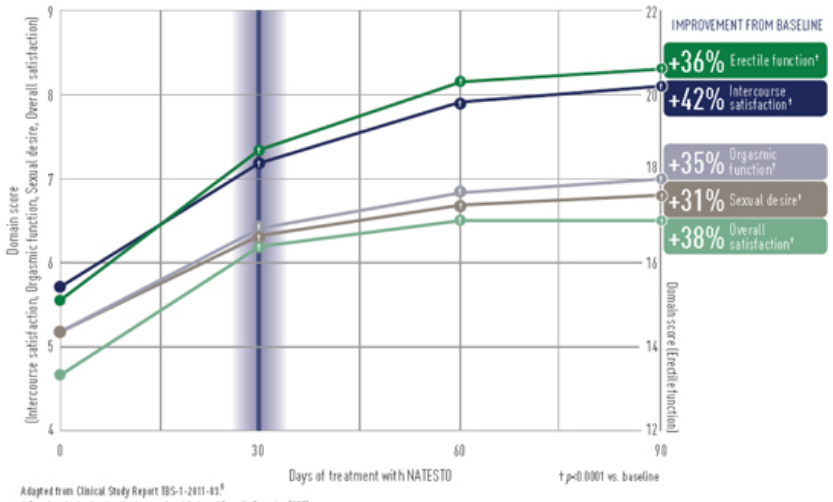
Newly Presented Natesto Safety and Efficacy Data

Secondary endpoints that were measured in the above-referenced pivotal trial included the impact on Natesto – over 90 days – on erectile function as well as on mood. The 90-day clinical trial demonstrated that – within 30 days of initiating treatment with Natesto – subjects exhibited a statistically significant and clinically meaningful improvement in all five domains of erectile function. Specifically, at the end of the 90-day treatment period, improvement from baseline for each domain were as follows:

- 36% improvement in erectile function
- 42% improvement in intercourse satisfaction
- 35% improvement in orgasmic function
- 31% improvement in sexual desire
- 38% improvement in overall satisfaction

Erectile Function: International Index of Erectile Function (IIEF)[1†]

Figure 4 Change in mean sexual function domain scores in patients taking Natesto®. b.i.d (ITT population; n=141).



Adapted from Clinical Study Report TBS-1-2011-03.[5]
* Results obtained using the International Index of Erectile Function (IIEF).
ITT=intent-to-treat

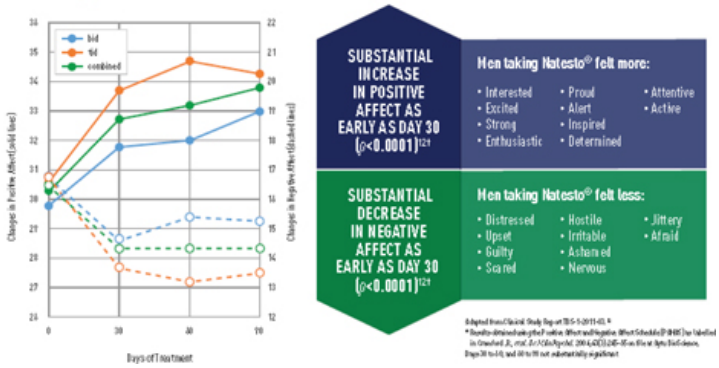
‡Claims associated with b.i.d. administration have not been evaluated by FDA.

In addition to demonstrating a significant improvement in erectile function, Natesto also exhibits a substantial impact on mood as measured by Positive Affect and Negative Affect Schedule (PANAS). As early as 30 days – and continuing up to day 90 – Natesto demonstrates a substantial increase in Positive Affect and a substantial decrease in Negative Affect.

Mood: Positive Affect And Negative Affect Schedule (PANAS)[1†]

Figure 3

Change in mean positive and negative mood** scores in patients taking Natesto® b.i.d., t.i.d. & combined (ITT population; n=288)[1]



In addition to efficacy parameters, safety parameters have also been examined and recently reported. Natesto restores serum testosterone to normal levels _while Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) remained well within the reference range over 90 days. Also, hematocrit (increased blood thickness) was not significantly impacted by Natesto over 360 days of treatment. Other testosterone products alter levels of Follicle Stimulating Hormone (FSH) and Luteining Hormone (LH) and increase hematocrit.

Phase III 90-Day Clinical Trial: Select Safety Data[1]

Follicle Stimulating Hormone and Luteinizing Hormone Results[1]:

Treatment with Natesto® restored serum TT to normal levels while FSH and LH levels were reduced but remained well within the reference range.

Table 4

Follicle Stimulating Hormone (FSH) Reference FSH range in males = 1.6 - 8.0		
	b.i.d†	t.i.d
Mean Baseline (Day 0) (IU/L)	8.5	6
Mean Day 90 (IU/L)	6	3.1
Mean Change (IU/L)	-2.5	-2.9
Luteinizing Hormone (LH) Reference LH range in males = 1.5 - 9.3		
	b.i.d	t.i.d
Mean Baseline (Day 0) (IU/L)	5.4	5.3
Mean Day 90 (IU/L)	3.6	2.2
Mean Change (IU/L)	-1.8	-3.1

Hematocrit Results[1]:

Mean % Hematocrit (SD)		
	Combined BID†	Combined TID
Baseline avg (Day 0)	44.8% (3.5)	44.7% (3.5)
Day 90	43.5% (3.8)	44.6% (4.0)
180 Day Extension	45.1% (3.6)	45.9% (4.0)
360 Day Extension	45.5% (3.8)	45.2% (3.7)

- 8 subjects had hematocrit values >54% during the study (after baseline/screening): 3 (2.1%) subjects in the BID† group, and 5 (3.0%) subjects in the combined TID group.
- No hematocrit and hemoglobin value above the normal range was clinically significant.
- No post-treatment hematocrit value was above 58%.
- No subjects discontinued the study due to hematologic abnormalities.

†Claims associated with b.i.d. administration have not been evaluated by FDA.

Natesto® (testosterone) nasal gel ©

Please see additional Important Safety Information on page 8 and refer to accompanying complete prescribing information

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; significant symptom improvement, notably:
  - Natesto caused statistically significant improvements in each of the 5 domains of erectile function ($P < 0.0001$); The majority of the effect on erectile dysfunction was evident by Day 30
  - Substantial Increase in Positive Affect *and* Substantial Decrease in Negative Affect (PANAS) as Early as Day 30 ($P < 0.0001$)

- 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;

- 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. Additionally, Natesto restored serum testosterone to normal levels while Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) remained well within the reference range over 90 days. Also, hematocrit (increased blood thickness) was not significantly impacted by Natesto over 360 days of treatment.

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 $2.0 billion TRT market. As previously indicated, AndroGel's patent expired in 2015 and 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.

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 have started early commercialization efforts outside the U.S.

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 510k 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

A. Agarwal,[1] S. S. Du Plessis,[1,2] R. Sharma,1 L. Samanta,[1,3] A. Harlev,[1,4] G. Ahmad,[1,5] S. Gupta,[1] E. S. Sabanegh[6]; 1. Center For Reproductive Medicine, Cleveland Clinic, Cleveland, OH, 2. Medical Physiology, Stellenbosch University, Tygerberg, South Africa, 3. Redox Biology Laboratory, School of Life Sciences, Ravenshaw University, Orissa, India, 4. Soroka Medical Center, Ben-Gurion University, Beer Sheva, Israel, 5. Physiology and Cell Biology, University of Health Sciences, Lahore, Pakistan, 6. Department of Urology, Cleveland Clinic, Cleveland, OH

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

R. Sharma,[1] S. S. Du Plessis,[1,2] A. Agarwal,[1] A. Harlev,[1,3] L. Samanta,[1,4] G. Ahmad,[1,5] S. Gupta,[1] E. S. Sabanegh[6]; 1. Center For Reproductive Medicine, Cleveland Clinic, Cleveland, OH, 2. Medical Physiology, Stellenbosch University, Tygerberg, South Africa, 3. Soroka Medical Center, Ben-Gurion University, Beer Sheva, Israel, 4. Redox Biology Laboratory, School of Life Science, Ravenshaw University, Orissa, India, 5. Physiology and Cell Biology, University of Health Sciences, Lahore, Pakistan, 6. Department of Urology, Cleveland Clinic, Cleveland, OH

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.

Recently additional studies have further demonstrated the clinical utility of the MiOXSYS System in Male Infertility.

Correlation of Sperm DNA fragmentation and Seminal oxidation reduction potential in infertile men.

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Abstract:

Objective: To determine if Sperm DNA fragmentation is really correlated to seminal oxidative stress.

Design: Prospective study performed on 312 patients attending the male infertility clinic at a tertiary medical center between February and August, 2016. Patients receiving medical or surgical treatment for infertility prior to their presentation or who had a sperm concentration less than 5 million/ml sperm were excluded. Patients were subjected to history taking, clinical examination as well as semen analysis and SDF assessment using Halosperm kit (cut off value <30%) and static oxidation reduction potential (sORP) using MiOXSYS system. Patients were divided according to SDF result (normal/ high) and to age (<40 years / > 40 years).

Results: A total number of 312 patients were included in the study. Patients with high SDF had significantly higher age than those with normal SDF. The mean total and progressive motility was significantly higher in the normal SDF group while sORP was significantly lower in the normal SDF group compared with the high SDF group. Presence of varicocele did not significantly affect SDF level (Table 1). SDF was negatively correlated with total (-0.526, $p<0.001$) and progressive motility (-0.415, $p<0.001$) and positively correlated with abnormal morphology, sORP and age (0.351, 0.222 and 0.192, respectively, $p<0.001$ for all). SDF was significantly lower while total motility was significantly higher in patients <40 years compared with patients >40 years of age.

Conclusions: Sperm DNA fragmentation is positively correlated with seminal oxidative stress measured by Seminal oxidation reduction potential. Sperm DNA fragmentation and seminal oxidation reduction potential should be included in assessment of male infertility. Using ORP testing can help in detecting the target patients for antioxidant therapy.

Effect of seminal ORP value on embryo quality and clinical pregnancy rate

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Abstract:

Objective: To determine whether ORP in semen of men undergoing ART affects embryo quality during IVF and plays any role in predictive value for clinical pregnancy.

Design: Prospective study was carried out in the VKF American Hospital, Assisted Reproduction Unit, Istanbul, Turkey. The study was approved by Koc University the institutional review board and patients signed a consent prior to participation. The 154 male patients who were visiting Andrology laboratory (between May 31, 2016 and Jan 1, 2017) were grouped in according to semen ORP values. IVF was performed using the semen samples by our routine established protocol. Exclusion criteria included azoospermia, presence of STD or chronic disease, use of any prescription drug or OTC medications or antioxidants. Semen samples were collected and assessed for routine parameters using the WHO-2010 guidelines. sORP was measured (mV) using the MiOXSYS system and normalized to concentration (mV/10 sperm/mL). Embryo was graded based on the quality (Grade 1 for best quality and Grade 5 is poor).

Results: All semen samples were grouped as 'High ORP" and 'Low ORP" based upon seminal ORP cut-off value of 1.36 mV/10 sperm. Mean Grade 1 embryo quality in High ORP group (n=81) and low ORP group (n=26) was 2.88 ± 1.76 and 1.33 ± 0.47 respectively. In addition, Mean Grade 2 embryo in High ORP group was 2.47 ± 1.54 and in low group was 4 ± 1.63 accordingly. Clinical pregnancy rate (Mean 0.48; 19/40) was significantly higher (p=0.006) in low ORP group compared to high ORP group (1/8) however there was no significant difference in embryo quality in both high and low ORP groups (Grade I embryo p=0.67, Grade II G2 embryo p=0.33). Also, mean mother age in two groups was not significantly different (low ORP = 37.2 years and high ORP=35.2 years; p=0.23). These data suggest that ORP may play an important role in determining the success of clinical pregnancy irrespective of oocyte quality in women >35 yrs. of age.

Conclusions: Semen ORP measurement can be used as an indicator of oxidative stress and help determine the successful embryo development during IVF. These findings may have important diagnostic and prognostic implications for couples experiencing male infertility and undergoing assisted reproductive technique (ART). Further studies are warranted to explore the mechanism of increased ORP in a subset of couples (male factor, no female factor) undergoing ART to corroborate the significance of these findings.

High levels of seminal oxidation reduction potential (ORP) in infertile men with clinical varicocele

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Abstract:

Objective: To determine if seminal oxidation reduction potential (ORP) increases in infertile men with clinical varicocele.

Design: A prospective controlled pilot study was conducted on 36 men seeking medical advice for an infertility problem between October, 2016 and January, 2017. Following clinical examination, and scrotal color Doppler ultrasound, infertile men were divided into two groups. Group1: infertile men with clinical varicocele; and group 2: infertile men with idiopathic infertility (no detectable abnormality in their genital examination). Patients were examined in an infertility center by the same Andrologist. Semen analysis was performed according to the WHO manual (2010). Seminal ORP was measured using the MiOXSYS system (Aytu BioScience, Inc., Englewood, CO, USA). Absolute values of ORP, in millivolts (mV), were normalized for sperm concentrations and results were expressed as mV/10 sperm/mL. Quantitative measures were presented as median and inter-quartile range (25 and 75 centiles). P value less than 0.05 was considered significant.

Results: The study included 17 patients in group 1 and 19 in group 2. Patient's age and duration of infertility in group 1 [32 (30, 34) years] & [4 (1.5, 5) years] were not significantly different from group 2 [33 (30, 36.5) years] & [2 (1.25, 3.5) years] (P values = 0.64 & 0.27; respectively). Patients in group 1 had significantly lower sperm concentrations [20 (5, 30) × 10 /mL], and normal forms [3 (2, 4) %] as compared to those in group 2 [30 (20, 72.5 × 10 /mL]; and [4 (3, 5) %] (P values = 0.03 & 0.005; respectively). Levels of seminal ORP were significantly higher in group 1 [3.04 (1.94, 7.75) mV/10 sperm/mL] as compared to group 2 [1.12 (0.42, 2.25) mV/10 sperm/mL]. A significant inverse correlation was found between ORP and sperm concentration (= -0.531, = 0.001), total sperm count (= -0.453, = 0.008), progressive motility (= -0.460, = 0.007), total motility (= -0.526, = 0.002) and normal forms (= -0.597, < 0.001). A significant positive correlation was found between ORP and seminal leukocytes (= 0.476, = 0.003).

Conclusions: Seminal ORP is significantly higher in infertile men with clinical varicocele as compared to those with no detectable abnormality in their genital examination (idiopathic infertility). These findings may have important diagnostic and therapeutic implications. Further studies are warranted to explore the mechanism of increased ORP in a subset of infertile men with clinical varicocele. In addition, future studies may help determine those patients who would benefit from antioxidant therapy and/or surgical repair of varicocele.

RedoxSYS System for Research Use

We completed the development of the RedoxSYS System (MiOXSYS' predecessor product) during the two years preceding the April 2015 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.

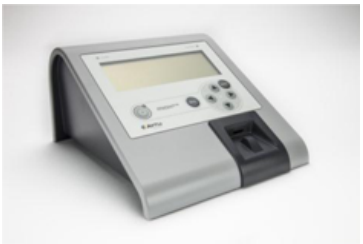
The analyzer contains a 10 MHz external crystal (internal 4X PLL for 40 MHz operation), and a programming/serial header is externally accessible. The device has internal power/heart-beat indicator LED, primary storage of 128Mbit (16Mbyte) SPI Flash (3.3V) (Bulk data storage), and secondary storage of 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 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 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 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. We envision selling the MiOXSYS analyzers for approximately $2,500 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 established distribution arrangements with multiple distributors in multiple countries, and through these distributors, we have sold MiOXSYS in over 20 countries around the world. 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.

Nuelle and the Fiera® Personal Care Device

Fiera is a revenue-generating women's personal care product marketed in the United States primarily through consumer promotion. Fiera is the first of its kind, hands-free, personal care device for women that enhances physical arousal and interest in sex. In scientific and consumer studies conducted with hundreds of women with stated sexual desire and response concerns, Fiera has demonstrated highly consistent benefit. Importantly, Fiera is also endorsed by and receives professional recommendations from leading sexual health experts across the United States and has been studied and presented by the same experts.

Fiera was created with OB-GYNs and has multiple scientific studies showing it works. Fiera helps women who have changing levels of arousal, interest, and vaginal dryness, enter a sexual experience with enhanced levels of excitement and interest. Fiera works naturally with a woman's body and provides a hands-free experience thanks to the innovative design. Fiera uses light stimulation and a gentle suction action to enhance blood flow and increase lubrication in advance of sex, in as little as 5 minutes.

Product Features of *Fiera* Personal Care Devices:

- Proprietary dual-action technology enhances blood flow to the genitals
- Small, fast-acting and hands-free, typically worn for 5-15 minutes and then removed in preparation for sexual activity
- Features pattern and intensity settings for a customizable experience
- Made with comfortable, body-safe materials (phthalate free)
- Uses rechargeable battery
- Does not require a prescription (consumer device)

The Fiera Device

The Fiera Device + Remote

The Fiera SofSense™ Rings

The Fiera SofSense™ ring refills are available and sold in two styles, for a custom fit. Each refill box contains three SofSense™ rings, and each ring is designed to be used up to five times.

United States-Based Consumer Study

Fiera has been extensively studied and tested by consumers and physicians. Fiera is scientifically proven to enhance genital arousal in women of all ages, including pre and post-menopausal women.

Consumer study results in women ages 25-75 showed that after 4 weeks of using Fiera + Remote:

- 97% of women felt physically aroused
- 96% looked forward to being intimate with their partner
- 93% felt excited and ready for sex
- 89% of women felt more “in the mood”
- 87% felt as ready for sex as their partner did

Previous studies also showed that 87% of women felt increased desire and 67% felt increased lubrication. In a separate scientific study of pre and post-menopausal women, arousal occurred on average in 5 minutes.

Clinical Data on the Fiera Personal Care Device

Fiera serves several important functions:

1. It helps to encourage blood flow in the clitoris (vasocongestion), a key physical reaction that signals your body that you are ready for sex.
2. It provides direct stimulation, accelerating the effect of the suction.
3. A soft, silicone ring adheres with a gentle suction holding the product in place so that your hands are free.

Fiera is tucked under the labia and worn over the clitoris, a woman’s most sensitive sexual organ to enhance arousal through a proprietary combination of gentle suction and multi-focal stimulation. As the nerve endings in the clitoris respond, a woman begins to experience enhanced sensation to the genital area, which triggers a physical state of arousal.

Our research shows that use of Fiera regularly over a 4-week period also increases a woman’s level of sexual desire. Women also report looking forward to and enjoying sexual activity more.

A study of 14 sexually active, *premenopausal* women was conducted to determine the degree of engorgement – as measured by temperature change in the external genitalia – produced by Fiera. Fiera produced statistically significant increases in vulvar temperatures, which is a marker of genital blood flow and engorgement. 100% of study participants reported feeling “In the Mood” for sex after use of Fiera. Additionally, 100% of study participants experienced genital sexual arousal during use of Fiera. Another study of 12 sexually active, postmenopausal women demonstrated that Fiera produced statistically significant increases in vulvar temperature. Use of Fiera in this population of postmenopausal women produced sexual desire in 100% of the subjects while 83% experienced genital arousal.

ProstaScint for the Detection of Prostate Cancer

On May 20, 2015, we acquired ProstaScint® from Jazz Pharmaceuticals. The 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. At June 30, 2017, the ProstaScint asset was impaired based upon sales projections that we intend to only sell this product through mid-fiscal 2019, when this product expires.

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.

In late fiscal 2017, we decided to implement a harvest strategy for the ProstaScint product, due to increased competition and the cost to continue manufacturing. Based upon our current projections, we believe that we will continue to sell this product through fiscal 2018 and the first half of fiscal 2019.

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 will continue to look to identify 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 wellness and vitality, hypogonadism, prostate and other urological cancers, urinary tract infections, and other urological conditions. However, during fiscal 2018, our primary focus will be on growing our current core assets and working towards cash-flow breakeven.

Government Regulation

While we do not have any pharmaceutical product candidates that we are actively developing as of the date of this 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 within the United States. 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 new drug applications, 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 $100,000 per product and $600,000 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 510k 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 510k 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 510k 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 510k clearance process, however, the 510k clearance process has also become increasingly stringent and expensive. The FDA has provided initial guidance to us that the MiOXSYS and RedoxSYS Systems are appropriate for the 510k clearance process.

510k Clearance. To obtain 510k 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 510k clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510k 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 510k 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 510k 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 510k 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 510k 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. Natesto is also 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. We do not anticipate that the sales of the MiOXSYS System, if approved for sale in the U.S., will be heavily dependent upon reimbursement by third-party payors. Traditionally, sales of pharmaceuticals, diagnostics, ad devices that are not “lifestyle” 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. The sexual wellness market is typically known as a cash payor market, and because Fiera is not classified as a pharmaceutical or a medical device by the FDA, there will be no reimbursement paid by third parties on the product.

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 three patents that are not listed in the Orange Book directed at a testosterone formulation, 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 ten nonprovisional patent applications, some of which may be abandoned. These patent applications include at least four 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 MiOXSYS, RedoxSYS, Fiera and ProstaScint. 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.

Our patent portfolio related to RedoxSYS/MiOXSYS is focused on the United States and core foreign jurisdictions which include Europe, Canada, Israel, Japan and China. The portfolio is supported in the United States and core foreign jurisdictions and consists of 20 issued patents and 27 pending applications.

The portfolio primarily consists of seven families filed in the United States and in core foreign jurisdictions. The first family includes seven issued patents and three 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 eight issued patents and three 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, two issued patents in core foreign jurisdictions and three 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. The fifth family includes one pending United States application and one pending application filed under the Patent Cooperative Treaty with claims directed to methods for monitoring food production and quality. The standard 20-year expiration for patents in this family is in 2035. The sixth family includes one pending United States application and six pending applications in core foreign jurisdictions with claims directed to methods for determining fertility characteristics from the ORP of a biological sample. The standard 20-year expiration for patents in this family is in 2035. The seventh family includes one pending United States application and one pending application filed under the Patent Cooperation Treaty with claims directed to methods for evaluating stroke patients from the ORP characteristics of a biological sample. The standard 20-year expiration for patents in this family is in 2036.

The Fiera portfolio includes multiple utility patent families in the United States and foreign jurisdictions with claims to the Fiera device. The United States portfolio includes one issued patent and nine pending applications; the foreign portfolio includes six issued patents, nine pending applications and one PCT application. In addition, Fiera is protected by a substantial design patent portfolio with four issued United States design patents and three pending United States design applications. As well, the design portfolio includes forty-one issued design patents.

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 life sciences company compared to other companies that we are competing against. Our current and potential competitors include large pharmaceutical, biotechnology, diagnostic, and medical device companies, as well as 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 growing market. The U.S. TRT market is large, with annual revenues in the U.S. in 2016 of approximately $2.0 billion. At the current market size of approximately $2.0 billion, a product with 5% market penetration could achieve sales of approximately $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. 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.

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 fiscal 2018 and the first half of fiscal 2019.

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, 2017, we had 63 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://www.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://www.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

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, 2017 and 2016 was $22.5 million and $28.2 million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date. With the financing that occurred in August 2017 of $11.8 million, we believe that we can get to cash flow break even and profitability but we still expect to incur substantial losses during fiscal 2018. Even though we expect to have revenue growth in the next several fiscal years, it is uncertain that the revenue growth will be significant enough to offset our expenses and generate a profit in the 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;
- lack of sufficient capital;
- U.S. regulatory approval of our products and product candidates;
- foreign regulatory approval of our products and product candidates;
- unanticipated problems, delays, and expense relating to product development and implementation;
- lack of sufficient intellectual property;
- the ability to attract and retain qualified employees;
- 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, 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 Natesto, MiOXSYS, ProstaScint and Fiera. 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 Natesto are each an approved drug that we are marketing, we only acquired ProstaScint in May 2015 and Natesto in April 2016. In addition, we only acquired Fiera in May 2017 and launched our MiOXSYS device in early fiscal 2017. As a result, we have limited experience on which to base the revenue we could expect to receive from sales of these products. 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 may 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, MiOXSYS and Fiera, none of which might be as successful as we anticipate or at all and all of which might take longer and be more expensive to market than we anticipate. We also are currently advancing our MiOXSYS device 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. As of June 30, 2017, our cash, cash equivalents and restricted cash totaling $878,000, available to fund our operations offset by an aggregate $3.0 million in accounts payable and other and accrued liabilities. In November 2016, we conducted a public offering of our common stock and warrants from which we received net cash proceeds of approximately $7.6 million. We closed on a private placement of common stock, Series A preferred stock and warrants in August 2017 from which we received gross proceeds of approximately $11.8 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 Fiera 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.

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, MiOXSYS or Fiera and/or be required to significantly curtail, delay or discontinue one or more of our research or development programs for 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 Fiera 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 Fiera;
- 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 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. 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 up to approximately $500,000 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, 2017, and concluded that such control was effective.

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 NASDAQ Capital Market or the NYSE American, LLC.

Risks Related to Product Development, Regulatory Approval and Commercialization

Natesto, MiOXSYS, ProstaScint and Fiera 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, MiOXSYS, ProstaScint and Fiera. Specifically, we may encounter difficulty by virtue of:

- our inability to adequately market and increase sales of any of these products;
- 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, MiOXSYS, or ProstaScint; 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 MiOXSYS, ProstaScint or Fiera.

We have limited experience selling our current products as they were acquired from other companies or were recently 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, MiOXSYS, ProstaScint and Fiera. 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. Further, the economic environment at any given time 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 our former product candidate, 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. As an example, we discontinued the development of Zertane in June 2016 and sold Primsol in March 2017.

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, 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 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 parts;
- 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 510k 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 510k clearance, pre-market approval, or foreign regulatory approvals. The 510k 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 510k clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510k clearance or pre-market approval may never be obtained. We have limited experience in filing FDA applications for 510k 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 Authorisation 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 black box 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 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 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 and sexual wellbeing 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, MiOXSYS and Fiera;
- 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 Fiera, we compete with numerous companies who produce sexual wellbeing related products. There are any number of products available on the market that could compete with Fiera.

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, significantly impacted the provision of, and payment for, health care in the United States. Various provisions of these laws 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 and ProstaScint 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 and ProstaScint are already FDA-approved and generating revenues in the U.S., they may not receive, or continue to receive, physician or hospital 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 or hospital acceptance, or it may not obtain adequate reimbursement from third party payors. In the future, we might possibly sell 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. Although this contract is currently on hold as we evaluate our strategic options for the ProstaScint product. In the event that this manufacturing transfer does not occur or we do not find a replacement manufacturer by the time our current inventory expires, which could adversely impact our continued sales of ProstaScint or its disposition should we elect to do so, 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. We have an agreement with a third party manufacturer for our Fiera product as well. 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 Fiera, 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 for our current and any future FDA-approved products 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 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 are 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, 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, personal care products and 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, Natesto in April 2016 and Fiera in May 2017. As an example, we acquired Primsol in October 2015, but sold it in March 2017. Depending on the success or lack thereof of any of our existing or future acquired products and product candidates, we might seek to out-license, sell or otherwise dispose of any of those products or product candidates, which could adversely impact our operations if the dispositions triggers a loss, accounting charge or other negative impact.

In fiscal 2017, the great majority of our net revenue and gross accounts receivable were due to three significant customers, the loss of which could materially and adversely affect our results of operations.

During fiscal 2017 and fiscal 2016, three customers accounted for 74% and one customer that accounted for 86%, respectively, of our net revenue. At June 30, 2017 and 2016, the same customers accounted for 60% and 69%, respectively, of our gross accounts receivable. Although we expect to increase revenue and not be as reliant on only a few customers, at least for fiscal 2018, and perhaps beyond, the loss of any of these customers could have a material adverse effect on our results of operations.

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 June 30, 2017, we had 60 full-time employees, and in connection with being a public company, we expect to continue 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 directors, officers and key personnel. Any of our directors could resign from our board at any time and for any reason. Although our executive officers Joshua Disbrow, Jarrett Disbrow and Gregory Gould have employment agreements, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time, and each agreement obligates us to pay the officer lump sum severance of two years of salary if we terminate him without cause, as defined in the agreement, which could hurt our liquidity. 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 directors or 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, including directors, 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, medical device and personal care products and devices. 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.

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.

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

As of June 30, 2017, we had federal net operating loss carryforwards of approximately $42.3 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 2036. 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 were 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. We believe that the August 2017 financing created over a 50% change in our equity ownership so our current tax loss carryforward will be limited in the future. Either the deconsolidation or the ownership change scenario could result in increased future tax liability to us.

Our outstanding warrants may result in dilution to our stockholders and may impede our ability to raise equity capital.

The exercise of some or all of our outstanding warrants to purchase our common stock may dilute the ownership interests of existing stockholders. In particular, on August 15, 2017, we had outstanding warrants to purchase up to an aggregate of 6,600,714 shares. Included in these warrants are warrants that we issued in August 2017 to purchase up to an aggregate of 5,919,998 shares of common stock (the August 2017 warrants), with a current exercise price of $3.60 per share, that contain certain price adjustment and anti-dilution provisions. Until such time as our common stock is listed on any NASDAQ or NYSE exchange, these anti-dilution provisions may be triggered upon any future issuance by us of securities convertible into shares of our common stock or any rights, warrants or options to purchase shares of our common stock at a price per share below the then-exercise price of the warrants, subject to some exceptions.

To the extent that these anti-dilution provisions are triggered in the future, we would be required to reduce the exercise price of all of the warrants on a full-ratchet basis, which would have a dilutive effect on our stockholders. In addition, any sales in the public market of the shares of our common stock issuable upon such exercise could adversely affect prevailing market prices of our common stock.

Furthermore, the existence of these August 2017 warrants may encourage short selling by market participants because the anticipated exercise of such warrants for shares of our common stock could depress the market price of our common stock.

The anti-dilution provisions of the August 2017 warrants also may impede our ability to raise equity capital in the future due to the limitation on issuing any common stock or securities convertible into common stock at a price less than $3.60 per share. On August 22, 2017, the closing price of our common stock as reported on the OTCQX was $4.00. Should we be unable to list our common stock on any NASDAQ or NYSE exchange and should our common stock price remain at or near that level, any equity financing in the future may be too onerous due to the anti-dilution protection afforded the August 2017 warrants.

Several stockholders potentially own a significant percentage of our stock and could be able to exert significant control over matters subject to stockholder approval.

At August 15, 2017, eight entities who invested in our August 2017 common and preferred stock and warrant financing own common and/or preferred stock and warrants that potentially would enable them to beneficially own in excess of 4.99% or 9.99% of our common stock. The preferred stock and warrants held by these investors contain a provision that prohibits the conversion or exercise of the preferred stock or warrants should the holder beneficially own in excess of 4.99% or 9.99%, as elected by the investor, after giving effect to such conversion or exercise. However, the significant ownership potential of these investors, and the significant investment that they have made in our company, could give these stockholders the ability to influence us through their ownership positions, even if they are prohibited from converting or exercising their preferred stock or warrants to acquire more than 4.99% or 9.99% of our common stock at any time. Further, this significant ownership potential 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.

Restrictions under our August 2017 Securities Purchase Agreement may limit our ability to raise funds and operate our business.

The August 2017 Securities Purchase Agreement contains covenants described below that may restrict our ability to finance future operations or capital needs or to engage in other business activities.

For the 24 months following the Effective Date, as defined in the Securities Purchase Agreement, upon any issuance by us of any common stock or common stock equivalents for cash consideration or indebtedness or a combination thereof (a “Subsequent Financing”), each investor in the offering will have the right to participate in up to an amount of the Subsequent Financing equal to 35% of the Subsequent Financing on the same terms, conditions and price provided for in the Subsequent Financing. The “Effective Date” is the earliest of the date that (a) the initial registration statement registering all of the shares of common stock and the shares of common stock into which the Series A Preferred Stock is convertible and the warrants (collectively, the “Securities”) are exercisable has been declared effective by the SEC, (b) all of the Securities have been sold pursuant to Rule 144 or may be sold pursuant to Rule 144 without the requirement for our company to be in compliance with the current public information required under Rule 144 and without volume or manner-of-sale restrictions or (c) following the one year anniversary of August 15, 2017, all of the Securities may be sold pursuant to an exemption from registration under Section 4(1) of the Securities Act of 1933, as amended (the “Securities Act”), without volume or manner-of-sale restrictions.

Until the later of (i) 270 days after the Effective Date and (ii) 365 days from August 15, 2017, without the consent of investors that purchased at least 51% of the shares of common stock in the offering, we may not issue, enter into any agreement to issue or announce the issuance or proposed issuance of any shares of common stock or common stock equivalents, or file any registration statement covering the issuance or resale of any shares of common stock or common stock equivalents. If the value weighted average price of our common stock exceeds $1.00 (as adjusted for stock splits, stock dividends and similar corporate events) for five or more consecutive trading days, this right will terminate.

Until such time as no investor in the August 2017 offering holds any of the warrants, we are prohibited from effecting or entering into an agreement to affect any issuance by us of our common stock or common stock equivalents involving a Variable Rate Transaction, as defined in the Securities Purchase Agreement. "Variable Rate Transaction" means a transaction in which we (i) issue any debt or equity securities that are convertible into common stock either (A) at a conversion price, exercise price or exchange rate or other price that is based upon, and/or varies with, the trading prices of or quotations for the shares of our common stock at any time after the initial issuance of such debt or equity securities or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to our business or the market for our common stock or (ii) enter into any transaction under, any agreement, including, but not limited to, an equity line of credit, an "at-the-market" offering or similar agreement, whereby we may issue securities at a future determined price.

The restrictions and covenants in the August 2017 Securities Purchase Agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control and we may not be able to meet those covenants.

Risks Related to Securities Markets and Investment in our Securities

There is a limited trading market for our common stock, which could make it difficult to liquidate an investment in our common stock, in a timely manner.

Our common stock is currently traded on the OTCQX. Because there is a limited public market for our common stock, investors may not be able to liquidate their investment whenever desired. We cannot assure that we will maintain an active trading market for our common stock and the lack of an active public trading market could mean that investors may be exposed to increased risk. In addition, if we failed to meet the criteria set forth in SEC regulations, various requirements would be imposed by law on broker-dealers who sell our securities to persons other than established customers and accredited investors. Consequently, such regulations may deter broker-dealers from recommending or selling our common stock, which may further affect its liquidity.

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

We intend to apply for our common stock to be listed on the NASDAQ or NYSE American, each a national securities exchange. Each exchange requires companies desiring to list their common stock 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 either exchange. 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 either exchange. 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 NASDAQ or NYSE American, our failure to meet the continued listing requirements of such exchange could result in a delisting of our common stock.

If our common stock were to be uplisted on the NASDAQ or NYSE American, and thereafter we fail to satisfy the continued listing requirements of such exchange, such as the corporate governance requirements or the minimum closing bid price requirement, the 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 applicable exchange requirements, such as 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.

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, 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 currently authorized to award up to a total of 3.0 million 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, 2017, options to purchase 38,263 shares of common stock issued under our 2015 Stock Plan at a weighted average exercise price of $16.31 per share were outstanding. In addition, at June 30, 2017, there were outstanding warrants to purchase an aggregate of 286,049 shares of our common stock at a weighted average exercise price of $50.29. 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 products and 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;
- 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; and
- 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 100.0 million shares of our common stock and up to 50.0 million shares of preferred stock with the rights, preferences and privileges that our Board of Directors may determine from time to time. At the next annual shareholders meeting, we may seek approval to increase our authorized common shares from 100.0 million common shares authorized to 200.0 million or 300.0 million shares. As of June 30, 2017, we had 824,831 shares of our common stock issued and outstanding, which represents less than 1% of our total authorized shares of common stock. In addition to capital raising activities, which we expect to continue to pursue 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 could need significant additional capital 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 50.0 million 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.

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, 2016	High	Low
First Quarter (ended September 30, 2015)	$ 1,140.00	$ 1,111.20
Second Quarter (ended December 31, 2015)	$ 1,140.00	$ 753.60
Third Quarter (ended March 31, 2016)	$ 840.00	$ 134.40
Fourth Quarter (ended June 30, 2016)	$ 146.40	$ 72.00

Fiscal Year ended June 30, 2017	High	Low
First Quarter (ended September 30, 2016)	$ 100.00	$ 60.20
Second Quarter (ended December 31, 2016)	$ 77.80	$ 20.40
Third Quarter (ended March 31, 2017)	$ 25.20	$ 14.82
Fourth Quarter (ended June 30, 2017)	$ 18.20	$ 10.20

On August 21, 2017, the closing price as reported on the OTCQX of our common stock was $3.80. As of August 21, 2017, there were 570 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"). At the Special meeting of stockholders on July 26, 2017, the Aytu Stockholders voted to increase the plan to 3.0 million shares. 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, 2017.

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	38,263	$	16.31	61,737
Equity compensation plans not approved by security holders	32,641	$	44.12	-
Total	70,904	$	29.11	61,737

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 444 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 $1,087.20. 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 1,115 shares of our common stock at a weighted average exercise price of $156.00 per share, and an aggregate of 1,129 shares of our common stock at an exercise price of $96.00 per share. In connection with our May 2016 public offering, we issued warrants to purchase an aggregate of 5,474 shares of common stock at an exercise price of $120.00 to the underwriters of the public offering. In July 2016, we issued warrants to purchase an aggregate of 4,402 shares of common stock at an exercise price of $80.00 to initial investors. In connection with our November 2016 public offering, we issued warrants to purchase an aggregate of 20,077 shares of common stock with an exercise price of $15.00.

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 pharmaceutical 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, male infertility, urological cancers and female personal care.

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. Additionally, on August 25, 2017 we completed another reverse split in which each common stockholder received one share of common stock for each 20 shares then owned. 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 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. Based upon the estimated expiration date, per our projections we could stop selling this product mid-fiscal 2019, thus, we impaired the non-tangible assets related to this product.

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 paid $250,000 in November 2016 (together, the "Installment Payments"), for a total purchase price of $1,892,000. During fiscal 2017 we sold our Prismol product which was used in the treatment of urinary tract infections.

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. In October 2016 we paid an additional $2.0 million and in January of 2017, we paid the final upfront payment of $4.0 million. We also purchased on April 28, 2016, an aggregate of 12,245,411 shares of Acerus common stock for Cdn. $2,535,000 (approximately US $2.0 million), with a purchase price per share equal to Cdn. $0.207 or approximately US $0.16 per share. We also agreed to make various payments based upon certain sales milestones 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 our third fiscal quarter of 2017. We sold all of the shares of common stock of Acerus Pharmaceutics Corporation that we acquired in April 2016 for approximately $2.0 million as a condition to our licensing of Natesto. Acerus common stock is traded on the Toronto Stock Exchange. The gross proceeds from the sale of the Acerus shares was approximately $1.1 million.

In May 2016, we sold in an underwritten public offering 78,125 shares of our common stock, par value $0.0001 per share, and warrants to purchase up to an aggregate 78,125 shares of common stock at a combined public offering price of $96.00 per share and related warrant. Each warrant is exercisable for five years from issuance and has an exercise price equal to $120.00. In addition, we granted the underwriters a 45-day option to purchase up to an additional 11,719 shares of common stock and/or 11,719 additional warrants. The underwriters elected a partial exercise of their over-allotment option to purchase 8,542 warrants. The net cash proceeds from the sale of the shares and warrants were approximately $6.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

In July 2016, Aytu issued 50,000 shares of restricted stock to executive officers and directors.

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 6,684 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 2,625 shares of common stock. During fiscal 2017, Lincoln Park purchased 10,000 common shares for $240,000. As part of our August 2017 private placement financing, we terminated the Purchase Agreement, effective August 16, 2017.

On October 27, 2016, we priced an underwritten public offering of 286,749 shares of our common stock and warrants to purchase up to an aggregate of 286,749 shares of our common stock at a combined public offering price of $30.00 per share and related warrant. The gross proceeds from the offering to Aytu was $8.6 million, before deducting the underwriting discount and estimated offering expenses payable by Aytu, but excluding the exercise of any warrants. The Company also granted the representative of the underwriters a 45-day option to purchase up to an additional 43,013 shares and/or 43,013 additional warrants. The shares of common stock were immediately separable from the warrants and were issued separately. The warrants are exercisable immediately upon issuance, expire five years after the date of issuance and have an exercise price of $37.20 per share. On November 2, 2016, we completed the public offering. In connection with the closing, the underwriters purchased a portion of their 45-day option and purchased an additional 14,263 additional warrants at closing. Our net cash proceeds from the offering, after deducting the placement agent fees and the offering expenses, was $7.6 million.

On February 28, 2017, we consummated our warrant tender offer to exercise, at a temporarily reduced exercise price of $15.00 per share, (i) outstanding warrants to purchase 86,667 shares of our common stock with an exercise price of $120.00 per share, which were originally issued to investors in our May 2016 financing (the “May 2016 Warrants”), and (ii) outstanding warrants to purchase 301,013 shares of our common stock with an exercise price of $37.20 per share, which were originally issued to investors in our October 2016 financing (the “October 2016 Warrants” and together with the May 2016 Warrants, the “Original Warrants”).

The warrant tender offer expired at 11:59 p.m. Eastern Time on the evening of February 27, 2017 (the “Expiration Date”). Original warrants to purchase an aggregate of 149,552 shares of our common stock were tendered and exercised in the warrant tender offer, for aggregate gross proceeds to our Company of approximately $2.2 million. Original warrants tendered and exercised represent approximately 38.6% of the original warrants outstanding immediately prior to the Expiration Date. Original warrants that were not tendered and exercised remain in effect at the pre-tender offer exercise prices of $120.00 per share and $37.20 per share, respectively.

Joseph Gunnar & Co., LLC and Fordham Financial Management, Inc. acted as warrant solicitation agents and received a fee equal to 6% of the aggregate gross proceeds to our Company, plus reimbursement of approximately $25,000 in out-of-pocket expenses and indemnification against certain liabilities. We also reduced the exercise prices of an aggregate of 25,541 warrants to purchase shares of our common stock, which were originally issued as underwriters’ compensation in the May 2016 and October 2016 financings, from $120.00 per share and $37.20 per share, respectively, to $15.00 per share. In March, we also reduced the price of the 429 warrants issued to the bankers that helped us with the Convertible Promissory Notes in fiscal 2016 to an exercise price of $15.00.

On March 16, 2017, we reduced the exercise price of outstanding options issued to directors, employees and consultants to purchase an aggregate of 36,834 shares of our common stock from a weighted average exercise price of $70.60 to $16.40 to incentivize the holders of these options.

On March 31, 2017, we entered into and closed on an Asset Purchase Agreement with Allegis Holdings, LLC (the “Purchaser”). Pursuant to the agreement, we sold to the Purchaser all of our assets related to our Primsol product, including certain intellectual property and contracts, inventory, work in process and all marketing assets and materials related solely to Primsol (together, the “Primsol Asset”). We evaluated this transaction and concluded that it is not significant to our business.

On May 5, 2017, we acquired Nuelle, Inc, or Nuelle, a women's sexual health company. This transaction expanded our product portfolio with the addition of the Fiera® personal care device for women. Fiera was recently launched in the U.S. and is a proprietary, revenue-generating product scientifically proven to enhance physical arousal and sexual desire in the millions of adult women around the world impacted by changes in sexual desire. This acquisition adds a novel, commercial-stage product in a complementary adjacency readily accessible by our U.S.-based commercial infrastructure. We purchased Nuelle for 125,000 common shares at closing and future contingent royalty payment averaging the high single digits and milestone payments dependent on achieving certain annualized sales amounts. Nuelle was previously a portfolio company of leading venture capital firm New Enterprise Associates.

On August 11, 2017, we entered into a Securities Purchase Agreement with various investors pursuant to which we agreed to sell Class A and Class B equity units for gross proceeds of approximately $11.8 million. Class A units consist of one (1) share of common stock and a warrant to purchase one and one-half (1.5) shares of common stock and were sold at a negotiated price of $3.00 per unit. Class B units consist of one (1) share of our newly created Series A Convertible Preferred Stock (the "Series A Preferred Stock") and warrants to purchase one and one-half (1.5) shares of common stock for each share of common stock into which the Series A Preferred Stock is convertible and were sold at a negotiated price of $1,000 per unit to those purchasers who, together with their affiliates and certain related parties, would beneficially own more than 9.99% of our outstanding common stock following the offering. The offering closed on August 15, 2017.

In the offering, we issued an aggregate of 3,196,665 shares of our common stock, 2,250 shares of Series A Preferred Stock and warrants to purchase up to an aggregate of 5,919,998 shares of our common stock.

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 into the first half of fiscal 2019, at which point we anticipate nearing or reaching cash-flow breakeven. See "Liquidity and Capital Resources."

We have only begun to generate material revenues from the commercialization of our product candidates in the last fiscal year. We have recognized approximately $3.2 million in revenue from Natesto, ProstaScint, Primsol, MiOXSYS and Fiera sales during fiscal 2017. We have incurred accumulated net losses since our inception, and at June 30, 2017, we had an accumulated deficit of $69.1 million. Our net loss was $22.5 million for fiscal 2017 and we used $13.8 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, 2017) is contained in Note 2 to the Financial Statements.

Results of Operations—June 30, 2017 Compared to June 30, 2016

Results of operations for the year ended June 30, 2017 ("fiscal 2017") and the year ended June 30, 2016 ("fiscal 2016") reflected losses of approximately $22.5 million and $28.2 million, respectively.

Revenue

Product and service revenue

The total product and service revenue recognized during 2017 was $3.2 million, related to the sales of our products Natesto, ProstaScint,and Primsol, the MiOXSYS and RedoxSYS Systems, as well as products in the Fiera line. The product and service revenue in fiscal 2016 was $2.1 million, which was from the ProstaScint and Primsol product lines, as well as the RedoxSYS and MiOXSYS Systems. The increase in product revenue of over 57% from fiscal 2016 to 2017 is due to our acquisitions and ensuing sales of the Natesto and Fiera products, which occurred late in fiscal 2016 and late fiscal 2017, respectively, and expanded marketing of our commercial 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,	
	2017	2016
Gross product and service revenue	$ 4,694,000	$ 2,657,000
Provisions to reduce gross product sales to net product and service sales	(1,472,000)	(606,000)
Net product and service revenue	$ 3,222,000	$ 2,051,000
Percentage to net sales	68.6%	77.2%

License revenue

During fiscal 2017 and fiscal 2016, we recognized $0 and $512,000, respectively, in license revenue. In 2012, we received a payment of $500,000 for our license agreement of our former product candidate 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 $1.4 million and $1.0 million recognized for fiscal 2017 and fiscal 2016, respectively, are related to the Natesto, ProstaScint and Primsol products, the MiOXSYS and RedoxSYS Systems, as well as products in the Fiera line. We expect to see cost of sales to continue to increase in the year ending June 30, 2018 (“fiscal 2018”) as we expect our sales of our current products to continue to grow.

Research and Development

Research and development costs consist of clinical trials and sponsored research, 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,	
	2017	2016
Clinical trials and sponsored research	$ 956,000	$ 2,278,000
Manufacturing tech transfer	-	3,304,000
Labor	-	427,000
Stock-based compensation	-	89,000
Sponsored research - related party	388,000	192,000
Consultants and other	4,000	30,000
	$ 1,348,000	$ 6,320,000

Comparison of Years Ended June 30, 2017 and 2016

Research and development expenses decreased $5.0 million, or 78.7%, in fiscal 2017 compared to fiscal 2016. This was due primarily to placing the contract for our manufacturing tech transfer on hold for our ProstaScint product, as well as shifting our focus to our existing commercialized products. We expect that the research and development expenses will decrease in fiscal 2018 as compared to fiscal 2017 due to the fact that we will continue to focus on our existing products.

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,	
	2017	2016
Labor	$ 7,488,000	$ 3,671,000
Stock-based compensation	3,227,000	814,000
Professional fees	1,133,000	1,630,000
Occupancy, travel and other	5,267,000	2,086,000
Patent costs	168,000	303,000
Director fees	160,000	13,000
Management fee - related party	165,000	308,000
	$ 17,608,000	$ 8,825,000

Comparison of Years Ended June 30, 2017 and 2016

General and administrative costs increased $8.8 million, or 99.5%, in fiscal 2017 over fiscal 2016. The increase in labor costs, stock-based compensation, and occupancy, travel and other primarily relates to increased costs related to the increase in commercial department staffing during fiscal 2017 as compared to fiscal 2016, 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 remain flat in fiscal 2018.

Impairment of Intangible Assets

Impairment of intangible assets was $1.3 million for fiscal 2017, which was related to the impairment of the ProstaScint product. Impairment of intangible assets was $7.5 million for fiscal 2016 related to the impairment of the Zertane in process research and development (IPRD).

Amortization of Intangible Assets

Amortization of intangible assets was $1.7 million and $665,000 for fiscal 2017 and fiscal 2016, respectively. This expense increased due to the acquisition of the Natesto and Fiera businesses in late fiscal 2016 and late fiscal 2017, respectively, and the corresponding amortization of their finite-lived intangible assets.

Net Cash Used in Operating Activities

During fiscal 2017, our operating activities used $13.8 million in cash. The use of cash was approximately $8.7 million lower than the net loss due primarily to non-cash charges for asset impairment, stock-based compensation, issuance of restricted stock, depreciation, amortization and accretion, amortization of prepaid research and development related party, common stock issued to executives, warrants issued to initial investors, and an increase in accounts payable. These charges were offset by a decrease in accrued compensation, accrued liabilities, and accounts receivable, a gain on the sale of an asset, and derivative income.

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.

Net Cash Used in Investing Activities

During fiscal 2017, cash was received through the sale of Primsol, the sale of our investment in Acerus and the merger with Nuelle, Inc. Cash was used to make additional required payments for Natesto and Primsol, and to purchase fixed assets.

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

Net Cash from Financing Activities

Net cash of $10.2 million provided by financing activities during fiscal 2017 was primarily related to our warrant tender offer of $2.2 million offset by issuance costs of $312,000, our registered public offering of $8.6 million of common stock and warrants offset by cash issuance costs of $998,000, and the issuance of common stock to Lincoln Park Capital of $740,000 offset by issuance costs of $91,000.

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 cash 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.

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, 2017, we had cash, cash equivalents and restricted cash totaling $878,000 available to fund our operations offset by an aggregate of $3.0 million in accounts payable and other and accrued liabilities.

With the additional capital that we raised in August 2017 of approximately $11.8 million, we believe we have sufficient resources to fund our operations through fiscal 2018 and into the middle of fiscal 2019. We believe, if our sales continue to grow as we have projected, this could be sufficient until we reach cash-flow breakeven and potentially profitability. If necessary, in the future we will evaluate the capital markets from time to time to determine if we need 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 may 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.

At this time, we expect to satisfy our future cash needs through sales revenue related to our current products and if necessary, 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 and 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 as of June 30, 2017 was dependent upon us obtaining further financing for our business. With the completion of our financing of $11.8 million in August 2017, we believe this going concern has been remediated as we believe that we now have enough capital to operate through fiscal 2018 and into the middle of fiscal 2019 and possibly achieve cash-flow breakeven and profitability with no additional financing, please see Note 3 for additional information.

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, 2017. 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, 2017, 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

There were no changes in our internal controls over financial reporting, known to the chief executive officer or the chief financial officer that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control 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 15, 2017. 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	42	Chairman and Chief Executive Officer
Jarrett T. Disbrow	42	Chief Operating Officer
Gregory A. Gould	51	Chief Financial Officer, Secretary, and Treasurer
Michael Macaluso	65	Director
Carl C. Dockery	54	Director
John A. Donofrio, Jr.	49	Director
Gary V. Cantrell	62	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. However, prior to joining Aytu on a full time basis in June 2017, he split his time between Aytu and Ampio Pharmaceuticals, Inc. from April 2015 until June 2017. Mr. Gould joined Ampio as their Chief Financial Officer, Secretary and Treasurer in 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. (now Novelion Therapeutics, 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.

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 3 and Form 4 for John Donofrio to report the appointment as a director, the issuance of restricted stock and stock options, which reports were due on July 15, 2016, and were filed on July 18, 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://www.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 10th 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.

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.

The following table provides information regarding all compensation paid to non-employee directors of Aytu during the fiscal year ended June 30, 2017.

Name	Fees Earned or Paid in Cash	Stock Option Awards (1)	All Other Compensation (2)	Total
Gary V. Cantrell (3)	$ 45,000	$ 46,860	$ 209,950	$ 301,810
Carl C. Dockery (3)	$ 45,000	$ 20,840	$ 209,950	$ 275,790
John A. Donofrio Jr. (3)	$ 45,000	$ 46,860	$ 209,950	$ 301,810
Michael E. Macaluso (3)	$ 25,000	$ 70,331	$ 209,950	$ 305,281

(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) This column reflects the aggregate grant date fair value of restricted stock.

(3) As of June 30, 2017, the number of shares underlying options and restricted shares held by each non-employee director was as follows: 750 options and 3,250 restricted shares for Mr. Cantrell; 334 options and 3,250 restricted shares for Mr. Dockery; 750 options and 3,250 restricted shares for Mr. Donofrio; 1,125 options and 3,250 restricted shares for Mr. Macaluso. 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, 2017 and 2016 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 Executive Officers									
Joshua R. Disbrow									
Chief Executive Officer	2017	250,000	-	614,000	189,000	-	-	-	1,053,000
since December 2012	2016	250,000	313,000	-	559,000	-	-	-	1,122,000
Jarrett T. Disbrow									
Chief Operating Officer,									
Secretary	2017	250,000	-	533,000	189,000	-	-	-	972,000
and Treasurer	2016	250,000	288,000	-	559,000	-	-	-	1,097,000
Gregory A. Gould (2)									
Chief Financial Officer	2017	10,000	-	533,000	79,000	-	-	-	622,000
since June 2014	2016	-	250,000	-	-	-	-	-	250,000
Jonathan H. McGrael (3)									
VP of Commercial Operations	2017	144,000	75,000	452,000	91,000	-	-	61,000(4)	823,000
	2016	140,000	238,000	-	186,000	-	-	13,000(4)	577,000

(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 11 — Equity Instruments.”
(2) Mr. Gould was appointed to Chief Financial Officer, Secretary and Treasurer full time effective June 16, 2017.
(3) Mr. McGrael was hired in September 2015 and he resigned in March, 2017.
(4) Represents reimbursed relocation expenses and severance.

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.

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, 2017:

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 Executive Officers				
Joshua R Disbrow	7/7/2016	3,000	$ 16.40	$ 188,895
Jarrett T Disborw	7/7/2016	3,000	$ 16.40	$ 188,895
Gregory A Gould	7/7/2016	1,250	$ 16.40	$ 78,706

(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.

Outstanding Equity Awards at Fiscal Year-End 2017

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2017.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)	Equity Incentie Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Named Executive Officers									
Joshua R. Disbrow	834	1,666	-	$ 16.40	11/11/2025	9,500	112,100	-	-
Joshua R. Disbrow	1,000	2,000	-	$ 16.40	7/7/2026	-	-	-	-
Jarrett T. Disbrow	834	1,666	-	$ 16.40	11/11/2025	8,250	97,350	-	-
Jarrett T. Disbrow	1,000	2,000	-	$ 16.40	7/7/2026	-	-	-	-
Gregory A. Gould	1,042	-	-	$ 16.40	11/11/2025	825	97,350	-	-
Gregory A. Gould	417	833	-	$ 16.40	7/7/2026	-	-	-	-
Jonathan H. McGrael	834	-	-	$ 16.40	11/11/2025	-	-	-	-
Jonathan H. McGrael	1,167	-	-	$ 16.40	7/7/2026	-	-	-	-

(1) Based on $11.80 per share which was the closing price of our common stock on OTCQX on June 30, 2017, the last trading day of that fiscal year.

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. On April 16, 2017, we extended this agreement for another 24 months.

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. On April 16, 2017, we extended this agreement for another 24 months.

On June 15, 2017, we entered into an employment agreement with Gregory A. Gould, effective June 16, 2017, to serve as our Chief Financial Officer. Mr. Gould had been serving as our Chief Financial Officer on a part-time basis since April 2015.

The agreement is identical to the two-year employment agreement entered into effective April 16, 2017, with Jarrett Disbrow, our Chief Operating Officer, except for the positon that Mr. Gould is to occupy. The agreement is for a term of 24 months beginning on June 16, 2017, subject to termination by us with or without Cause (as defined below) or as a result of Mr. Gould's disability, or by Mr. Gould with or without Good Reason (as defined below). Mr. Gould is entitled to receive $250,000 in annual salary, plus a discretionary performance bonus with a target of 125% of his base salary, based on his individual achievements and company performance objectives established by the board or the compensation committee in consultation with Mr. Gould. Mr. Gould 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.

Payments Provided Upon Termination for Good Reason or Without Cause

Pursuant to the employment agreements, in the event employment is terminated without Cause by us or the 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" 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", 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 or 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.

Payments Provided Upon a Change in Control

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, Jarrett Disbrow and Gregory A. Gould had a Change in Control occurred as of June 30, 2017, would be the acceleration of the vesting of all options held by them at that date. On June 30, 2017, the closing price of our common stock was below the exercise price for all of the options held by Joshua Disbrow, Jarrett Disbrow and Gregory A. Gould 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, 2017 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, 2017. The percentage ownership information shown in the table is based upon 4,021,822 shares of common stock outstanding as of August 15, 2017.

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, 2017. 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:		
G. Nicholas Farwell & Gale Farwell TTEE U/A 12-2-98 FBO Farwell Family Trust [1]	583,334	13.34%
AIGH Partners LP[2]	453,750	10.57%
Armistice Capital Master Fund Ltd [3]	405,667	9.99%
Jeb Partners, L.P. [4]	424,000	9.99%
Galileo Partners Fund I, L.P. [5]	375,000	8.83%
Pacific Capital Mgmt LLC [6]	291,663	6.95%
Triple Gate Partners, LP [7]	250,000	5.99%
Lincoln Park Capital [8]	250,000	5.99%
Manchester Management Company, LCC [9]	210,331	5.10%
Clifford Disbrow [10]	208,334	5.02%
Sheila Ryan Disbrow [11]	208,334	5.02%
Directors and Named Executive Officers:		
Joshua R. Disbrow [12]	243,125	5.86%
Jarrett T. Disbrow [13]	240,219	5.79%
Gregory A. Gould [14]	18,471	*%
Michael Macaluso [15]	6,802	*%
Carl C. Dockery[16]	45,865	1.14%
John Donofrio[17]	4,000	*%
Gary Cantrell[18]	7,521	*%
All directors and executive officers as a group (seven persons)	566,003	13.22%

* Represents beneficial ownership of less than 1%.

(1) Consists of 233,334 shares of common stock and 350,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(2) Consists of 181,500 shares of common stock and 272,250 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(3) Based on information provided in a Schedule 13G filed by Armistice Capital, LLC ("Armistice") on August 24, 2017. Includes 366,667 shares of common stock and 39,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017. Armistice is contractually limited to beneficial ownership of our common shares not to exceed 9.99% and this limitation has been taken into account in calculating the number of shares shown in the table for Armistice. The table does not include the following securities held by Armistice: (i) 633,333 shares of common stock underlying shares of Series A Preferred Stock and (ii) 1,461,000 shares of common stock issuable upon the exercise of warrants. The Managing Member of Armistice is Steven Boyd and its address is 510 Madison Avenue, 22nd Floor, New York, New York 10022.

(4) Consists of 200,000 shares of common stock and 224,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017. Jeb Partners, L.P. is contractually limited to beneficial ownership of our common shares not to exceed 9.99% and this limitation has been taken into account in calculating the number of shares shown in the table for Jeb Partners, L.P. The table does not include 76,000 shares of common stock issuable upon the exercise of warrants held by Jeb Partners, L.P.

(5) Based on information provided in a Schedule 13G filed by Manchester Management Company, LCC ("Manchester") on August 23, 2017. Consists of 4,206,614 shares held by Manchester and 1,357,341 shares held by the managing member of Manchester, James E. Besser. Manchester's address is 3 West Hill Place, Boston, Massachusetts 02114.

(6) Consists of 150,000 shares of common stock and 225,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(7) Consists of 116,665 shares of common stock and 174,998 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(8) Consists of 100,000 shares of common stock and 150,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(9) Consists of 100,000 shares of common stock and 150,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(10) Consists of 83,334 shares of common stock and 125,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(11) Consists of 83,334 shares of common stock and 125,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017.

(12) Consists of (i) 105,344 shares, (ii) 9,500 restricted shares (iii) 1,834 vested options to purchase shares of stock, (iv) 1,447 shares issuable upon the exercise warrants and (v) 125,000 shares issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017. Does not include 2,328 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.

(13) Consists of (i) 105,135 shares, (ii) 8,230 restricted shares, (iii) 1,834 vested options to purchase shares of common stock and (iv) 125,000 shares issuable upon the exercise of warrants exercisable within 60 days of August 15, 2017. Does not include 2,328 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.

(14) Consists of (i) 8,762 shares, (ii) 8,250 restricted shares, and (iii) vested options to purchase 1,459 shares of common stock.

(15) Consists of (i) 1,489 shares, (ii) 3,250 restricted shares, and (iii) vested options to purchase 2,063 shares of common stock.

(16) Consists of (i) 3,250 restricted shares, (ii) vested options to purchase 750 shares of common stock, and (iii) 41,865 shares 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.

(17) Consists of (i) 3,250 restricted shares, and (ii) vested options to purchase 750 shares of common stock.

(18) Consists of (i) 3,250 restricted shares, (ii) 3,521 shares, and (iii) vested options to purchase 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.

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 periodically to reflect the amount of resources used from Ampio, the final amount was $4,000 for the month of June 2017. This agreement was cancelled in June 2017 and Ampio is no longer considered a related party.

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. This agreement was cancelled in 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://www.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

EKS&H LLLP has served as our independent auditor since April 2015, and has been appointed by our Board of Directors to continue as our independent auditor for the fiscal year ending June 30, 2018.

The following table presents aggregate fees for professional services rendered by our independent registered public accounting firm, EKS&H LLLP, for the audit of our annual financial statements for the respective periods, all of which were approved by our full Board of Directors for fiscal 2016 and by the Audit Committee for fiscal 2017.

	Year Ended June 30,	
	2017	**2016**
Audit fees (1)	132,000	199,000
Audit-related fees (2)	90,000	108,000
Tax fees (3)	-	4,000
Total Fees	222,000	311,000

(1) Audit fees are comprised of annual audit fees and quarterly review fees.
(2) Audit-related fees for both fiscal year 2016 and 2017 were comprised of fees related to registration statements, including for our May 2016 public offering and November 2016 public offering, respectively.
(3) Tax fees are comprised of tax compliance, preparation and consultation fees.

PART IV

Item 15. Exhibits and Consolidated 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
- Consolidated Balance Sheets as of June 30, 2017 and 2016
- Consolidated Statements of Operations for the years ended June 30, 2017 and 2016
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2017 and 2016
- Consolidated Statements of Cash Flows for the years ended June 30, 2017 and 2016
- Consolidated 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
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, effective June 30, 2016	8-K	7/01/16	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, filed on August 11, 2017.	8-K	8/16/17	3.1	
3.5	Certificate of Amendment of Certificate of Incorporation, effective August 25, 2017	8-K	8/29/17	3.1	
3.6	Bylaws	8-K	6/09/15	3.2	
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	First Amendment to May 6, 2016 Warrant Agent Agreement between Aytu BioScience, Inc. and VStock Transfer LLC.	S-1	9/21/16	4.5	
4.5	Warrant Agent Agreement, dated November 2, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC.	8-K	11/2/16	4.1	
4.6	Form of Amended and Restated Underwriters' Warrant (May 2016 Financing)	8-K	3/1/17	4.1	
4.7	Form of Amended and Restated Underwriters' Warrant (October 2016 Financing)	8-K	3/1/17	4.2	
4.8	Form of Common Stock Purchase Warrant issued on August 15, 2017.	8-K	8/16/17	4.1	
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#	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	
10.3#	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	
10.4	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)				
10.5#	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	
10.6#	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	
10.7#	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	
10.8#	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	
10.9	Promissory Note issued by Ampio to the Registrant on April 16, 2015	8-K	4/22/15	10.11	
10.10	Subscription Agreement between the Registrant and Ampio, dated April 16, 2015	8-K	4/22/15	10.12	
10.11	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)				

10.12	Asset Purchase Agreement between Jazz Pharmaceuticals, Inc. and Rosewind Corporation, dated May 20, 2015	8-K	5/27/15	10.14
10.13	Form of Note Purchase Agreement for 2015 Convertible Note Financing	8-K	7/24/15	10.17

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.14	Asset Purchase Agreement, dated October 5, 2015, between Aytu BioScience, Inc. and FSC Laboratories, Inc.	8-K	10/07/15	10.18	
10.15	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	
10.16	Form of Subscription Agreement for January 2016 common stock purchases	8-K	1/20/16	10.1	
10.17	License and Supply Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016	8-K	4/25/16	10.1	
10.18	Subscription Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016	8-K	4/25/16	10.2	
10.19	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	
10.20	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	
10.21	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	
10.22†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Joshua R. Disbrow.	8-K	4/18/17	10.1	
10.23†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Jarrett T. Disbrow.	8-K	4/18/17	10.2	
10.24	Asset Purchase Agreement, dated March 31, 2017, between Allegis Holdings, LLC and Aytu BioScience, Inc.	8-K	5/11/17	10.1	
10.25^	Merger Agreement, dated May 3, 2017, between Nuelle, Inc. and Aytu BioScience, Inc.				X
10.26†	Employment Agreement, effective as of June, 2017, between Aytu BioScience, Inc. and Gregory A. Gould.	8-K	6/19/17	10.1	
10.27†	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	7/27/17	10.1	
10.28	Securities Purchase Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	8/16/17	10.1	
10.29	Registration Rights Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	8/16/17	10.2	
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
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, 2017 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.

^ Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

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: August 31, 2017

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 August 31, 2017.

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 CONSOLIDATED 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 consolidated balance sheets of Aytu BioScience, Inc. (the "Company") as of June 30, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of Aytu BioScience, Inc. as of June 30, 2017 and 2016, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/EKS&H LLLP

August 31, 2017
Denver, Colorado

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Balance Sheets

	June 30, 2017	June 30, 2016
Assets		
Current assets		
Cash and cash equivalents	$ 802,328	$ 8,054,190
Restricted cash	75,214	-
Accounts receivable, net	528,039	162,427
Inventory, net	1,312,221	524,707
Prepaid expenses and other	310,760	215,558
Prepaid research and development - related party (Note 11)	-	121,983
Investment in Acerus	-	1,041,362
Total current assets	3,028,562	10,120,227
Fixed assets, net	647,254	231,430
Developed technology, net	1,337,333	1,159,736
Customer contracts, net	77,667	1,353,375
Trade names, net	164,037	194,472
Natesto asset	9,231,072	10,549,797
Goodwill	238,426	221,000
Patents, net	271,278	296,611
Long-term portion of prepaid research and development - related party (Note 11)	-	213,471
Deposits	2,888	2,888
Total long-term assets	11,969,955	14,222,780
Total assets	$ 14,998,517	$ 24,343,007
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other	$ 2,220,400	$ 2,322,605
Accrued liabilities	782,536	1,197,106
Natesto payable	-	5,379,675
Accrued compensation	339,704	1,200,930
Deferred rent	6,673	4,109
Current contingent consideration	261,155	-
Total current liabilities	3,610,468	10,104,425
Contingent consideration	7,386,782	3,869,122
Deferred rent	1,451	8,215
Warrant derivative liability	-	275,992
Total liabilities	10,998,701	14,257,754
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 824,831 in 2017 and 187,098 in 2016	82	19
Additional paid-in capital	73,069,463	56,646,659
Ampio stock subscription	-	-
Accumulated deficit	(69,069,729)	(46,561,425)
Total stockholders' equity	3,999,816	10,085,253
Total liabilities and stockholders' equity	$ 14,998,517	$ 24,343,007

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

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Statements of Operations

	Year Ended June 30,	
	2017	**2016**
Revenue		
Product and service revenue	$ 3,221,590	$ 2,050,838
License revenue	-	511,607
Total revenue	3,221,590	2,562,445
Operating expenses		
Cost of sales	1,417,355	957,076
Research and development	959,857	6,127,772
Research and development - related party (Note 11)	387,960	191,991
Sales, general and administrative	17,442,627	8,517,592
Sales, general and administrative - related party (Note 11)	165,131	307,704
Impairment of intangible assets	1,265,125	7,500,000
Amortization of intangible assets	1,708,771	664,707
Total operating expenses	23,346,826	24,266,842
Loss from operations	(20,125,236)	(21,704,397)
Other (expense)		
Interest (expense)	(2,534,358)	(5,491,486)
(Loss) on investment	(61,519)	(971,629)
Derivative income (expense)	212,809	(12,572)
Total other (expense)	(2,383,068)	(6,475,687)
Net loss	$ (22,508,304)	$ (28,180,084)
Weighted average number of Aytu common shares outstanding	466,024	87,057
Basic and diluted Aytu net loss per common share	$ (48.30)	$ (323.70)

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

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Statements of Stockholders' Equity

	Common Stock		Additional paid-in	Ampio	Accumulated	Total Stockholders'
	Shares	Amount	capital	Stock Subscription	Deficit	Equity
Balance - June 30, 2015	59,415	$ 6	$38,997,787	$ (5,000,000)	$ (18,381,341)	$ 15,616,452
Ampio stock subscription	-	-	-	5,000,000	-	5,000,000
Stock subscription	1,282	-	200,000	-	-	200,000
Conversion of convertible promissory notes and interest to common stock, net of $29,754 conversion costs	48,108	5	10,090,844	-	-	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	78,125	8	4,237,866	-	-	4,237,874
Warrants issued in connection with registered financing	-	-	2,059,895	-	-	2,059,895
Warrants issued in connection with registered offering to the placement agents for the over-allotment option	-	-	20,493	-	-	20,493
Adjustment for rounding of shares due to stock split	168	-	-	-	-	-
Stock-based compensation	-	-	902,946	-	-	902,946
Net loss	-	-	-	-	(28,180,084)	(28,180,084)
Balance - June 30, 2016	187,098	19	56,646,659	-	(46,561,425)	10,085,253
Lincoln Park stock issuance, net of issuance costs $90,924	19,309	2	648,931	-	-	648,933
Stock-based compensation	-	-	2,502,092	-	-	2,502,092
Issuance of restricted stock	50,000	5	724,608	-	-	724,613
Common stock issued to executives	7,123	-	509,996	-	-	509,996
Issurance of warrants to initial investors	-	-	596,434	-	-	596,434
Issuance of common stock, net of $997,865 in issuance costs	286,749	29	3,671,552	-	-	3,671,581
Warrants issued in connection with registered offering			3,470,646	-	-	3,470,646
Warrants issued in connection with registered offering to the placement agents for the over-allotment option	-	-	172,629	-	-	172,629
Warrants issued in connection with the registered offering to the placement agents, non-cash issuance costs	-	-	292,630	-	-	292,630
Warrant tender offer, net of $312,159 in issuance costs	149,552	15	1,931,108	-	-	1,931,123
Warrant amendments	-	-	64,690	-	-	64,690
Investment in Subsidiary	125,000	12	1,837,488	-	-	1,837,500
Net loss	-	-	-	-	(22,508,304)	(22,508,304)
Balance - June 30, 2017	824,831	$ 82	$73,069,463	$ -	$ (69,069,729)	$ 3,999,816

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

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Statements of Cash Flows

	Year Ended June 30,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$ (22,508,304)	$ (28,180,084)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	4,364,680	874,789
Asset impairment	1,265,125	7,500,000
Stock-based compensation expense	2,502,092	902,946
Issuance of restricted stock	724,613	-
Amortization of debt issuance costs	-	182,759
Amortization of beneficial conversion feature	-	4,943,073
Noncash interest expense	-	221,024
Derivative (income) expense	(212,809)	12,572
Amortization of prepaid research and development - related party (Note 11)	335,454	121,983
Loss on investment	61,519	971,629
Common stock issued to executives	509,996	-
Issuance of warrants to initial investors	596,434	-
Gain on sale of asset	(428,374)	-
Warrant amendment	1,507	-
Adjustments to reconcile net loss to net cash used in operating activities:		
(Increase) in accounts receivable	(355,031)	(5,369)
Decrease (increase) in inventory	195,427	(485,265)
(Increase) decrease in prepaid expenses and other	(95,202)	155,330
Increase in accounts payable and other	493,217	698,237
(Decrease) increase in accrued liabilities	(414,570)	925,232
(Decrease) increase in accrued compensation	(861,226)	1,004,427
(Decrease) increase in deferred rent	(4,200)	10,875
(Decrease) in deferred revenue	-	(511,607)
Net cash used in operating activities	(13,829,652)	(10,657,449)
Cash flows used in investing activities:		
Purchases of fixed assets	(111,608)	(252,932)
Purchase of Natesto assets	(6,000,000)	(2,000,000)
Investment in Acerus	1,071,707	(2,012,991)
Sale of investment in Acerus cost	(91,864)	-
Sales of Primsol assets	1,750,000	-
Purchase of Primsol asset	(750,000)	(1,040,000)
Cash proceed from Nuelle	613,309	-
Cost related to Nuelle acquisition	(16,082)	-
Deposits	-	1,998
Net cash used in investing activities	(3,534,538)	(5,303,925)
Cash flows from financing activities:		
Issuance of common stock to Lincoln Park	739,857	-
Costs related to the sale of common stock	(90,924)	-
Warrant tender offer	2,243,282	-
Warrant tender offer cost	(312,159)	-
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
Registerd offering	8,602,499	7,520,493
Registered offering costs	(997,865)	(904,914)
Over-allotment warrants purchased by placement agents	2,852	-
Sale of stock subscription	-	200,000
Net cash provided by financing activities	10,187,542	16,662,503
Net change in cash and cash equivalents	(7,176,648)	701,129
Cash and cash equivalents at beginning of period	8,054,190	7,353,061
Cash and cash equivalents at end of period	$ 877,542	$ 8,054,190
Non-cash transactions:		
Issuance of common stock to Nuelle share holders	$ 1,837,500	$ -
Fixed assets included in accounts payable	$ 10,789	$ -
Warrants issued in connection with the equity financing to the placement agents	$ 292,630	$ -
Warrants amended in connection with warrant tender offer	$ 63,182	$ -
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, Merger 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 hypogonadism, urological cancers, male infertility, and sexual wellness and vitality.

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; On August 25, 2017, Aytu effected another reverse stock split in which each common stockholder received one share of common stock for every 20 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, 2017 at $54,000 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 was 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 at May 2015 was 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 both fiscal 2017 and 2016.

At June 30, 2017, the ProstaScint asset was impaired based upon sales projections that we intend to only sell this product through mid-fiscal 2019, when this product expires. The value for the intangible assets were adjusted to $54,000 for developed technology, $7,000 for trade names and $0 for customer contracts. The estimated future amortization of ProstaScint after June 30, 2017 is as follows:

Total ProstaScint	
2018	$ 47,000
2019	14,000
2020	-
2021	-
2022	-
Thereafter	-
	$ 61,000

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 which was paid in November 2016 (together, the "Installment Payments").

The Company's allocation on consideration transferred for Primsol as of the purchase date of October 5, 2015 was 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 was $102,000 of inventory and $80,000 of work-in-process inventory. Included in the intangible assets was developed technology of $520,000, customer contracts of $810,000 and trade names of $140,000, each of which was being amortized over a six-year period. Amortization expense of $184,000 and $174,000 was recognized in fiscal 2017 and fiscal 2016, respectively.

Divestiture – Primsol

In March 2017, we entered into and closed on an Asset Purchase Agreement with Allegis Holdings, LLC (the "Purchaser"). Pursuant to the agreement, we sold to the Purchaser all of our assets related to our Primsol product, including certain intellectual property and contracts, inventory, work in process and all marketing assets and materials related solely to Primsol (together, the "Primsol Asset"). We retain any liability associated with the Primsol Asset that occurred prior to the closing. The Purchaser paid us $1,750,000 at the closing for the Primsol Asset. We recognized a gain of approximately $428,000 on the sale which is included in sales, general and administrative expense on our statement of operations.

We have evaluated this transaction and concluded that it is not significant to our business and therefore the results are included in continuing operations, as the criteria to be presented as discontinued operations was not satisfied.

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 acquired 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. In October 2016, we paid an additional $2.0 million. In January 2017, Aytu paid the final upfront payment of $4.0 million. Aytu also purchased, on April 28, 2016, an aggregate of 12,245,411 shares of Acerus common stock for Cdn. $2.5 million (approximately US $2.0 million), with a purchase price per share equal to Cdn. $0.207 or approximately US $0.16 per share. These shares were a held for sale trading security and were valued at fair market value. Aytu could not dispose of these shares until after August 29, 2016. During fiscal 2017, Aytu sold all of these shares. The gross proceeds from the sales totaled $1.1 million, the cost of the sales totaled $92,000, and we recognized a loss on investment of $62,000 and $972,000 during fiscal 2017 and 2016, respectively.

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 $37.5 million):

- $2.5 million if net sales during any four consecutive calendar quarter period equal or exceed $25.0 million (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;
- $5.0 million if net sales during any four consecutive calendar quarter period equal or exceed $50.0 million;
- $7.5 million if net sales during any four consecutive calendar quarter period equal or exceed $75.0 milion;
- $10.0 million if net sales during any four consecutive calendar quarter period equal or exceed $100.0 million; and
- $12.5 million if net sales during any four consecutive calendar quarter period equal or exceed $125.0 million.

The fair value of the net identifiable asset acquired totaled $10.5 million which is being amortized over eight years. The amortization expense for fiscal 2017 was $1.3 million and zero for fiscal 2016. The estimated future amortization of Natesto after June 30, 2017 is as follows:

2018	1,319,000
2019	1,319,000
2020	1,319,000
2021	1,319,000
2022	1,319,000
Thereafter	2,636,000
	$ 9,231,000

The contingent consideration was valued at $3.2 million using a Monte Carlo simulation, as of June 30, 2016. The contingent consideration accretion expense for fiscal 2017 and 2016 was $228,000, and zero respectively. As of June 30, 2017, the contingent consideration was revalued and increased to $5.7 million based on increased future estimated sales performance of Natesto using a Monte Carlo simulation.

Merger/Subsidiary

In May 2017, Aytu Women's Health, LLC., a wholly-owned subsidiary of Aytu, acquired Nuelle, Inc., or Nuelle, a women's sexual health company. This transaction expanded our product portfolio with the addition of the Fiera® personal care device for women.

In the Merger, (i) each share of Nuelle common stock and each option or warrant to purchase Nuelle stock was cancelled, and (ii) each share of Nuelle preferred stock was converted into the right to receive shares of our common stock. We issued to the Nuelle preferred stockholders an aggregate of 125,000 shares of our common stock.

In addition, Nuelle preferred stockholders will be entitled to revenue earn-out payments equal to a designated percentage of net sales on tiers of net sales up to $100.0 million, with an average rate for all tiers in the mid-single digit range and a maximum aggregate payout of $6.9 million.

Nuelle stockholders additionally will be entitled to milestone earn-out payments of up to a potential aggregate of $24.0 million, upon the attainment by us of designated net sales thresholds over any sequential four calendar quarter period.

The first $1.0 million of earn-out payments will be paid in shares of our common stock and all other earn-out payments will be comprised of 60% cash and 40% shares of our common stock. The stock portion of any earn-out will be calculated by dividing each Nuelle stockholder's portion of the earn-out by the average closing price of our common stock for the 10 trading days prior to the earlier of the date we deliver notice to the Nuelle stockholders of the earn-out or any public disclosure by us of the earn-out being due and payable.

In the event that we do not make all of the required earn-out payments to the Nuelle stockholders before May 3, 2022, and we also close a divestiture before May 3, 2022 of any of the products acquired in the transaction, we will pay the Nuelle stockholders a combination of (i) cash in an amount equal to 10% of the value of all cash, securities and other property paid to us in the divestiture (cash is to be 60% of the total consideration), and (ii) shares of our common stock equal to the Nuelle stockholders' portion of the divestiture payment divided by the average closing price of our common stock for the 10 trading days prior to the earlier of the closing date of the divestiture or the public disclosure of the divestiture (shares of common stock are to be 40% of the total consideration).

In addition to the upfront issuance of common stock, we must make the following one-time payments to the Nuelle stockholders within 90 days of the occurrence of the following events (provided that, the maximum aggregate amount payable under such milestone payments will be $24.0 million):

- Upon achieving the first occurrence of Net Sales of $10.0 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $1.0 million;
- Upon achieving the first occurrence of Net Sales of $17.5 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $1.8 million.
- Upon achieving the first occurrence of Net Sales of $25.0 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $2.5 million.
- Upon achieving the first occurrence of Net Sales of $37.5 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $3.8 million;
- Upon achieving the first occurrence of Net Sales of $50.0 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $5.0 million; and
- Upon achieving the first occurrence of Net Sales of $100.0 million over any sequential four calendar quarter period, Aytu will make a one-time payment to the Nuelle security holders of an amount equal to $10.0 million.

The Company's allocation on consideration transferred for Nuelle as of the purchase date May 5, 2017 is as follows:

	Fair Value
Tangible assets	$ 2,061,000
Intangible assets	1,540,000
Goodwill	238,000
Total assets acquired	$ 3,839,000

Included in the intangible assets is developed technology of $1.3 million, customer contracts of $80,000 and trade names of $160,000, each of which will be amortized over a nine to twelve-year period. Amortization expense of $22,000 and $0 was recognized in fiscal 2017 and 2016, respectively.

Future amortization after the year ended June 30, 2017 is as follows:

2018	$ 144,000
2019	144,000
2020	144,000
2021	144,000
2022	144,000
Thereafter	798,000
	$ 1,518,000

The contingent consideration was valued at $1.9 million using a Monte Carlo simulation, as of May 2017. The contingent consideration accretion expense for fiscal 2017 and 2016 was $12,000, and zero respectively.

Additionally, we assumed liabilities of $47,000.

Note 2 – Summary of Significant Accounting Policies

Principals of Consolidation

These consolidated financial statements include the accounts of Aytu and its wholly-owned subsidiary, Aytu Women's Health. All material intercompany transactions and balances have been eliminated.

Cash, Cash Equivalents and Restricted Cash

Aytu considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Restricted cash consist primarily of a certificate of deposit investment account. 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

The Company recognizes revenue only when all of the following criteria have been met:

- Persuasive evidence of an arrangement exists,
- Delivery has occurred or services have been performed,
- The fee for the arrangement is fixed or determinable, and
- Collectability is reasonably assured.

Persuasive evidence of an arrangement exists - The Company documents all terms of an arrangement in a written contract by the customer prior to recognizing revenue.

Delivery has occurred or services have been performed - The Company delivers all products prior to recognizing revenue. Equipment is considered delivered upon delivery to a customer's designated location.

Device sales are recorded when products are shipped to customers. Drug sales are recorded when the product arrives at the customer’s dock. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments are provided for in the same period the related sales are recorded and are estimated at the time of sale.

The fee for the arrangement is fixed or determinable - Prior to recognizing revenue, a customer's fee is either fixed or determinable under the terms of the written contract.

Collectability is reasonably assured - The Company determines that collectability is reasonably assured prior to recognizing revenue. Collectability is assessed on a customer-by-customer basis based on criteria outlined by management. New customers are subject to a credit review process, which evaluates the customer's financial position and ultimately its ability to pay. The Company does not enter into arrangements unless collectability is reasonably assured at the outset. Existing customers are subject to ongoing credit evaluations based on payment history and other factors. If it is determined during the arrangement that collectability is not reasonably assured, revenue is recognized on a cash basis.

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. As of June 30, 2017 and 2016, we accrued $58,000 and $284,000, respectively, in our estimated returns allowance.

Shipping and Handling

The Company's shipping and handling costs are included in cost of goods sold for all periods presented.

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, 2017 we had an allowance for doubtful accounts of $44,000, and as of June 30, 2016, there had been an allowance for doubtful accounts of $41,000.

Concentration of Business Risks

The following counterparties contributed greater than 10% of the Company's total revenue during the year ended June 30, 2017 and 2016, respectively. The revenue from these counterparties as a percentage of total revenue was as follows:

	Year Ended June 30,	
	2017	2016
Customer A	34%	-
Customer B	22%	-
Customer C	18%	-
Customer D	0%	86%

The loss of one or more of the Company's significant partners or collaborators could have a material adverse effect on its business, operating results or financial condition. Although the Company is impacted by economic conditions in the biotechnology and pharmaceutical sectors, management does not believe significant credit risk exists as of June 30, 2017.

We are also subject to credit risk from our accounts receivable related to our product sales. Historically, we have not experienced significant credit losses on our accounts receivable and we do not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on our financial position, liquidity or results of operations. As of June 30, 2017, three customers accounted for 60% of gross accounts receivable. As of June 30, 2016, one customer accounted for 69% of gross accounts receivable.

	Year Ended June 30,	
	2017	2016
Customer A	25%	-
Customer B	17%	-
Customer C	18%	-
Customer D	0%	69%

Inventories

Inventories consist of raw materials, work in process and finished goods and are recorded at the lower of cost or net realizable value, 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. We currently have a reserve of $311,000 for slow moving inventory as of June 30, 2017 and $199,000 at June 30, 2016.

Inventory consist of the following:

	June 30,	
	2017	2016
Raw materials	$ 442,000	$ 77,000
Work in process	442,000	-
Finished goods	738,000	647,000
Reserve	(310,000)	(199,000)
	$ 1,312,000	$ 525,000

Trading Securities

Trading securities are carried at fair value with realized and 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, 2017	June 30, 2016
Office equipment, furniture and other	2 - 5	$ 405,000	$ 201,000
Lab equipment	3 - 5	111,000	90,000
Leasehold improvements	3	287,000	45,000
Manufacturing equipment	2 - 5	90,000	7,000
Less accumulated depreciation and amortization		(246,000)	(112,000)
Fixed assets, net		$ 647,000	$ 231,000

Aytu recorded the following depreciation expense in the respective periods:

	Year Ended June 30, 2017	Year Ended June 30, 2016
Depreciation expense	$ 134,000	$ 51,000

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 by Ampio, the former parent company of Aytu, and were being amortized over the remaining U.S. patent lives of approximately 11 years, which were to expire in March 2022. In fiscal 2016, we redirected our resources towards our commercial-stage products and the Company determined that this asset had no further value as the Company did not have the resources to complete the necessary clinical trials and bring it to market before the patents expired. The remaining fair value of the Zertane patents were 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 are 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, 2017	June 30, 2016
Patents	$ 880,000	$ 880,000
Less accumulated amortization	(609,000)	(583,000)
Patents, net	$ 271,000	$ 297,000

Aytu recorded the following amortization expense in the respective periods:

	Year Ended June 30, 2017	Year Ended June 30, 2016
Amortization expense	$ 26,000	$ 332,000

Future amortization from the year ended June 30, 2017 is as follows:

2018	$ 25,000
2019	25,000
2020	25,000
2021	25,000
2022	25,000
Thereafter	146,000
	$ 271,000

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 Nuelle, ProstaScint and Primsol purchase price allocations were 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, Primsol that occurred on October 5, 2015 and Nuelle that occurred on May 5, 2017. There was an impairment of $74,000 related to the ProstaScint goodwill for the year ended June 30, 2017.

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, collectability of accounts receivable, 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 were 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 carryforwards 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 taxes 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 740-1 "Accounting for Uncertainty in Income Taxes-an interpretation of FASB Statement 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 2017 and 2016. Although there were common stock equivalents of 367,312 and 126,239 shares outstanding at June 30, 2017 and 2016, 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, restricted cash, 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 liability 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 were 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 was 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.

Adoption of Newly Issued Accounting Pronouncements

In November 2016, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2016-18, "Statement of Cash Flows: Restricted Cash." The amendments address diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. ASU 2016-18 is effective for the fiscal year commencing after December 15, 2017. During fiscal 2017, the Company early adopted this pronouncement, the impact of which was minimal, which is now shown on the statements of cash flows within cash and cash equivalents.

In August 2016, the FASB issued ASU 2016-15 “Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments,” which provides guidance on the presentation of certain cash receipts and cash payments in the statement of cash flows in order to reduce diversity in existing practice. ASU 2016-15 is effective for interim and annual periods beginning after December 15, 2017. Early adoption is permitted. During fiscal 2017, the Company early adopted this standard. The primary cash flow categorization that will impact the Company will be contingent consideration payments, however, no such payments have been made to date.

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 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. The Company adopted this standard during fiscal, 2017. Aytu has elected to account for forfeitures as they occur, rather than estimate expected forfeitures. Prior to adopting this standard, the Company had not estimated any forfeitures, therefore, no adjustments were necessary. Aytu is also operating at a net operating loss, therefore, there was no tax implication.

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 was effective for fiscal years and interim periods beginning after December 15, 2016. ASU 2015-11 is required to be applied prospectively. The amendments in ASU 2015-11 were adopted by the Company during fiscal 2017. The adoption of this standard did not have an 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. The Company adopted this standard during fiscal 2017 and has included the required disclosure in the Company’s financial statements (Note 3).

Recently Issued Accounting Pronouncements, Not Adopted as of June 30, 2017

In May 2017, the FASB issued ASU No. 2017-09, “Compensation-Stock Compensation (Topic 718) Scope of Modification Accounting (ASU 2017-09).” ASU 2017-09 clarifies which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The standard is effective for interim and annual reporting periods beginning after December 15, 2017, with early adoption permitted. The Company is currently evaluating the impact of its adoption of this standard on its financial statements.

In January 2017, the FASB issued ASU 2017-04, “Intangibles - Goodwill and Other (Topic 350).” The amendment simplifies the subsequent measurement of goodwill by removing the second step of the two-step impairment test. The amendment requires an entity to perform its annual, or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. An entity still has the option to perform the qualitative assessment for a reporting unit to determine if the quantitative impairment test is necessary. The amendment should be applied on a prospective basis. ASU 2017-04 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company does not believe that adoption of this amendment will have a material impact on its financial statements.

In January 2017, the FASB issued ASU 2017-01, “Business Combinations (Topic 805) Clarifying the Definition of a Business.” The amendment clarifies the definition of a business, which is fundamental in the determination of whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This determination is important given the diverging accounting models used for each type of transaction. The guidance is generally expected to result in fewer transactions qualifying as business combinations. The amendment is effective prospectively for public business entities for interim and annual periods beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. The Company does not expect an immediate impact on its financial statements from this codification however, if Aytu seeks to purchase additional assets in the future it could have an impact if that purchase is accounted for as a business combination or an asset purchase.

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 leases 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 No. 2016-01, *Financial Instruments - Recognition and Measurement of Financial Assets and Financial Liabilities (Topic 825)*. ASU No. 2016-01 revises the classification and measurement of investments in certain equity investments and the presentation of certain fair value changes for certain financial liabilities measured at fair value. ASU No. 2016-01 requires the change in fair value of many equity investments to be recognized in net income. ASU No. 2016-01 is effective for interim and annual periods beginning after December 15, 2017, with early adoption permitted. Adopting ASU No. 2016-01 may result in a cumulative effect adjustment to the consolidated statement of equity retained earnings as of the beginning of the year of adoption. The Company is currently evaluating the impact of this standard on its financial statements.

In May 2014, the FASB issued 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 guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. The New Revenue Standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early application is permitted for interim and annual periods beginning after December 5, 2017. 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. We will adopt the standard in our third quarter of fiscal 2018 and preliminarily expect to use the modified prospective method. However, we are continuing to evaluate the impact of the standard, and our adoption method is subject to change. We currently do not anticipate these standards to have a material impact on our consolidated financial statements outside of the expanded disclosure requirements.

Note 3 – Going Concern

As reflected in the accompanying financial statements, the Company had a net loss of $22.5 million and net cash used in operations of $13.8 million, for the year ended June 30, 2017. At June 30, 2017, Aytu had $878,000 of cash, cash equivalents and restricted cash, stockholders' equity of $4.0 million and an accumulated deficit of $69.1 million at June 30, 2017. In addition, the Company is in the early stage of commercialization and has not yet generated any profits. These factors raised substantial doubt about the Company's ability to continue as a going concern.

However, with the completion of the August 2017 financing of $11.8 million, the Company expects that its current cash resources plus this additional funding will be sufficient to fund operations through fiscal 2018 and into mid-fiscal 2019.

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 Pharmaceuticals, Inc., ("Ampio"), Aytu's former parent company, 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 $3.0 million 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 had no further value as Aytu did 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

The carrying amounts of financial instruments, including cash and cash equivalents, restricted cash, 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. 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, 2017 and 2016, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	**Level 2**	**Level 3**	**Total**
June 30, 2017				
ASSETS				
Investment in Acerus	$ -	$ -	$ -	$ -
LIABILITIES				
Warrant derivative liability	$ -	$ -	$ -	$ -
Contingent consideration	$ -	$ -	$ 7,648,000	$ 7,648,000
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

The estimated fair value of the Company's investment, which is classified as Level 1 (quoted price is available), was $1.0 million as of June 30, 2016. This investment was sold during fiscal 2017.

The warrant derivative liability was valued using the Black-Scholes valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. The warrants related to the warrant derivative liability are not actively traded and therefore classified as Level 3. Significant assumptions in valuing the warrant derivative liability, based on estimates of the value of Aytu common stock and various factors regarding the warrants, were as follows as of February 28, 2017, the date when the derivative instruments converted into equity, and at June 30, 2016:

	February 28, 2017	June 30, 2016
Warrants:		
Volatility	160.7%	75.0%
Equivalent term (years)	4.18	4.84
Risk-free interest rate	1.87%	0.99%
Dividend yield	0.00%	0.00%

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, 2016	$ 276,000
Warrant issuances	-
Change in fair value included in earnings (February 28, 2017)	(213,000)
Reclassification of warrant from liability to equity upon amendment	(63,000)
Balance as of June 30, 2017	$ -

The contingent consideration was valued using the Monte-Carlo valuation methodology because that model embodies all of the relevant assumptions that address the features underlying these instruments. Contingent consideration is not actively traded and therefore classified as Level 3.

As of June 30, 2016, we had $3.9 million in contingent consideration. During fiscal 2017, this balance increased to $7.6 million as a result of $305,000 in accretion, which is included in our interest expense, as well as an increase of $1.9 million related to our Nuelle merger and adjustments of $1.5 million related to the revaluation of our ProstaScint and Natesto products.

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 ending 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 did not have a tax sharing agreement for the consolidated return periods. 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 interest in Aytu fell below 80% so that Aytu will no longer be included in the Ampio consolidated tax return. The deconsolidation resulted in approximately $4.5 million of net operating loss carryforwards originating prior to the incorporation of Vyrix and Luoxis no longer being available to Aytu. Upon deconsolidation, the deferred 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 various states) differs from the income tax provision (benefit) in the Aytu financial statements. The following table reflects the reconciliation for the respective periods.

	Year Ended June 30,			
	2017		2016	
Benefit at statutory rate	$ (7,653,000)	(34.00)%	$ (9,581,000)	(34.00)%
State income taxes, net of federal benefit	(681,000)	(3.02)%	(853,000)	(3.03)%
Stock based compensation	116,000	0.51%	7,000	0.03%
Interest on convertible debt	-	0.00%	75,000	0.27%
Offering costs	203,000	0.90%	-	0.00%
Contingent consideration	4,000	0.02%	-	0.00%
Change in tax rate	(11,000)	(0.05)%	-	0.00%
Change in valuation allowance	7,922,000	35.19%	8,672,000	30.77%
Reduction of net operating losses upon deconsolidation	-	0.00%	1,674,000	5.94%
Other	100,000	0.45%	6,000	0.02%
Net income tax provision (benefit)	$ -	0.00%	$ -	0.00%

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:

	2017	2016
Deferred tax assets (liabilities):		
Deferred revenue	$ -	$ -
Deferred rent	3,000	5,000
Accrued expenses	127,000	445,000
Net operating loss carry forward	15,435,000	9,202,000
Intangibles	1,559,000	606,000
Share-based coompensation	1,362,000	327,000
Fixed assets	191,000	-
Unrealized loss on investment	-	360,000
Capital loss carry forward	385,000	-
Contribution carry forward	41,000	-
Warrant liability	75,000	153,000
Inventory	174,000	192,000
Allowance for doubtful accounts	17,000	15,000
Total deferred income tax assets (liabilities)	19,369,000	11,305,000
Less: Valuation allowance	(19,369,000)	(11,305,000)
Total deferred income tax assets (liabilities)	$ -	$ -

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 losses of approximately $42.3 million and $24.8 million as of June 30, 2017 and June 30, 2016, respectively that, subject to limitation, may be available in future tax years to offset taxable income. The available federal net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2031 through 2036. The Company has state net operating losses of approximately $32.8 million and $17.3 million as of June 30, 2017 and June 30, 2016, respectively that, subject to limitation, may be available in future tax years to offset taxable income. The available state net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2025 through 2036. 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. 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.

As of June 30, 2017 and 2016, 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 judgement 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 tax years prior to 2013 and 2012, 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, 2017:

	Total	2018	2019	2020	2021	2022	Thereafter
Prescription database	$ 1,342,000	$ 769,000	$ 573,000	$ -	$ -	$ -	$ -
Natesto	15,000,000	-	-	2,500,000	5,000,000	-	7,500,000
Manufacturing/commercial supply agreements	-	-	-	-	-	-	-
Office lease	175,000	145,000	30,000	-	-	-	-
	$ 16,517,000	$ 914,000	$ 603,000	$ 2,500,000	$ 5,000,000	$ -	$ 7,500,000

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 $1.9 million over three years for access to the database of prescriptions written for Natesto. The payments have been broken down into quarterly payments, the first of which was made in November 2016, the second payment was made in January 2017 and the third payment was made in April 2017.

Natesto

In April 2016, the Company entered into an agreement with Acerus whereby Aytu agreed to pay $8.0 million for the exclusive U.S. rights to Natesto (see Note 1). The first payment totaling $2.0 million was paid in April, the second installment payment was paid in October 2016. The final payment totaling $4.0 million was paid in January 2017. Additionally, Aytu is required to make the first milestone payment of $2.5 million even if the milestone is not reached and anticipates making the second milestone payment of $5.0 million along with the third milestone payment of $7.5 million.

Manufacturing/Commercial Supply Agreements

In October 2015, Aytu entered into a Master Services Agreement with Biovest International, Inc. (“Biovest”). The agreement provides that Aytu may engage Biovest from time to time to provide services in accordance with mutually agreed upon project addendums and purchase orders. Aytu expects to use the agreement from time to time for manufacturing services, including without limitation, the manufacturing, processing, quality control testing, release or storage of its products for the ProstaScint product. In September 2016, Aytu entered into a Commercial Supply Agreement with Grand River Aseptic Manufacturing, Inc. (“GRAM”). The agreement provides that Aytu may engage GRAM from time to time to provide services in accordance with mutually agreed upon work orders. As of June 30, 2017, both contracts were on hold as the Company evaluates its strategic options for the ProstaScint product. If the contracts are not restarted, Aytu does not anticipate any future liability related to either contract.

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 September 2015, the Company entered into a 37 month operating lease in Englewood, Colorado. 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. 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, 2017	2016
Rent expense	$ 139,000	$ 120,000

Note 8 – 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 included 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 offering sold the institutional portion of the offering of the Notes. Aytu sold the balance of the Notes to individuals and entities with whom Aytu had 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 was obligated to issue warrants for an amount of shares 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 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 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 and upon conversion were moved to equity classification.

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) $92.60. 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, 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 $156.00, 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 $4.1 million of principal and $143,000 of accrued interest on the Notes converted into an aggregate of 32,830 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 automatically converted on the same terms as 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 $96.00, which was the per share purchase price in the registered offering. On May 6, 2016, the date of conversion, an aggregate of $1.1 million of principal and $78,000 of accrued interest on the Notes converted into an aggregate of 15,279 shares of Aytu's common stock and 15,279 warrants.

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 1,113 shares of common stock at an exercise price of $156.00 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 1,129 shares of common stock at an exercise price of $96.00 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, 2017 and June 30, 2016, Aytu had 824,831 and 187,098 common shares outstanding, respectively, and no preferred shares outstanding at either June 30, 2017 or June 30, 2016. The Company has 100.0 million shares of common stock authorized with a par value of $0.0001 per share and 50.0 million shares of preferred stock authorized with a par value of $0.0001 per share.

In May 2016, Aytu raised gross proceeds of approximately $7.5 million through a public offering of 78,125 Units. Offering costs totaled $1.2 million resulting in net proceeds of $6.3 million. Each Unit consisted 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 $120.00 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 to an additional 11,719 shares of common stock and/or warrants. The underwriters exercised 8,542 of this over-allotment option for the warrants and paid $2.40 per over-allotment warrant resulting in proceeds of $20,000. These warrants have the same terms as the warrants sold in the registered offering.

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’’). Upon signing the Purchase Agreement, Lincoln Park agreed to purchase 6,684 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 2,625 shares of common stock. Between September 2016 and June 2017, Lincoln Park purchased an additional 10,000 shares for $240,000, the issuance costs related to these purchases totaled $91,000, resulting in net proceeds of $649,000. We terminated the Purchase Agreement effective August 16, 2017.

In July 2016, we issued 50,000 shares of restricted stock as compensation to certain executive officers and directors, which vest in July 2026. This expense is included in sales, general and administrative. For the year ended June 30, 2017, the expense was $725,000. The original fair value of the restricted stock was $3.2 million. As of June 30, 2017, the remaining unrecognized expense is $2.5 million. During fiscal 2017, one of the Company’s executive officers resigned and his restricted stock vested in full upon this event. This resulted in the Company recognizing the remainder of the expense related to this executive’s restricted stock grant of $430,000.

In August 2016, we issued an aggregate of 7,123 shares of common stock as bonuses for performance in 2016 to three executive officers.

In November 2016, we raised gross proceeds of approximately $8.6 million through a public offering of 286,749 Units. Offering costs totaled $1.0 million resulting in net cash proceeds of $7.6 million. We also issued underwriter warrants in connection with the offering with a fair value of $293,000, resulting in net proceeds of $7.3 million. Each Unit consisted 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 $3.7 million and a fair value of $4.4 million. The investor warrants have an exercise price of $37.20 per share and will expire five years from the date of issuance. These investor warrants have a relative fair value of $3.5 million and a fair value of $4.2 million. We also granted the underwriters a 45-day option (the Over-Allotment Option) to purchase up to an additional 43,013 shares of common stock and/or warrants. The underwriters purchased 14,263 of this Over-Allotment Option for the warrants and paid $0.20 per over-allotment warrant. These warrants have the same terms as the warrants sold in the registered offering. These warrants have a relative fair value of $173,000, a fair value of $208,000, and proceeds of $3,000, which was the purchase price per the underwriting agreement.

In February 2017, the Company consummated its warrant tender offer to exercise, at a temporarily reduced exercise price of $15.00 per share, (i) outstanding warrants to purchase 86,667 shares of common stock with an exercise price of $120.00 per share, which were originally issued to investors in the Company’s May 2016 financing (the “May 2016 Warrants”), and (ii) outstanding warrants to purchase 301,013 shares of common stock with an exercise price of $37.20 per share, which were originally issued to investors in the Company’s October 2016 financing (the “October 2016 Warrants” and together with the May 2016 Warrants, the “Original Warrants”). Original warrants to purchase an aggregate of 149,552 shares of common stock were tendered and exercised in the warrant tender offer, for aggregate gross proceeds to the Company of approximately $2.2 million. Original warrants that were not tendered and exercised remain in effect at the pre-tender offer exercise prices of $120.00 per share and $37.20 per share, respectively (see Note 11).

In May 2017, we entered into a Merger Agreement with Nuelle, Inc. and its stockholders, pursuant to which Nuelle would become our wholly owned subsidiary (the "Merger"). The Merger closed on May 5, 2017. As part of the Merger, we issued to the Nuelle preferred stockholders an aggregate of 125,000 shares of our common stock.

Note 10 – Equity Instruments

Stock Option Repricing

In March 2017, our Board of Directors approved a common stock option repricing program whereby all previously granted and unexercised options were repriced on a one-for-one basis to $16.40 per share which represented the closing price of our common stock as of the date of the repricing. There was no other modification to the vesting schedule of the previously issued options. As a result, 36,864 unexercised options originally granted to purchase common stock at prices ranging from $64.60 to $1,111.20 per share were repriced under this program.

We treated the repricing as a modification of the original awards and calculated additional compensation costs for the difference between the fair value of the modified award and the fair value of the original award on the modification date. The repricing resulted in an incremental stock-based compensation expense of $34,000. The full expense was recognized during fiscal 2017.

In July 2016, our Board of Directors approved a common stock option repricing program whereby previously granted and unexercised options held by our then current employees, consultants and directors with exercise prices above $120.00 per share were repriced on a one-for-one basis to $64.60 per share which represented the per share fair value of our common stock as of the date of the repricing. There was no other modification to the vesting schedule of the previously issued options. As a result, 15,803 unexercised options originally granted to purchase common stock at prices ranging from $134.40 to $362.40 per share were repriced under this program.

We treated the repricing as a modification of the original awards and calculated additional compensation costs for the difference between the fair value of the modified award and the fair value of the original award on the modification date. The repricing resulted in an incremental stock-based compensation expense of $318,000. Expense related to vested shares was expensed on the repricing date and expense related to unvested shares is being amortized over the remaining vesting period of such stock options.

Options

On June 1, 2015, Aytu's stockholders approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which, as amended in November 2016, provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 100,000 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, 100,000 shares of its common stock, are reserved for issuance. The fair value of options granted 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 used for the year ended June 30, 2017 are as follows:

	Year Ended June 30,	
	2017	2016
Expected volatility	178% - 185%	75%
Risk free interest rate	0.97% - 1.88%	1.16% - 1.90%
Expected term (years)	5.0 -6.5	3.75 - 6.25
Dividend yield	0%	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	16,340	$ 360.20	
Exercised	-	$ -	
Forfeited/Cancelled	(209)	$ 362.40	
Outstanding June 30, 2016	16,131	$ 360.20	9.33
Granted	23,608	$ 18.20	
Exercised	-	$ -	
Forfeited	(1,408)	$ 83.20	
Cancelled	(68)	$ 64.60	
Outstanding June 30, 2017	38,263	$ 16.31	8.40
Exercisable at June 30, 2017	19,341	$ 16.40	7.95
Available for grant at June 30, 2017	61,737		

The following table details the options outstanding at June 30, 2017 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
$ 14.00	1,500	$ 14.00	9.85	-	$ 14.00
$ 16.40	36,763	$ 16.40	8.34	19,341	$ 16.40
	38,263	$ 16.31	8.40	19,341	$ 16.40

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, 2017 and 2016:

	Year Ended June 30,	
	2017	2016
Research and development expenses		
Stock-based compensation	$ -	$ 89,000
Selling, general and administrative expenses		
Stock-based compensation	2,502,000	814,000
	$ 2,502,000	$ 903,000
Unrecognized expense at June 30, 2017	$ 775,000	
Weighted average remaining years to vest	1.81	

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, 2015	444	$ 1,087.20	2.92
Warrants issued to placement agents for convertible promissory notes	1,115	$ 156.00	
Warrants issued to investors in connection with the registered offering	86,667	$ 120.00	
Warrants issued to placement agents for convertible promissory notes	1,129	$ 96.00	
Warrants issued to placement agents for the registered offering	5,474	$ 120.00	
Warrants issued to convertible note holders who converted May 5, 2016	15,279	$ 120.00	
Outstanding June 30, 2016	110,108	$ 124.02	4.71
Issuance of settlement warrants to initial investors	4,402	$ 80.00	
Warrants issued to investors in connection with the registered offering	301,014	$ 37.20	
Warrants issued to placement agents for the registered offering	20,077	$ 15.00	
Warrants exercised	(149,552)	$ 15.00	
Outstanding June 30, 2017	286,049	$ 50.29	4.23

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 1,115 shares of our common stock at an exercise price of $156.00 per share, and an aggregate of 1,129 shares of our common stock at an exercise price of $96.00 per share. These warrants have a fair value of $87,000 and $50,000, respectively.

Also in connection with the conversion of the notes in May 2016, the noteholders that converted also received 15,279 warrants (see Note 9). These warrants have a term of five years with an exercise price of $120.00 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 5,474 shares of common stock at an exercise price of $120.00 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 6).

Also in connection with our May 2016 public offering, we issued to investors warrants to purchase an aggregate of 86,667 shares of common stock, which includes the over-allotment warrants, at an exercise price of $120.00 with a term of five years. These warrants are accounted for under equity treatment (see Note 10).

Included in the warrant balance at June 30, 2016 are warrants to purchase of 5,474 shares of common stock issued to the underwriters of our May registered offering. These warrants were accounted for under liability accounting and were fair valued at each reporting period (see Note 7). On February 28, 2017, these warrants had a fair value of $63,000. Upon the amendment to these warrant agreements, in connection with the closing of our warrant tender offer, this value was reclassified from liability accounting to equity after we removed any provision in the amendment that could cause this to be paid in cash.

Included in the warrant balance at June 30, 2016 are warrants to purchase of 429 shares of common stock issued to the bankers that assisted us with our Notes (see Note 9). In March 2017, the Company reduced the exercise price of $156.00 to $15.00. This modification resulted in an expense of $1,500 which was recognized during the quarter ended March 31, 2017 in sales, general and administrative.

During fiscal 2017, Aytu issued warrants to purchase 4,402 shares of common stock to initial investors of the Company at an exercise price of $80.00 and a term of five years from July 2016. These warrants generated a non-cash expense of $596,000 for the year ended June 30, 2017, which is included in sales, general and administrative expense. These warrants are accounted for under equity treatment.

In connection with our November 2016 public offering, we issued to the underwriters of the public offering warrants to purchase an aggregate of 20,077 shares of common stock at an exercise price of $37.20 and a term of five years. These warrants are accounted for under equity treatment. In February, we reduced the exercise price of these warrants to $15.00.

Also in connection with our November 2016 public offering, we issued to investors warrants to purchase an aggregate of 301,014 shares of common stock, which includes the over-allotment warrants, at an exercise price of $37.20 with a term of five years. These warrants are accounted for under equity treatment (see Note 10).

In February 2017, the Company consummated its warrant tender offer to exercise, at a temporarily reduced exercise price of $15.00 per share, (i) outstanding warrants to purchase 86,667 shares of common stock with an exercise price of $120.00 per share, which were originally issued to investors in the Company's May 2016 financing (the "May 2016 Warrants"), and (ii) outstanding warrants to purchase 301,014 shares of common stock with an exercise price of $37.20 per share, which were originally issued to investors in the Company's October 2016 financing (the "October 2016 Warrants" and together with the May 2016 Warrants, the "Original Warrants"). Original Warrants to purchase an aggregate of 149,552 shares of common stock were tendered and exercised in the warrant tender offer, for aggregate gross proceeds to the Company of approximately $2.2 million. Original warrants that were not exercised remain in effect at the pre-tender offer exercise prices of $120.00 per share and $37.20 per share, respectively. The incremental fair value, which had no book impact, was $178,000.

The Company also reduced the exercise prices of an aggregate of 25,541 warrants to purchase shares of common stock, which were originally issued as underwriters' compensation in the May 2016 and October 2016 financings, from $120.00 per share and $37.20 per share, respectively, to $15.00 per share. The amended warrants related to the May 2016 financing adjusted the accounting for these warrants from liability classification to equity. The incremental fair value of these warrant modifications, which had no book impact, was $23,000.

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 selling price or fair market value 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. During fiscal 2017, Aytu modified 175,522 warrants. We used the value of $15.20 per the valuation of our common stock issued in March 2017.

Significant assumptions in valuing the warrants issued and modified during the year ended June 30, 2017 were as follows:

	Year Ended June 30,	
	2017	**2016**
Expected volatility	156.64% - 169.22%	75%
Risk free interest rate	1.63% - 1.87%	1.07 - 1.76%
Contractual term (years)	3.46 - 4.67	4.2 - 5.0
Dividend yield	0%	0%

Note 11 – Related Party Transactions

Services Agreement

In July 2015, Aytu entered into an agreement with Ampio, whereby Aytu agreed to pay Ampio a set amount per month for shared overhead, which includes costs related to the shared corporate staff and other miscellaneous overhead expenses. This agreement was amended in November 2015, April 2016, July 2016, and again in January 2017 resulting in an amount of $12,000 per month. This agreement was terminated in June 2017.

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 provided 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 was being amortized over the contractual term of 60.5 months and was divided between current and long-term on the balance sheet; as of September 2014, this amount had been paid in full. This agreement was terminated in March 2017.

Note 12 – Segment Information

Aytu manages our Company and aggregated our operational and financial information in accordance with two reportable segments: Aytu and Aytu Women's Health. The Aytu segment consists of our core male urology products. The Aytu Women's Health segment contains our women's health platform which consists of sexual wellness platform. Select financial information for these segments is as follows:

	Year Ended June 30,	
	2017	2016
Revenue:		
Aytu	$ 3,175,000	$ 2,562,000
Aytu Women's Health	47,000	-
Consolidated revenue	$ 3,222,000	$ 2,562,000
Consolidated net loss:		
Aytu	$(22,349,000)	$(28,180,000)
Aytu Women's Health	(159,000)	-
Consolidated net loss	$(22,508,000)	$(28,180,000)
Total assets:		
Aytu	$ 11,779,000	$ 24,343,000
Aytu Women's Health	3,220,000	-
Total assets	$ 14,999,000	$ 24,343,000

Note 13 – 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. The Company matches 50% of the first 6% contributed to the plan by employees. In fiscal 2017, the Company's match was $99,000.

Note 14 – Subsequent Events

In July 2017, our stockholders approved an amendment to our 2015 Stock Option and Incentive Plan to (i) increase the number of authorized shares of common stock reserved for issuance thereunder from 2.0 million to 3.0 million, (ii) increase the number of shares that may be issued as incentive stock options from 2.0 million to 3.0 million, (iii) increase the maximum number of shares of common stock (A) underlying stock options or stock appreciation rights that may be granted to any one individual during any calendar year period, and (B) granted to any one individual that is intended to qualify as "performance-based compensation" under Section 162(m) of the Internal Revenue Code of 1986, as amended, for any performance cycle from 1.0 million to 2.0 million, and (iv) in the event that we effect a reverse stock split prior to November 14, 2018 (or such other date that is one year after the date of our 2018 annual meeting of stockholders), immediately after the effective time of such reverse stock split, (A) the maximum number of shares reserved under the Plan will be automatically increased to 3.0 million, (B) the maximum number of shares that may be issued pursuant to any type of award will be automatically increased to 3.0 million, (C) the number of shares that may be granted to any one individual during any one calendar year period as stock options or stock appreciation rights will be automatically increased to 2.0 million, and (D) the number of shares that may be issued in the form of incentive stock options will be automatically increased to 3.0 million.

In July 2017, our stockholders also approved an amendment to our Certificate of Incorporation to effect a reverse stock split at a ratio of any whole number up to 1-for-20, as determined by our board of directors, at any time before November 14, 2018 (or such other date that is one year after the date of our 2018 annual meeting of stockholders), if and as determined by our board of directors.

August 11, 2017, our board of directors approved a reverse stock split in which each common stockholder received one share of common stock for every 20 shares outstanding, which was effected on August 25, 2017. This adjustment is reflected in this Annual Report.

On August 11, 2017, we entered into a Securities Purchase Agreement with various investors pursuant to which we agreed to sell Class A and Class B equity units for gross proceeds of approximately $11.8 million. Class A units consist of one (1) share of common stock and a warrant to purchase one and one-half (1.5) shares of common stock and were sold at a negotiated price of $3.00 per unit. Class B units consist of one (1) share of our newly created Series A Convertible Preferred Stock (the “Series A Preferred Stock”) and warrants to purchase one and one-half (1.5) shares of common stock for each share of common stock into which the Series A Preferred Stock is convertible and were sold at a negotiated price of $1,000.00 per unit to those purchasers who, together with their affiliates and certain related parties, would beneficially own more than 9.99% of our outstanding common stock following the offering. These Series A Preferred Shares concert into common shares at $3.00 per share, which when fully exercised will increase the common shares outstanding by 750,000 shares. The offering closed on August 15, 2017.

In the offering, we issued an aggregate of 3,196,665 shares of our common stock, 2,250 shares of Series A Preferred Stock and warrants to purchase up to an aggregate of 5,919,998 shares of our common stock.

We incurred certain expenses related to this transaction to attorneys and underwriters inclusive of a 9% cash fee and warrants to purchase 10% of the aggregate number of shares issued in the transaction.

In connection with the closing of the financing, we terminated the Purchase Agreement, dated as of July 27, 2016, by and between us and Lincoln Park Capital Fund, LLC. The termination was effective on August 16, 2017.

EXECUTION VERSION

Exhibit 10.25

Portions of this exhibit marked [*] are requested to be treated confidentially.

MERGER AGREEMENT

among

AYTU BIOSCIENCE, INC.,

NUELLE, INC.,

AYTU ACQUISITION CORPORATION, INC.,

AYTU HOLDINGS, LLC,

and

EARL BRIGHT,

AS REPRESENTATIVE

dated as of

May 3, 2017

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MERGER AGREEMENT

This Merger Agreement (this "**Agreement**"), dated as of May 3, 2017 (the "**Agreement Date**"), is entered into among NUELLE, INC., a Delaware corporation ("**Company**"), AYTU BIOSCIENCE, INC., a Delaware corporation (" **Parent**"), AYTU ACQUISITION CORPORATION, INC., a Delaware corporation and wholly-owned Subsidiary of Parent ("**Merger Sub**"), AYTU HOLDINGS, LLC, a Delaware limited liability company and wholly-owned Subsidiary of Parent ("**Second Merger Sub**", and together with the Merger Sub, the " **Merger Subs**") and, solely in its capacity as representative of the Company Securityholders, Earl Bright (the "**Representative**"). Capitalized terms used herein (including in the immediately preceding sentence) and not otherwise defined herein shall have the meanings set forth in Article 9 hereof.

RECITALS

A. The Board of Directors of Parent, Company and Merger Sub believe it is in the best interests of their respective companies for Company and Merger Sub to combine into a single company through the statutory merger of Merger Sub, a direct wholly-owned subsidiary of Parent, with and into Company, with Company surviving the merger (the "**Merger**"), upon the terms and conditions set forth in this Agreement and pursuant to the First Certificate of Merger (as defined in Section 1.2);

B. Immediately following the Merger, the Initial Surviving Corporation (as defined in Section 1.1) will merge (the " **Second Merger**", and together with the Merger, the "**Mergers**") with and into Second Merger Sub upon the terms and conditions set forth in this Agreement and pursuant to the Second Certificate of Merger (as defined in Section 1.2);

C. In furtherance of the foregoing recitals, the Board of Directors of Company (the " **Company Board**") has unanimously (a) determined that it is in the best interests of Company and its stockholders (the "**Stockholders**"), and declared it advisable, to enter into this Agreement with Parent and Merger Subs, (b) approved the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, including the Mergers, and (c) resolved, subject to the terms and conditions set forth in this Agreement, to recommend adoption of this Agreement by the Stockholders;

D. The Board of Directors of Parent and Merger Sub, and Parent, in its capacity as the sole stockholder of Merger Sub and the sole member of Second Merger Sub, have each, upon the terms and subject to the conditions set forth herein, approved and consented to the Mergers, the execution by Parent and Merger Subs of this Agreement and the consummation of the transactions contemplated hereby in accordance with the DGCL (as defined in Section 1.1) and the DLLCA (as defined in Section 1.1) as well as all other applicable Law;

E. Promptly following the execution of this Agreement, in order to induce Parent and Merger Subs to enter into this Agreement, Company shall use its commercially reasonable efforts to obtain and deliver to Parent an executed Action by Written Consent of the Stockholders adopting this Agreement, executed by Stockholders holding at least 95% of the outstanding equity securities of the Company (the "**Required Stockholder Approval**");

F. For federal income Tax purposes, it is intended that (i) the Merger and the Second Merger constitute an integrated plan described in Rev. Rul. 2001-46, 2001-2 C.B. 321 (the "**Integrated Transaction**"), (ii) the Integrated Transaction shall qualify as a reorganization under Section 368 of the Code and the Treasury Regulations promulgated thereunder, and (iii) this Agreement constitutes a plan of reorganization within the meaning of Section 368(a) of the Code; and

G. The parties desire to make certain representations, warranties, covenants and agreements in connection with the Mergers and the transactions contemplated by this Agreement and also to prescribe certain conditions to the Mergers.

NOW, THEREFORE, in consideration of the foregoing and of the representations, warranties, covenants and agreements contained in this Agreement, the parties, intending to be legally bound, agree as follows:

ARTICLE 1.
THE MERGERS

Section 1.1 The Mergers.

(a) On the terms and subject to the conditions set forth in this Agreement, and in accordance with the Delaware General Corporation Law (the "**DGCL**"), at the Effective Time, (a) Merger Sub will merge with and into Company, and (b) the separate corporate existence of Merger Sub will cease and Company will continue its corporate existence under the DGCL as the surviving corporation in the Merger (sometimes referred to herein as the "**Initial Surviving Corporation**"). As a result of the Merger, the Initial Surviving Corporation shall become a wholly-owned Subsidiary of Parent.

(b) Immediately following the consummation of the Merger, upon the terms and subject to the conditions set forth in this Agreement, and in accordance with the DGCL and the Delaware Limited Liability Company Act (the "**DLLCA**"), the Initial Surviving Corporation will be merged with and into Second Merger Sub pursuant to the Second Certificate of Merger (as defined in Section 1.2). Upon consummation of the Second Merger, the separate corporate existence of the Initial Surviving Corporation will cease and Second Merger Sub shall continue as the surviving company (the "**Surviving Company**").

(c) At the Effective Time (as defined below), the effect of the Mergers shall be as provided in this Agreement and the Certificates of Merger (as defined below) and as provided by the applicable provisions of the DGCL and DLLCA. Without limiting the generality of the foregoing, and subject thereto, upon the consummation of the Merger, all the property, rights, privileges and powers of Company and the Merger Sub shall vest in the Initial Surviving Corporation, and all debts, liabilities, obligations, restrictions, disabilities and duties of each of those corporations shall become the debts, liabilities, obligations, restrictions, disabilities and duties of the Initial Surviving Corporation, all as provided under the DGCL, and then upon the consummation of the Second Merger, all the property, rights, privileges and powers of the Initial Surviving Corporation shall vest in the Surviving Company, and all debts, liabilities, obligations, restrictions, disabilities and duties of each of those corporations shall become the debts, liabilities, obligations, restrictions, disabilities and duties of the Surviving Company, all as provided under the DLLCA.

Section 1.2 Closing; Effective Time. The closing of the Merger, the Second Merger and the other transactions contemplated by this Agreement (the "**Closing"**) shall take place through the remote exchange of electronic copies of executed documents (a) on the next Business Day following the satisfaction or waiver of the conditions to the Closing set forth in Article 2 below (other than conditions which are to be satisfied or waived on the Closing Date, which conditions shall be satisfied on the Closing Date), or (b) at such other place or such other date as is mutually agreeable to the parties hereto. The date of the Closing is herein referred to as the "**Closing Date.**" The parties anticipate the Closing Date will be May 5, 2017. At the Closing, Merger Sub and Company shall cause a certificate of merger (the "**First Certificate of Merger"**) to be executed and filed with the Secretary of State of the State of Delaware in accordance with Section 251 of the DGCL. Also at the Closing, the Second Merger Sub and the Initial Surviving Company shall cause a certificate of merger to be executed and filed with the Secretary of State of the State of Delaware in accordance with the DLLCA (the "**Second Certificate of Merger**", and together with the First Certificate of Merger, the "**Certificates of Merger**"). The Mergers shall become effective as of the date and time of such filing or such other time after such filing as the parties shall agree in the Certificates of Merger (the "**Effective Time"**). In the event of a conflict between this Agreement and the Certificates of Merger, to the extent permitted by applicable Law, this Agreement shall govern.

Section 1.3 Certificate of Incorporation; Bylaws; Directors and Officers.

(a) At the Effective Time, the certificate of incorporation of the Initial Surviving Corporation shall be amended so as to read in its entirety as set forth in Exhibit A, until thereafter changed or amended as provided therein or by applicable Law.

(b) At the Effective Time, the bylaws of the Initial Surviving Corporation shall be the bylaws of Company as in effect immediately prior to the Effective Time, until thereafter changed or amended or repealed as provided therein, in the certificate of incorporation of the Initial Surviving Corporation or by applicable Law.

(c) From and after the Effective Time, Josh Disbrow, Michael Malcaluso, Gary Cantrell, Carl Dockery and John Donofrio, Jr. shall be the directors, and Josh Disbrow (CEO), Jarrett Disbrow (COO) and Greg Gould (CFO) shall be the officers, of the Initial Surviving Corporation and Surviving Company until their successors have been duly elected or appointed and qualified or until their earlier death, resignation or removal or otherwise ceasing to be a director or officer or until their respective successors are duly elected or appointed and qualified.

(d) At the Effective Time all Convertible Debt and Unpaid Contractual Obligations shall be converted into the right to receive a portion of the Aggregate Merger Consideration, as set forth in the Distribution Schedule.

(e) At the Effective Time, except as otherwise provided in Section 1.5, each share of Company Preferred Stock outstanding immediately prior to the Effective Time shall be converted, without any action on the part of holders thereof, into the right to receive a portion of the Aggregate Merger Consideration, without interest, calculated and distributed in accordance with the Company Charter, as in effect immediately prior to the Effective Time, and as set forth in the Distribution Schedule.

(f) At the Effective Time, except as otherwise provided in Section 1.5, each share of Company Common Stock outstanding immediately prior to the Effective Time and each option or Warrant to purchase Company Stock shall be cancelled.

(g) At the Effective Time, each share of common stock of Merger Sub outstanding immediately prior to the Effective Time shall be converted into and become one share of common stock of the Initial Surviving Corporation.

(h) From and after the Effective Time, the holders of certificates evidencing ownership of the shares of Company Stock (" **Company Stock Certificates**") outstanding immediately prior to the Effective Time shall cease to have any rights with respect to such shares of Company Stock except as otherwise provided for herein or under applicable Law.

Section 1.4 Surrender and Payment.

(a) Prior to the Effective Time, Parent shall appoint VStock Transfer, LLC (the " **Paying Agent**") to act as paying agent in connection with the consideration to be paid to the Company Securityholders pursuant to a paying agent agreement among Parent, Representative and Paying Agent in the form attached hereto as Exhibit B (the "**Paying Agent Agreement**"). All of Paying Agent's fees and expenses shall be borne by Parent.

(b) As soon as practicable following the date hereof, Company shall, or shall cause the Paying Agent to, send a notice, Letter of Transmittal in the form attached hereto as Exhibit C (the "**Letter of Transmittal**") and acknowledgements of cancellation to each Company Securityholder advising such holder of the Mergers and the procedure for surrendering to the Paying Agent such holder's certificate(s) representing Company Stock or Convertible Debt (collectively, "**Exchange Documentation**") in exchange for the payment of such portion of the Aggregate Merger Consideration to which the Company Securityholders are entitled pursuant to Section 1.3. Each Company Securityholder, upon proper surrender of Exchange Documentation to the Paying Agent in accordance with the instructions in such notice, shall be entitled to receive, in exchange therefor, the payments required by Section 1.3. Until properly surrendered, such Exchange Documentation shall be deemed for all purposes to evidence only the right to receive the payments required by Section 1.3. All Parent Shares will be book entry only.

(c) Company shall deliver to Parent, at least three (3) Business Days prior to the Closing Date, a distribution schedule (the " **Distribution Schedule**"), setting forth Company's calculation of how the Aggregate Merger Consideration shall be allocated among the Company Securityholders and Creditors with Unpaid Contractual Obligations, in addition to an electronic copy thereof in Microsoft Excel format. Parent shall be able to rely on, and shall have no liability to any party to this Agreement or to any Company Securityholder, Company shareholder or Company Creditor for any payment not reflected on the Distribution Schedule. The Distribution Schedule shall include:

(i) the name and address (as listed in the corporate record books of Company);

(ii) the allocation of the Aggregate Merger Consideration among the Creditors and Company Securityholders, determined in accordance with the Company Charter as in effect as of immediately prior to the Effective Time, including the allocation of any cash consideration and any Parent Shares issuable to each Company Securityholder and the allocation of the Closing Merger Consideration payable to each Creditor and Company Securityholder.

(d) At the Closing, Parent shall deposit the Closing Merger Consideration with the Paying Agent. Promptly after the Effective Time, Parent shall cause the Paying Agent to deliver to each Company Securityholder who has completed and returned the requisite Exchange Documentation to the Paying Agent, together with Company Stock Certificates representing outstanding shares of Company Stock or original copies of the Company's Convertible Debt notes (or an affidavit of lost instrument in form reasonably acceptable to Parent but without any bond) and any Company Creditors, the Closing Merger Consideration payable to such Company Securityholder or Creditor, and in any event within three (3) Business Days after return of such documentation to the Paying Agent; provided, however, that Parent shall cause the Paying Agent to deliver the Closing Merger Consideration on the Closing Date to each Company Securityholder who at least three (3) Business Days prior to the Closing has completed and returned the requisite Exchange Documentation to the Paying Agent, together with Company Stock Certificates representing outstanding shares of Company Stock or original copies of the Company's Convertible Debt notes (or an affidavit of lost instrument in form reasonably acceptable to Parent but without any bond) and any Company Creditors.

(e) Parent shall not be required to pay any amount of the Closing Merger Consideration or any portion of any Earnout Payment to any Company Securityholder until receipt by the Paying Agent from such Company Securityholder of properly completed and executed Letters of Transmittal and the applicable Company Stock Certificate or original Convertible Debt note (or an affidavit of lost instrument in form reasonably acceptable to Parent but without any bond (except as may be required by the Paying Agent)).

(f) The Parent Shares pursuant to the terms of this Agreement will be issued in a transaction exempt from registration under the Securities Act by reason of Section 4(a)(2) thereof and/or Regulation D promulgated under the Securities Act and may not be re-offered or resold other than in conformity with the registration requirements of the Securities Act and such other applicable rules and regulations or pursuant to an exemption therefrom. Until the resale by the Company Securityholders or Creditors of their Parent Shares has become registered under the Securities Act, or otherwise transferable pursuant to an exemption from such registration otherwise required thereunder, the Parent Shares issued to the Company Securityholders or Creditors shall be characterized as "restricted securities" under the Securities Act and, if certificated, shall bear the following legend (or if held in book entry form, will be noted with a similar restriction):

"THE SHARES OF STOCK REPRESENTED BY THIS CERTIFICATE HAVE BEEN ACQUIRED FOR INVESTMENT PURPOSES ONLY, AND THE RESALE OF SUCH SHARES HAS NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE RESOLD OR OTHERWISE TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION WITHOUT AN EXEMPTION UNDER THE SECURITIES ACT."

Parent agrees to cooperate in a timely manner with the Company Securityholders or Creditors holding registrable securities to remove any restrictive legends or similar transfer instructions from the registrable Securities upon the registration of the registrable securities or in the event that the registrable securities are otherwise transferable pursuant to an exemption from registration otherwise required thereunder.

(g) At such times and subject to the terms and conditions set forth in Annex 1 hereto, as additional consideration for the Merger, and subject to the setoff rights of Parent Indemnitees pursuant to Article 7 hereof, after the Effective Time, Parent shall deliver the Earnout Payments to Paying Agent to distribute to the Company Securityholders and Creditors in accordance with each the Distribution Allocation. Any such Earnout Payments, including, without limitation, the Accelerated Payment, shall be payable in cash and/or Parent Shares (valued at the average closing price of Parent Shares as reported on OTC Markets (or such national or foreign securities exchange on which Parent's shares are listed) for the ten (10) trading days immediately prior to the date of issuance), pursuant to an allocation of 60% in cash and 40% in Parent Shares, unless otherwise agreed by Parent and the Representative in writing.

(h) Until surrendered in accordance with this Agreement, each Company Stock Certificate or Convertible Debt note shall represent after the Effective Time for all purposes only the right to receive payment as provided in this Agreement.

(i) At any time following the day that is twelve (12) months after the Effective Time, the Parent shall be entitled to require the Paying Agent to deliver to it any funds (including any earnings received with respect thereto) and Parent Shares that had been made available to the Paying Agent with respect to the Closing Merger Consideration and that have not been disbursed to Company Securityholders and thereafter such Company Securityholders shall be entitled to look only to the Parent (subject to abandoned property, escheat or other similar Laws) and only as general creditors thereof with respect to the applicable portion of Closing Merger Consideration payable to them, without interest thereon.

Section 1.5 Treatment of Dissenting Shares. Notwithstanding anything in this Agreement to the contrary, Stockholders who have properly demanded appraisal of their shares of Company Stock ("**Dissenting Shares**") pursuant to, and who comply in all respects with, the provisions of Section 262 of the DGCL shall not have such shares converted as provided herein, but instead such Stockholders shall be entitled to such rights (and only such rights) as are granted under Section 262 of the DGCL. At the Effective Time, all Dissenting Shares shall no longer be outstanding and shall automatically be canceled and extinguished and shall cease to exist, and except as otherwise provided by Law, each holder of Dissenting Shares shall cease to have any rights with respect thereto other than the rights granted pursuant to Section 262 of the DGCL. Notwithstanding the foregoing, if any Stockholder shall fail to validly perfect or shall otherwise waive, withdraw or lose the right to appraisal under Section 262 of the DGCL, or if a court of competent jurisdiction shall determine that such Stockholders are not entitled to the relief provided by Section 262 of the DGCL, then the rights of such Stockholders under Section 262 of the DGCL shall cease and such Dissenting Shares shall be deemed to have been converted at the Effective Time as set forth in Section 1.4(a) or Section 1.4(b), as applicable. Prior to the Closing, Company shall give Parent prompt written notice of any demands for appraisal with respect to Dissenting Shares ("**Appraisal Demands**"), and Parent shall have the opportunity to participate in all negotiations and proceedings with respect to such Appraisal Demands, and any settlements with respect thereto shall not be entered into without the prior written consent of Representative and Parent (such consents not to be unreasonably conditioned, withheld or delayed). From and after the Closing, the Representative shall be entitled to assume the defense of any Appraisal Demands, whether such Appraisal Demands were commenced before or after the Closing; *provided* that Parent shall have the opportunity to participate in all negotiations and proceedings with respect to such Appraisal Demands, and any settlements with respect thereto shall not be entered into without the prior written consent of Parent (such consent not to be unreasonably conditioned, withheld or delayed). After the Closing, Parent shall give the Representative prompt written notice of any Appraisal Demands. Any payments to be made in respect of Dissenting Shares shall be made by Parent and/or the Surviving Company.

Section 1.6 **No Further Ownership Rights in Company Stock** . The consideration paid in accordance with the terms hereof (shall be deemed to have been paid in full satisfaction of all rights pertaining to Company Stock (including any rights to receive accrued but unpaid dividends or any liquidation preference on Company Stock, if any), and, from and after the Effective Time, the Stockholders shall cease to have any rights with respect to the shares of Company Stock (including any rights to receive any accrued but unpaid dividends or any liquidation preference on such shares, if any) except as otherwise expressly provided for in this Agreement. At the Effective Time, the stock transfer books of Company shall be closed, and thereafter there shall be no further registration of transfers on the records of the Surviving Company of shares of Company Stock. If, after the Effective Time, Company Stock Certificates are presented to Parent or the Surviving Company for any reason, they shall be canceled and exchanged as provided and in accordance with this Section 1.6.

Section 1.7 **Lost Certificates**. If any Company Stock Certificate or Convertible Debt note shall have been lost, stolen or destroyed, then upon the making of an affidavit of that fact by the Person claiming such Company Stock Certificate or Convertible Debt note to be lost, stolen or destroyed, and an indemnity, reasonably satisfactory to Parent, the Surviving Company and their Affiliates, against any claim that may be made against any of them with respect to such Company Stock Certificate or Convertible Debt note, but without any bond (except as may be required by the Paying Agent), Parent or the Surviving Company shall pay, or shall cause the Paying Agent to pay, in exchange for such lost, stolen or destroyed Company Stock Certificate or Convertible Debt note, the applicable Distribution Allocation as contemplated by this Article 1.

Section 1.8 **Withholding**. Parent, Merger Sub, the Company, the Surviving Company, the Paying Agent and the Representative (as applicable) shall be entitled to deduct and withhold from the amounts payable under this Agreement such amounts as may be required to be deducted and withheld under the Code, and any other applicable Tax Laws, that are set forth on the Distribution Schedule or that the Parent is entitled to withhold as set forth in the instructions in the Exchange Documentation. Any such withheld amount shall be timely paid over to the appropriate Governmental Authority and treated as though it had been paid to the Person in respect of which such withholding was required.

Section 1.9 **Interest; No Liability**. All payments made pursuant to this Article 1, whether at the Closing or afterwards, shall be without interest. None of Parent, Merger Sub or the Surviving Company shall be liable to any Person in respect of any cash or securities delivered to a public official pursuant to any applicable abandoned property, escheat or similar Law.

Section 1.10 **Adjustments to Prevent Dilution**. Without limiting the other provisions of this Agreement, in the event that Company changes the number of shares of Company Stock issued and outstanding prior to the Effective Time as a result of a reclassification, stock split (including a reverse stock split), stock dividend or distribution, recapitalization, merger, subdivision, issuer tender or exchange offer, or other similar transaction, the consideration paid in accordance with this Agreement shall be equitably adjusted to reflect such change.

Section 1.11 **Tax Treatment**. It is intended by the parties hereto that the Integrated Transaction constitute a reorganization within the meaning of Section 368(a) of the Code. Each of the parties hereto adopts this Agreement as a "plan of reorganization" within the meaning of Sections 1.368-2(g) and 1.368-3(a) of the Treasury Regulations. Both prior to and after the Closing, each party's books and records shall be maintained, and all federal, state and local income Tax Returns and schedules thereto of the parties hereto shall be filed, in a manner consistent with the Integrated Transaction's being qualified as a merger under Section 368(a)(1)(A) of the Code (and comparable provisions of any applicable state or local laws), except to the extent the Integrated Transaction is determined in a final administrative or judicial decision not to qualify as a reorganization within the meaning of Code Section 368(a).

ARTICLE 2.
CONDITIONS TO MERGERS

Section 2.1 **Conditions to All Parties' Obligations**. The obligations of Parent, Merger Subs and Company to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver of the following conditions:

(a) no court or other Governmental Authority shall have issued, enacted, entered, promulgated or enforced any Law or order (whether or not temporary or final and non-appealable, and that has not been vacated, withdrawn or overturned), restraining, enjoining or otherwise prohibiting the Merger;

(b) this Agreement shall not have been terminated in accordance with Article 6;

(c) the Required Stockholder Approval shall have been attained; and

(d) there shall be no Action pending against Parent, Merger Subs or Company or any of their respective Affiliates by any Governmental Authority in which such Governmental Authority is (i) seeking to enjoin or make illegal, delay or otherwise restrain or prohibit the consummation of, or to have rescinded, the Merger; or (ii) seeking to impose any criminal sanctions on Parent, Merger Subs or Company in connection with the Merger.

Section 2.2 Conditions to Parent's and Merger Subs' Obligations. The obligation of Parent and Merger Subs to consummate the transactions contemplated by this Agreement is subject to the satisfaction or waiver of the following conditions as of the Closing Date:

(a) each of the representations and warranties of Company contained in Article 3 that is (i) qualified as, to, or by Material Adverse Effect shall be true and correct in all respects as of the Closing Date as if made anew as of such date (except to the extent any such representation and warranty expressly relates to an earlier date (in which case as of such earlier date)) and (ii) not qualified as to or by Material Adverse Effect shall be true and correct as of the Closing Date as if made anew as of such date (except to the extent any such representation and warranty expressly relates to an earlier date (in which case as of such earlier date)), except where any failure of any such representation and warranty referred to in this clause (ii) to be true and correct has not had or will not have a Material Adverse Effect;

(b) Company shall have performed in all material respects all of the covenants and agreements under this Agreement that are required to be performed by it at or prior to the Closing;

(c) from the date of this Agreement, there shall not have occurred any Material Adverse Effect with respect to the Company;

(d) holders of no more than five percent (5.0%) of the aggregate outstanding Company Common Stock and Company Preferred Stock (calculated on an as-converted to Company Common Stock basis) as of the Effective Time will have elected to exercise (and will not have withdrawn or otherwise lost their ability to seek) dissenters', appraisal or similar rights under Delaware law with respect to such shares;

(e) Company will have delivered to Parent each of the following:

(i) a certificate of Company executed by a duly authorized officer thereof, dated as of the Closing Date, stating that the preconditions specified in subsections (a) and (b) above as they relate to Company have been satisfied;

(ii) evidence of Cash on Hand;

(iii) a copy of the Paying Agent Agreement duly executed by the Representative;

(iv) a certificate conforming to the requirements of Treasury Regulations Section 1.1445-2(c)(3);

(v) certified copies of the resolutions duly adopted by the Company Board authorizing the execution, delivery and performance of this Agreement, the Mergers and the other transactions contemplated hereby;

(vi) (A) a certified copy of the Company Charter and (B) a certificate of good standing from the Secretary of State of the State of Delaware dated within five (5) Business Days of the Closing Date;

(vii) the resignations, effective as of the Closing, from all Company directors, officers, employees and contractors;

(viii) an electronic copy of the true, correct and complete contents of the Dataroom, which shall be delivered promptly after the Closing; and

(ix) duly executed copies of consulting agreements with the following individuals in a form satisfactory to Parent: Karen Long, Leah Millheiser, Earl Bright, Traci Chu and Mary Beth Kreissler.

Section 2.3 Conditions to Company's Obligations. The obligations of Company to consummate the transactions contemplated by this Agreement are subject to the satisfaction or waiver of the following conditions as of the Closing Date:

(a) each of the representations and warranties of Parent contained in Article 4 that is (i) qualified as, to, or by Material Adverse Effect shall be true and correct in all respects as of the Closing Date as if made anew as of such date (except to the extent any such representation and warranty expressly relates to an earlier date (in which case as of such earlier date)) and (ii) not qualified as to or by Material Adverse Effect shall be true and correct as of the Closing Date as if made anew as of such date (except to the extent any such representation and warranty expressly relates to an earlier date (in which case as of such earlier date)), except where any failure of any such representation and warranty referred to in this clause (ii) to be true and correct has not had or will not have a Material Adverse Effect on Parent's or Merger Sub's ability to perform the transactions contemplated hereby;

(b) each of Parent and Merger Subs shall have performed in all material respects all of its respective covenants and agreements under this Agreement that are required to be performed by it at or prior to the Closing;

(c) from the date of this Agreement, there shall not have occurred any Material Adverse Effect with respect to Parent;

(d) Parent shall have delivered to Company each of the following:

(i) a certificate of Parent executed by a duly authorized officer thereof, dated as of the Closing Date, stating that the preconditions specified in subsections (a) and (b) hereof have been satisfied;

(ii) a copy of the Paying Agent Agreement duly executed by Parent and the Paying Agent;

(iii) certified copies of the resolutions duly adopted by Parent's and Merger Sub's Board of Directors and Parent, in its capacity as sole Stockholder of Merger Sub and the sole member of Second Merger Sub authorizing the execution, delivery and performance of this Agreement, the Mergers and the other transactions contemplated hereby; and

(iv) (A) a certified copy of the certificate of incorporation and bylaws of Parent and Merger Subs and (B) a certificate of good standing or equivalent certificate from the jurisdictions in which Parent and Merger Subs are incorporated, in each case, dated within five (5) Business Days of the Closing Date.

Section 2.4 **Waiver of Conditions**. All conditions to the Closing will be deemed to have been satisfied or waived from and after the Closing.

ARTICLE 3.
REPRESENTATIONS AND WARRANTIES OF COMPANY

Except as set forth in the correspondingly numbered Section of the Company Disclosure Schedules, Company represents and warrants to Parent and Merger Sub that the statements contained in this Article 3 are true and correct as of the date hereof. Any information, qualifications or disclosure in one section of the Company Disclosure Schedule shall be deemed to have been disclosed in all other sections of the Company Disclosure Schedule to the extent the relevance of such information, qualification or disclosure is readily apparent from the text of such disclosure and the corresponding Section of this Article 3, notwithstanding the omission of an appropriate cross-reference to such other section.

Section 3.1 **Organization and Qualification of Company**. Company is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware and has full corporate power and authority to own, operate or lease the properties and assets now owned, operated or leased by it and to carry on its business as it has been and is currently conducted. Section 3.1 of the Company Disclosure Schedules sets forth each jurisdiction in which Company is licensed or qualified to do business, and Company is duly licensed or qualified to do business and is in good standing in each jurisdiction in which the properties owned or leased by it or the operation of its business as currently conducted makes such licensing or qualification necessary, except where the failure to be so licensed, qualified or in good standing would not have a Material Adverse Effect.

Section 3.2 **Authorization.**

(a) Company has full corporate power and authority to enter into this Agreement, to carry out its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery by Company of this Agreement, the performance by Company of its obligations hereunder and the consummation by Company of the transactions contemplated hereby have been duly authorized by all requisite corporate action on the part of Company. This Agreement has been duly executed and delivered by Company, and this Agreement constitutes, legal, valid and binding obligations of Company enforceable against Company in accordance with their terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights, and (ii) general principles of equity that restrict the availability of equitable remedies.

(b) The Company Board, at a meeting duly called and held at which all directors of Company were present, duly and unanimously adopted resolutions (i) determining that the terms of this Agreement, the Mergers and the other transactions contemplated hereby are fair to and in the best interests of the Stockholders, (ii) approving and declaring advisable this Agreement and the transactions contemplated hereby, including the Mergers, (iii) directing that this Agreement be submitted to the Stockholders for adoption and approval and (iv) resolving to recommend that the Stockholders vote in favor of the adoption and approval of this Agreement and the transactions contemplated hereby, including the Mergers, which resolutions have not been subsequently rescinded, modified or withdrawn in any way.

(c) The Required Stockholder Approval is the only approval of the holders of any class or series of Company's capital stock or other securities required in connection with the consummation of the Merger.

Section 3.3 Capitalization.

(a) The authorized capital stock of Company consists of 65,000,000 shares of Company Common Stock, 29,313,755 shares of Series A Preferred Stock, and 14,686,245 shares of Series A-1 Preferred Stock. The respective rights, restrictions, privileges and preferences of Company Preferred Stock are as stated in the Company Charter. Each share of Company Preferred Stock is presently convertible into Company Common Stock on the basis set forth in the Company Charter and the consummation of the transactions contemplated hereby will not result in any anti-dilution adjustment or other similar adjustment to the outstanding shares of Company Preferred Stock.

(b) The Distribution Schedule sets forth a true and complete list of all Company Securityholders and the portion of the Aggregate Merger Consideration each is to receive. The Company represents and warrants that all Company Securityholders are "accredited investors" as such term is defined in Rule 501(a) under the Securities Act.

(c) All of the outstanding shares of Company Stock have been duly authorized and validly issued and are fully paid, non-assessable and, except as set forth on Section 3.3(c) of the Company Disclosure Schedules, free of preemptive or similar rights. All of the issued and outstanding shares of Company Stock were issued in compliance with all applicable state and federal Laws concerning the issuance of securities. Except as set forth on the Distribution Schedule, Company does not have any other equity securities or securities containing any equity features authorized, issued or outstanding, and there are no agreements, options, warrants or other rights or arrangements existing or outstanding which provide for the sale or issuance of any of the foregoing by Company.

Section 3.4 Subsidiaries. Section 3.4 of the Company Disclosure Schedules lists each of the Subsidiaries of Company as of the date hereof and its place of organization and sets forth, for each Subsidiary that is not, directly or indirectly, wholly-owned by Company, (x) the number and type of any capital stock of, or other equity or voting interests in, such Subsidiary that is outstanding as of the date hereof and (y) the number and type of shares of capital stock of, or other equity or voting interests in, such Subsidiary that, as of the date hereof, are owned, directly or indirectly, by Company. All of the outstanding shares of capital stock of, or other equity or voting interests in, each Subsidiary of Company that is owned directly or indirectly by Company have been validly issued, were issued free of pre-emptive rights and are fully paid and non-assessable, and are free and clear of all Encumbrances, including any restriction on the right to vote, sell or otherwise dispose of such capital stock or other equity or voting interests, except for any Encumbrances (x) imposed by applicable securities Laws or (y) arising pursuant to the certificate of incorporation, by-laws or similar organizational documents of any non-wholly-owned Subsidiary of Company. Except for the capital stock of, or other equity or voting interests in, its Subsidiaries, Company does not own, directly or indirectly, any capital stock of, or other equity or voting interests in, any Person.

Section 3.5 **No Conflicts; Consents**. The execution, delivery and performance by Company of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (a) conflict with or result in a violation or breach of, or default under, any provision of the Company Charter or the by-laws or other organizational documents of Company; (b) conflict with or result in a violation or breach in any material respect of any provision of any Law or Governmental Order applicable to Company; (c) except as set forth in Section 3.5 of the Company Disclosure Schedules, require the consent, notice or other action by any Person under, or to the Knowledge of Company, (i) conflict with, result in a violation or breach of, constitute a default or an event that, with or without notice or lapse of time or both, would constitute a default under, or (ii) result in the acceleration of or create in any party the right to accelerate, terminate, modify or cancel any Material Contract or any material Permit affecting the properties, assets or business of Company; or (d) result in the creation or imposition of any Encumbrance, other than Permitted Encumbrances, on any material properties or assets of Company. No consent, approval, Permit, Governmental Order, declaration or filing with, or notice to, any Governmental Authority is required by or with respect to Company in connection with the execution and delivery of this Agreement and the consummation of the transactions contemplated hereby.

Section 3.6 **Financial Statements**. Complete copies of Company's Financial Statements consisting of the unaudited balance sheet of Company as at December 31 in each of the years 2014, 2015 and 2016 and the related unaudited statements of income and retained earnings, stockholders' equity and cash flow for the years then ended (the "**Year-End Financial Statements**"), and statements consisting of the unaudited balance sheet of Company as at March 31, 2017 and the unaudited related statements of income and retained earnings, stockholders' equity and cash flow for the calendar period then ended (the "**Interim Financial Statements**" and together with the Year-End Financial Statements, the " **Financial Statements**") have been delivered to Parent. Except as disclosed on Section 3.6 of the Company Disclosure Schedules, the Financial Statements have been prepared in accordance with GAAP applied on a consistent basis throughout the period involved, subject to normal and recurring year-end adjustments (the effect of which will not be materially adverse) and the absence of notes. The Financial Statements are based on the books and records of Company, and fairly present in all material respects the financial condition of Company as of the respective dates they were prepared and the results of the operations of Company for the periods indicated, subject to normal and recurring year-end adjustments and the absence of notes. The balance sheet of Company as of December 31, 2016 is referred to herein as the "**Balance Sheet**" and the date thereof as the "**Balance Sheet Date**" and the balance sheet of Company as of March 31, 2017 is referred to herein as the " **Interim Balance Sheet**" and the date thereof as the "**Interim Balance Sheet Date**". Except as set forth on Section 3.6 of the Company Disclosure Schedules, Company maintains a standard system of accounting established and administered in accordance with GAAP.

Section 3.7 Undisclosed Liabilities; Cash on Hand. Company has no Liabilities that would be required to be disclosed, set forth or reserved against on a balance sheet of Company prepared in accordance with GAAP except (a) those which are adequately reflected or reserved against in the Interim Balance Sheet as of the Interim Balance Sheet Date, (b) Liabilities incurred in connection with the transactions contemplated hereby and that are included in the Securityholder Transaction Expenses, (c) those which have been incurred in the ordinary course of business consistent with past practice since the Interim Balance Sheet Date and (d) Liabilities set forth on Section 3.7 of the Company Disclosure Schedules. Company has not incurred additional liabilities in excess of $10,000 since the date of the Interim Balance Sheet. Company represents and warrants that Cash on Hand equals or exceeds $600,000 and aggregate liabilities of the Company do not exceed $100,000.

Section 3.8 Absence of Certain Changes, Events and Conditions. Except as set forth on Section 3.8 of the Company Disclosure Schedules or in accordance with Section 5.1(b) hereof, since the Interim Balance Sheet Date, and other than in the ordinary course of business consistent with past practice, there has not been, with respect to Company, any:

(a) event, occurrence or development that has had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect with respect to Company;

(b) an amendment of the Company Charter or the by-laws or other organizational documents of Company;

(c) split, combination or reclassification of any shares of its capital stock;

(d) issuance, sale or other disposition of any of its capital stock, or grant of any options, warrants or other rights to purchase or obtain (including upon conversion, exchange or exercise) any of its capital stock;

(e) declaration or payment of any dividends or distributions on or in respect of any of its capital stock or redemption, purchase or acquisition of its capital stock;

(f) material change in any method of accounting or accounting practice of Company except as required by GAAP or as disclosed in the notes to the Financial Statements;

(g) material change in Company's cash management practices and its policies, practices and procedures with respect to collection of accounts receivable, establishment of reserves for uncollectible accounts, accrual of accounts receivable, inventory control, prepayment of expenses, payment of trade accounts payable, accrual of other expenses, deferral of revenue and acceptance of customer deposits;

(h) entry into any Contract that would constitute a Material Contract;

(i) incurrence, assumption or guarantee of any indebtedness for borrowed money except unsecured current obligations and Liabilities incurred in the ordinary course of business consistent with past practice;

(j) transfer, assignment, sale or other disposition of any of the assets shown or reflected in the Balance Sheet or cancellation of any debts or entitlements other than in each case in the ordinary course of business consistent with past practice;

(k) transfer, assignment or grant of any license or sublicense of any material rights under or with respect to any Intellectual Property other than, in each case, in connection with a sale of Products in the ordinary course of business consistent with past practice;

(l) damage, destruction or loss (whether or not covered by insurance) to its property having a replacement cost in excess of Five Thousand Dollars ($5,000);

(m) any capital investment in, or any loan to, any other Person;

(n) acceleration, termination, material modification to or cancellation of any Material Contract to which Company is a party or by which it is bound;

(o) any capital expenditures in excess of Five Thousand Dollars ($5,000) individually or Fifteen Thousand Dollars ($15,000) in the aggregate;

(p) imposition of any material Encumbrance upon any of Company properties, capital stock or assets, tangible or intangible other than Permitted Encumbrances;

(q) (i) grant of any bonuses, whether monetary or otherwise, or increase in any wages, salary, severance, pension or other compensation or benefits in respect of its employees, officers, directors, independent contractors or consultants, other than as provided for in any written agreements or required by applicable Law, (ii) change in the terms of employment for any employee, or any termination of any employees, or (iii) action to accelerate the vesting or payment of any compensation or benefit for any employee, officer, director, independent contractor or consultant;

(r) adoption, modification or termination of any: (i) employment, severance, retention or other agreement with any current or former employee, officer, director, independent contractor or consultant, (ii) material Benefit Plan or (iii) collective bargaining or other agreement with a Union, in each case whether written or oral;

(s) any loan to (or forgiveness of any loan to) any of its stockholders, directors, officers and employees other than the advancement of expenses in the ordinary course of business consistent with past practice;

(t) entry into a new line of business or abandonment or discontinuance of existing lines of business;

(u) adoption of any plan of merger, consolidation, reorganization, liquidation or dissolution or filing of a petition in bankruptcy under any provisions of federal or state bankruptcy Law or consent to the filing of any bankruptcy petition against it under any similar Law;

(v) acquisition by merger or consolidation with, or by purchase of a substantial portion of the assets or stock of, or by any other manner, any business or any Person or any division thereof;

(w) except for Tax filings and positions in accordance with the Company's prior custom and practice and properly disclosed to Parent, action by Company to make, change or rescind any Tax election, amend any Tax Return, adopt or change any accounting method in respect of Taxes, enter into any closing agreement with respect to Taxes, settle any material claim or assessment in respect of Taxes, or consent to any extension or waiver of the limitation period applicable to any material claim with respect to the collection or assessment of Taxes; or

(x) any Contract to do any of the foregoing, or any action or omission that would result in any of the foregoing.

Section 3.9 Material Contracts.

(a) Section 3.9(a) of the Company Disclosure Schedules lists each of the following Contracts of Company and all Contracts relating to Intellectual Property set forth in Section 3.12(d) and Section 3.12(f) of the Company Disclosure Schedules, but excluding Excluded Contracts, collectively "**Material Contracts**"):

(i) each Contract of Company involving aggregate consideration in excess of $5,000 and which, in each case, cannot be cancelled by Company without penalty or without more than thirty (30) days' notice;

(ii) all Contracts that require Company to purchase its total requirements of any product or service from a third party or that contain "take or pay" provisions;

(iii) all Contracts that provide for the indemnification by Company of any Person or the assumption of any Tax, environmental or other Liability of any Person other than Contracts entered into in the ordinary course of business, the principal purpose of which is not the assumption of Taxes or environmental or other Liabilities of any Person;

(iv) all Contracts that relate to the acquisition or disposition of any business, a material amount of stock or assets of any other Person or any real property (whether by merger, sale of stock, sale of assets or otherwise);

(v) all broker, distributor, dealer, manufacturer's representative, franchise, agency, sales promotion, market research, marketing consulting and advertising Contracts to which Company is a party involving payments by Company in excess of $10,000;

(vi) all employment agreements, and Contracts with independent contractors or consultants (or similar arrangements) to which Company is a party, and which, in each case, are not cancellable without material penalty or without more than ninety (90) days' notice;

(vii) except for Contracts relating to trade receivables, all Contracts relating to Indebtedness for borrowed money (including, without limitation, guarantees of such Indebtedness) of Company;

(viii) all Contracts with any Governmental Authority to which Company is a party;

(ix) all Contracts that limit or purport to limit the ability of Company to compete in any line of business or with any Person or in any geographic area or during any period of time;

(x) all Contracts with "most favored nation" or "most favored customer" provisions;

(xi) all Contracts with rebate, "pay for performance" or "pay for results" provisions;

(xii) any Contracts to which Company is a party that provide for any joint venture, partnership or similar arrangement by Company;

(xiii) all Contracts between or among Company on the one hand and Company or any Affiliate of Company (other than Company) on the other hand;

(xiv) all collective bargaining agreements or Contracts with any Union to which Company is a party; and

(xv) any other Contract that is material to Company and not previously disclosed pursuant to this Section 3.9.

(b) Each Material Contract is valid and binding on Company in accordance with its terms and is in full force and effect. Neither Company nor, to Company's Knowledge, any other party thereto is in breach of or default under (or is alleged in writing to be in breach of or default under), in each case in any material respects, or has provided or received any notice of any intention to terminate, any Material Contract. To Company's Knowledge, no event or circumstance has occurred that, with notice or lapse of time or both, would constitute an event of default under any Material Contract or result in a termination thereof or would cause or permit the acceleration or other changes of any right or obligation or the loss of any material benefit thereunder. Complete and correct copies of each Material Contract (including all modifications, amendments and supplements thereto and waivers thereunder) have been made available to Parent.

Section 3.10 Title to Tangible Assets; Real Property. Company has good and valid title to all personal property and other tangible assets reflected in the Financial Statements or acquired after the Interim Balance Sheet Date, other than properties and assets sold or otherwise disposed of in the ordinary course of business consistent with past practice since the Interim Balance Sheet Date or as set forth in Section 3.8 of the Company Disclosure Schedules. Company represents and warrants that at Closing, no Contracts involving the leasing of any Real Property or personal property will be outstanding. All such properties and assets are free and clear of Encumbrances except for the following, all of which are listed on Section 3.10 of the Company Disclosure Schedules (collectively referred to as "**Permitted Encumbrances**"):

(i) liens for Taxes not yet due and payable or being contested in good faith by appropriate procedures and, with respect to any such Taxes, for which there are adequate accruals or reserves on the Balance Sheet;

(ii) mechanics, carriers', workmen's, repairmen's or other like liens arising or incurred in the ordinary course of business consistent with past practice or amounts that are not delinquent and which are not, individually or in the aggregate, material to the business of Company;

(iii) easements, rights of way, zoning ordinances and other similar encumbrances affecting Real Property which are not, individually or in the aggregate, material to the business of Company;

(iv) other than with respect to owned Real Property, liens arising under original purchase price conditional sales contracts and equipment leases with third parties entered into in the ordinary course of business consistent with past practice;

(v) liens in favor of customs and revenue authorities arising as a matter of Law to secure payments of customs duties in connection with the importation of goods;

(vi) any Encumbrances against the interest of the landlord or sublandlord of any leased Real Property that are not caused by Company and do not adversely affect Company's leasehold interest in, or Company's use of, such leased Real Property or otherwise impair Company's business operations at or relating to such leased Real Property;

(vii) such imperfections of title and non-monetary Encumbrances as do not and will not materially detract from or interfere with the use of the properties subject thereto or affected thereby, or otherwise materially impair business operations involving such properties;

(viii) pledges or deposits to secure obligations under workers' compensation Laws or similar legislation; or

(ix) non-exclusive licenses of Intellectual Property granted in the ordinary course of business.

Section 3.11 Condition and Sufficiency of Assets. The furniture, fixtures, machinery, equipment, vehicles and other items of tangible personal property of Company are structurally sound, are in good operating condition and repair in all material respects, and are materially adequate for the uses to which they are being put, and none of such furniture, fixtures, machinery, equipment, vehicles and other items of tangible personal property is in need of maintenance or repairs except for ordinary, routine maintenance and repairs that are not material in nature or cost. To Company's Knowledge, the furniture, fixtures, machinery, equipment, vehicles, and other items of tangible personal property currently owned or leased by Company, together with all other properties and assets of Company, are sufficient for the continued conduct of Company's business after the Closing in substantially the same manner as conducted prior to the Closing and constitute all of the rights, property and assets necessary in all material respects to conduct the business of the Company as currently conducted.

Section 3.12 Intellectual Property.

(a) "**Intellectual Property**" means all of the following and similar intangible property and related proprietary rights, interests and protections, however arising, pursuant to the Laws of any jurisdiction throughout the world, including such property that is owned by Company ("**Company Intellectual Property**") and that in which Company holds exclusive or non-exclusive rights or interests granted by license from other Persons (" **Licensed Intellectual Property**"):

(i) trademarks, service marks, trade names, brand names, logos, trade dress and other proprietary indicia of goods and services, whether registered or unregistered ("**Trademarks**"), and all registrations and applications for registration of such trademarks, including intent-to-use applications, all issuances, extensions and renewals of such registrations and applications and the goodwill connected with the use of and symbolized by any of the foregoing;

(ii) internet domain names, whether or not trademarks, registered in any top-level domain by any authorized private registrar or Governmental Authority;

(iii) original works of authorship in any medium of expression, whether or not published, all copyrights (whether registered or unregistered), all registrations and applications for registration of such copyrights, and all issuances, extensions and renewals of such registrations and applications;

(iv) confidential information, formulas, designs, devices, technology, know-how, research and development, inventions, methods, processes, compositions and other trade secrets, whether or not patentable; and

(v) patented and patentable designs and inventions, all design, plant and utility patents and applications, letters patent, utility models, inventor's certificates, and provisional applications and all issuances, divisions, continuations, continuations-in-part, reissues, extensions, reexaminations and renewals of such patents and applications, including the right to claim priority to such patents and applications, and the right to file such patents and applications under the Patent Laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or the domestic laws of the country in which any such application is filed.

(b) Section 3.12(b) of the Company Disclosure Schedules lists all Company Intellectual Property that is either (i) subject to any issuance, registration, application or other filing by, to or with any Governmental Authority or authorized private registrar in any jurisdiction (collectively, "**Intellectual Property Registrations**"), including registered trademarks, domain names and copyrights, issued and reissued patents and pending applications for any of the foregoing; or (ii) solely with respect to Trademarks, material to the conduct of the Company's current business or operations. All required filings and fees related to the Intellectual Property Registrations have been timely filed with and paid to the relevant Governmental Authorities and authorized registrars, and all Intellectual Property Registrations are in good standing, except in each case for any Intellectual Property Registrations that were abandoned or permitted to lapse in the ordinary course of business. Company has provided Parent with true and complete copies of file histories, documents, certificates, office actions, correspondence and other material documents related to all Intellectual Property Registrations.

(c) Except as set forth in Section 3.12(c) of the Company Disclosure Schedules, Company owns, exclusively or jointly with other Persons, all right, title and interest in and to Company Intellectual Property material to the conduct of its business or operations as currently conducted, free and clear of Encumbrances other than Permitted Encumbrances. Without limiting the generality of the foregoing, Company has entered into binding, written agreements, substantially in the form(s) provided to Parent, with every current and former employee of Company, and with every current and former independent contractor contributing to the conception or reduction to practice of Company Intellectual Property, whereby such employees and independent contractors (i) assign to Company any ownership interest and right they may have in Company Intellectual Property; and (ii) acknowledge Company's exclusive ownership of all Company Intellectual Property. To Company's Knowledge, Company is in compliance with all legal requirements applicable to Company Intellectual Property and Company's ownership and use thereof except in any such case where such failure to be in compliance would not reasonably be expected to have a Material Adverse Effect with respect to Company.

(d) Section 3.12(d) of the Company Disclosure Schedules lists all licenses, sublicenses and other agreements, excluding non-exclusive licenses to unmodified commercially available software agreements and other agreements entered into in the ordinary course of business, including without limitation Excluded Contracts, whereby Company is granted rights, interests and authority, whether on an exclusive or non-exclusive basis, with respect to any Licensed Intellectual Property that is used in or, in Company's reasonable judgment, necessary for Company's current business or operations. Company has provided Parent with true and complete copies of all such agreements. All such agreements are valid, binding and enforceable between Company and the other parties thereto, and Company and, to Company's Knowledge, such other parties are in compliance with the material terms and conditions of such agreements.

(e) To Company's Knowledge, the making, using, offering for sale, or selling of any process, machine, article of manufacture, or composition of matter, including the Products, in each case that is protected by the Company Intellectual Property and the Licensed Intellectual Property owned, exclusively licensed or used by Company, to the extent such actions are performed by or on behalf of Company in its conduct of its business as currently conducted, does not infringe, violate or misappropriate the Intellectual Property of any Person other than Company. Except as set forth in Section 3.12(e) of the Company Disclosure Schedules, Company has not received any written communication, and no Action has been settled or, to Company's Knowledge, been instituted or threatened that alleges any such infringement, violation or misappropriation, and none of Company Intellectual Property are subject to any outstanding Governmental Order.

(f) Section 3.12(f) of the Company Disclosure Schedules lists all licenses, sublicenses and other agreements pursuant to which Company grants rights or authority to any Person with respect to any Company Intellectual Property or Licensed Intellectual Property, other than such licenses, sublicenses or agreements entered into in the ordinary course of business, including without limitation Excluded Contracts. Company has provided Parent with true and complete copies of all such agreements. All such agreements are valid, binding and enforceable between Company and the other parties thereto, and Company and, to Company's Knowledge, such other parties are in compliance with the material terms and conditions of such agreements. Except as set forth in Section 3.12(f) of the Company Disclosure Schedules, to Company's Knowledge, no Person has infringed, violated or misappropriated, or is infringing, violating or misappropriating, any Company Intellectual Property.

Section 3.13 Inventory. To Company's Knowledge, inventory of Company reflected in the Interim Balance Sheet consists of a quality and quantity usable and/or salable in the ordinary course of business consistent with past practice, except for obsolete, damaged, defective or slow-moving items that have been or will be, as applicable, written off or written down to fair market value or for which adequate reserves have been established in accordance with GAAP applied on a basis consistent with Company's past practices used in preparing the Financial Statements. Except as set forth in Section 3.13 of the Company Disclosure Schedule, all such inventory is owned by Company free and clear of all Encumbrances, other than Permitted Encumbrances, and no inventory is held on a consignment basis.

Section 3.14 Accounts Receivable. The accounts receivable reflected on the Interim Balance Sheet and the accounts receivable arising after the date thereof (a) have arisen from bona fide transactions entered into by Company involving the sale of goods or the rendering of services in the ordinary course of business consistent with past practice; (b) constitute only valid, undisputed claims of Company not subject to claims of set-off or other defenses or counterclaims other than normal cash discounts accrued in the ordinary course of business consistent with past practice; and (c) subject to a reserve for bad debts shown on the Interim Balance Sheet or, with respect to accounts receivable arising after the Interim Balance Sheet Date, on the accounting records of the Company, are collectible in full, less Ten Thousand Dollars ($10,000), within one hundred eighty (180) days after billing. The reserve for bad debts and provisions for cash discounts and returns shown on the Interim Balance Sheet or, with respect to accounts receivable arising after the Interim Balance Sheet Date, on the accounting records of Company have been determined in accordance with GAAP, consistently applied, subject to normal year-end adjustments and the absence of disclosures normally made in footnotes.

Section 3.15 Customers and Suppliers.

(a) Section 3.15(a) of the Company Disclosure Schedules sets forth (i) each customer who has paid aggregate consideration to Company for goods or services rendered in an amount greater than or equal to $10,000 for each of the two most recent fiscal years (collectively, the "**Material Customers**"); and (ii) the amount of consideration paid by each Material Customer during such periods. Company has not received any notice, and has no reason to believe, that any of its Material Customers has ceased, or intends to cease after the Closing, to use its goods or services or to otherwise terminate or materially reduce its relationship with Company.

(b) Section 3.15(b) of the Company Disclosure Schedules sets forth (i) each supplier to whom Company has paid consideration for goods or services rendered in an amount greater than or equal to $10,000 for each of the two most recent fiscal years (collectively, the "**Material Suppliers**"); and (ii) the amount of purchases from each Material Supplier during such periods. The Company has not received any notice, and has no reason to believe, that any of its Material Suppliers has ceased, or intends to cease, to supply goods or services to Company or to otherwise terminate or materially reduce its relationship with Company.

Section 3.16 Insurance. Section 3.16 of the Company Disclosure Schedules sets forth a true and complete list, as of the Agreement Date, of all current policies or binders of fire, liability, product liability, umbrella liability, real and personal property, workers' compensation, vehicular, directors and officers' liability, representations and warranties, fiduciary liability and other casualty and property insurance maintained by Company or its Affiliates and relating to the assets, business, operations, employees, officers and directors of Company (collectively, the "**Insurance Policies**") and true and complete copies of such Insurance Policies have been made available to Parent. Such Insurance Policies are in full force and effect. Neither Company nor any of its Affiliates has received within the past year any written notice of cancellation of, premium increase with respect to, or alteration of coverage under, any of such Insurance Policies. All premiums due on such Insurance Policies have either been paid or, if due and payable prior to Closing, will be paid prior to Closing in accordance with the payment terms of each Insurance Policy unless otherwise agreed with Parent. All such Insurance Policies have not been subject to any lapse in coverage. Except as set forth on Section 3.16 of the Company Disclosure Schedules, there are no claims related to the business of Company pending under any such Insurance Policies as to which coverage has been questioned, denied or disputed or in respect of which there is an outstanding reservation of rights. None of Company or any of its Affiliates is in default under, or has otherwise failed to comply with, in any material respect, any provision contained in any such Insurance Policy. The Insurance Policies are sufficient for compliance with all applicable Laws and Material Contracts to which Company is a party or by which it is bound.

Section 3.17 Legal Proceedings; Governmental Orders.

(a) Except as set forth in Section 3.17(a) of the Company Disclosure Schedules, there are no Actions pending or, to Company's Knowledge, threatened (a) against or by Company affecting any of its properties or assets (or by or against Company or any Affiliate thereof and relating to Company); or (b) against or by Company, or any Affiliate of Company that challenges or seeks to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement. To Company's Knowledge, no event has occurred or circumstances exist that may give rise to or serve as a basis for any such Action.

(b) Except as set forth in Section 3.17(b) of the Company Disclosure Schedules, there are no outstanding Governmental Orders and no unsatisfied judgments, penalties or awards against or directly affecting Company or any of its properties or assets. Company is in compliance with the terms of each Governmental Order set forth in Section 3.17(b) of the Company Disclosure Schedules. To Company's Knowledge, no event has occurred or circumstances exist that may give rise to or serve as a basis for any such Governmental Order.

Section 3.18 Compliance With Laws; Permits.

(a) Except as set forth in Section 3.18(a) of the Company Disclosure Schedules, Company has complied for the past three (3) years, and is now complying, in all material respects with all Laws applicable to it or its business, properties or assets.

(b) All material Permits required for Company to conduct its business have been obtained by it and are valid and in full force and effect. All fees and charges with respect to such Permits as of the date hereof have been paid in full.

Section 3.19 Environmental Matters.

(a) Company is currently, and has been, in material compliance with all Environmental Laws and has not, and Company has not, received from any Person any: (i) Environmental Notice or Environmental Claim; or (ii) written request for information pursuant to Environmental Law, which, in each case, either remains pending or unresolved, or is the source of ongoing obligations or requirements as of the Closing Date.

(b) Company has obtained and is in material compliance with all Environmental Permits (each of which is disclosed in Section 3.19(b) of the Company Disclosure Schedules) necessary for the operation of its business and all such Environmental Permits are in full force and effect and shall be maintained in full force and effect by Company through the Closing Date in accordance with Environmental Law. With respect to any such Environmental Permits, Company will use commercially reasonable efforts to facilitate the transferability of the same, and Company has not received any Environmental Notice or written communication regarding any material adverse change in the status or terms and conditions of any such Environmental Permit.

(c) To the Knowledge of Company, no real property currently or formerly owned, operated or leased by Company is listed on, or has been proposed for listing on, the National Priorities List (or CERCLIS) under CERCLA, or any similar state list.

(d) To the Knowledge of Company, there has been no Release of Hazardous Materials in contravention of Environmental Law with respect to the business or assets of Company or any real property currently or formerly owned, operated or leased by Company. Company has not received an Environmental Notice that any real property currently or formerly owned, operated or leased in connection with the business of Company (including soils, groundwater, surface water, buildings and other structure located on any such real property) has been contaminated with any Hazardous Material which would reasonably be expected to result in an Environmental Claim against, or a violation of Environmental Law or term of any Environmental Permit by, Company.

(e) Section 3.19(e) of the Company Disclosure Schedules contains a complete and accurate list of all aboveground or active underground storage tanks owned or operated by Company. To the Knowledge of Company, there are no abandoned underground tanks on its leased Real Property.

(f) Section 3.19(f) of the Company Disclosure Schedules contains a complete and accurate list of all off-site Hazardous Materials treatment, storage, or disposal facilities or locations used by Company and any predecessors as to which Company may retain liability, and, to the Knowledge of Company, none of these facilities or locations has been placed or proposed for placement on the National Priorities List (or CERCLIS) under CERCLA, or any similar state list. Company has not received any Environmental Notice regarding potential liabilities with respect to such off-site Hazardous Materials treatment, storage, or disposal facilities or locations used by Company.

(g) Company has provided or otherwise made available to Parent and listed in Section 3.19(g) of the Company Disclosure Schedules: (i) any and all environmental reports, studies, audits, records, sampling data, site assessments, risk assessments, economic models and other similar documents with respect to the business or assets of Company or any currently or formerly owned, operated or leased real property which are in the possession or control of Company related to compliance with Environmental Laws, Environmental Claims or an Environmental Notice or the Release of Hazardous Materials; and (ii) any and all material documents concerning planned or anticipated capital expenditures required to reduce, offset, limit or otherwise control pollution and/or emissions, manage waste or otherwise ensure compliance with current or future Environmental Laws (including, without limitation, costs of remediation, pollution control equipment and operational changes).

(h) Notwithstanding anything in this Agreement to the contrary, the representations and warranties in Sections 3.19(a) through 3.19(g) above contain Company's sole representations and warranties with respect to the compliance of Company or its business, properties or assets with Environmental Laws or Permits, the presence of or liability for Hazardous Materials, or the existence of Environmental Claims.

Section 3.20 Employee Benefit Matters.

(a) Section 3.20(a) of the Company Disclosure Schedules contains a true and complete list of each pension, benefit, retirement, compensation, profit-sharing, deferred compensation, incentive, performance award, phantom equity, stock or stock-based, change in control, retention, severance, vacation, paid time off, fringe-benefit and other similar agreement, plan, policy, program or arrangement (and any amendments thereto), in each case whether or not reduced to writing and whether funded or unfunded, including each "employee benefit plan" within the meaning of Section 3(3) of ERISA, whether or not Tax-qualified and whether or not subject to ERISA, which is or has been maintained, sponsored, contributed to, or required to be contributed to by Company or an ERISA Affiliate for the benefit of any current or former employee, officer, director, retiree, independent contractor or consultant of Company or an ERISA Affiliate or any spouse or dependent of such individual, or under which Company or an ERISA Affiliate has or may have any Liability, or with respect to which Parent or any of its Affiliates would reasonably be expected to have any Liability, contingent or otherwise other than offer letters entered into in the ordinary course (as listed on Section 3.20(a) of the Company Disclosure Schedules, each, a "**Benefit Plan**").

(b) With respect to each Benefit Plan, Company has made available to Parent accurate, current and complete copies of each of the following: (i) where the Benefit Plan has been reduced to writing, the plan document together with all amendments; (ii) where the Benefit Plan has not been reduced to writing, a written summary of all material plan terms; (iii) where applicable, copies of any trust agreements or other funding arrangements, custodial agreements, insurance policies and contracts, administration agreements and similar agreements, and investment management or investment advisory agreements, now in effect; (iv) copies of any summary plan descriptions, summaries of material modifications, employee handbooks and any other written communications (or a description of any oral communications) relating to any Benefit Plan; (v) in the case of any Benefit Plan that is intended to be qualified under Section 401(a) of the Code, a copy of the most recent determination, opinion or advisory letter from the Internal Revenue Service; (vi) in the case of any Benefit Plan for which a Form 5500 is required to be filed, a copy of the most recently filed Form 5500, with schedules attached; (vii) actuarial valuations and reports related to any Benefit Plans with respect to the two most recently completed plan years; and (viii) copies of material notices, letters or other correspondence from the Internal Revenue Service, Department of Labor or Pension Benefit Guaranty Corporation relating to the Benefit Plan.

(c) Except as set forth in Section 3.20(c) of the Company Disclosure Schedules, each Benefit Plan (other than any multiemployer plan within the meaning of Section 3(37) of ERISA (each a "**Multiemployer Plan**")) has been established, administered and maintained in accordance with its terms and in material compliance with all applicable Laws (including ERISA and the Code). Each Benefit Plan that is intended to be qualified under Section 401(a) of the Code (a "**Qualified Benefit Plan**") is so qualified and has received a favorable and current determination letter from the Internal Revenue Service, or with respect to a prototype plan, can rely on an opinion letter from the Internal Revenue Service to the prototype plan sponsor, to the effect that such Qualified Benefit Plan is so qualified and that the plan and the trust related thereto are exempt from federal income Taxes under Sections 401(a) and 501(a), respectively, of the Code, and nothing has occurred that would reasonably be expected to cause the revocation of such determination letter from the Internal Revenue Service or the unavailability of reliance on such opinion letter from the Internal Revenue Service, as applicable, nor has such revocation or unavailability been threatened. Nothing has occurred with respect to any Benefit Plan that has subjected or would reasonably be expected to subject Company or, with respect to any period on or after the Closing Date, Parent or any of its Affiliates, to a penalty under Section 502 of ERISA or to a Tax or penalty under Section 4975 of the Code. Except as set forth in Section 3.20(c) of the Company Disclosure Schedules, all benefits, contributions and premiums relating to each Benefit Plan have been timely paid in accordance with the terms of such Benefit Plan and all applicable Laws and accounting principles, and all benefits accrued under any unfunded Benefit Plan have been paid, accrued or otherwise adequately reserved to the extent required by, and in accordance with, GAAP.

(d) Neither Company nor any of its ERISA Affiliates has (i) incurred or reasonably expects to incur, either directly or indirectly, any material Liability under Title I or Title IV of ERISA or related provisions of the Code or foreign Law relating to employee benefit plans; (ii) failed to timely pay premiums to the Pension Benefit Guaranty Corporation; (iii) withdrawn from any Benefit Plan; or (iv) engaged in any transaction which would give rise to liability under Section 4069 or Section 4212(c) of ERISA.

(e) With respect to each Benefit Plan (i) except as set forth in Section 3.20(e) of the Company Disclosure Schedules, no such plan is a Multiemployer Plan, and all contributions required to be paid by Company or its ERISA Affiliates have been timely paid to the applicable Multiemployer Plan; (ii) no such plan is a "multiple employer plan" within the meaning of Section 413(c) of the Code or a "multiple employer welfare arrangement" (as defined in Section 3(40) of ERISA); (iii) no Action has been initiated by the Pension Benefit Guaranty Corporation to terminate any such plan or to appoint a trustee for any such plan; (iv) no such plan is subject to the minimum funding standards of Section 302 of ERISA or Section 412 of the Code; and (v) no "reportable event," as defined in Section 4043 of ERISA, has occurred with respect to any such plan.

(f) Except as set forth in Section 3.20(f) of the Company Disclosure Schedules and required by applicable Law, no provision of any Benefit Plan or collective bargaining agreement could reasonably be expected to result in any limitation on Parent or any of its Affiliates from amending or terminating any Benefit Plan. Company has no commitment or obligation and has not made any representations to any employee, officer, director, independent contractor or consultant, whether or not legally binding, to adopt, amend or modify any Benefit Plan or any collective bargaining agreement, in connection with the consummation of the transactions contemplated by this Agreement or otherwise.

(g) Except as set forth in Section 3.20(g) of the Company Disclosure Schedules and other than as required under Section 601 et. seq. of ERISA or other applicable Law, no Benefit Plan provides post-termination or retiree welfare benefits to any individual for any reason, and neither Company nor any of its ERISA Affiliates has any Liability to provide post-termination or retiree welfare benefits to any individual or ever represented, promised or contracted to any individual that such individual would be provided with post-termination or retiree welfare benefits.

(h) Except as set forth in Section 3.20(h) of the Company Disclosure Schedules, there is no pending or threatened Action relating to a Benefit Plan (other than routine claims for benefits), and no Benefit Plan has within the three (3) years prior to the date hereof been the subject of an examination or audit by a Governmental Authority or the subject of an application or filing under or is a participant in, an amnesty, voluntary compliance, self-correction or similar program sponsored by any Governmental Authority.

(i) There has been no amendment to, announcement by Company or any of its Affiliates relating to, or change in employee participation or coverage under, any Benefit Plan or collective bargaining agreement that would increase the annual expense of maintaining such plan above the level of the expense incurred for the most recently completed fiscal year with respect to any director, officer, employee, independent contractor or consultant, as applicable. Neither Company, nor any of its Affiliates has any commitment or obligation or has made any representations to any director, officer, employee, independent contractor or consultant, whether or not legally binding, to adopt, amend or modify any Benefit Plan or any collective bargaining agreement.

(j) Each Benefit Plan that is subject to Section 409A of the Code has been operated in material compliance with such section and all applicable regulatory guidance (including notices, rulings and proposed and final regulations).

(k) Each individual who is classified by Company as an independent contractor has been properly classified for purposes of participation and benefit accrual under each Benefit Plan.

(l) Except as set forth in Section 3.20(l) of the Company Disclosure Schedules, neither the execution of this Agreement nor any of the transactions contemplated by this Agreement will (either alone or upon the occurrence of any additional or subsequent events): (i) entitle any current or former director, officer, employee, independent contractor or consultant of Company to severance pay or any other payment; (ii) accelerate the time of payment, funding or vesting, or increase the amount of compensation due to any such individual; (iii) limit or restrict the right of Company to merge, amend or terminate any Benefit Plan; (iv) increase the amount payable under or result in any other material obligation pursuant to any Benefit Plan; or (v) result in a "parachute payment" within the meaning of Section 280G of the Code.

Section 3.21 Employment Matters.

(a) Company represents and warrants that at Closing, it will have no employees and all such arrangements have been terminated without further liability to the Company.

(b) Company is currently under no duty to bargain with any union, works council or labor organization (collectively, a " **Union**").

(c) Company is, and has been, in all material respects, in compliance with all applicable Laws pertaining to employment and employment practices, including all Laws relating to labor relations, equal employment opportunities, fair employment practices, employment discrimination, harassment, retaliation, reasonable accommodation, disability rights or benefits, immigration, wages, hours, overtime compensation, child labor, hiring, promotion and termination of employees, working conditions, meal and break periods, privacy, health and safety, workers' compensation, leaves of absence and unemployment insurance. All individuals characterized and treated by Company as independent contractors or consultants are properly treated as independent contractors under all applicable Laws. All employees classified as exempt under the Fair Labor Standards Act and state and local wage and hour laws are properly classified. There are no Actions against Company pending, or to Company's Knowledge, threatened to be brought or filed, by or with any Governmental Authority or arbitrator in connection with the employment of any current or former applicant, employee, consultant or independent contractor of Company, including, without limitation, any claim relating to unfair labor practices, employment discrimination, harassment, retaliation, equal pay, wages and hours or any other employment -related matter arising under applicable Laws.

(d) Company has complied in all material respects with the WARN Act, if applicable, and it has no plans to undertake any action in the future that would trigger the WARN Act.

Section 3.22 **Taxes**. Except as set forth in Section 3.22 of the Company Disclosure Schedules:

(a) All material Tax Returns required to be filed on or before the Closing Date by Company have been, or will be, filed (taking into account any valid extensions). Such Tax Returns are, or will be, true, complete and correct in all material respects; *provided, however*, that regardless of any information or items reported on any Tax Returns, Company makes no representation regarding the amount of any net operating losses that are available to it or have been reported by the Company for any federal, state or other Tax purposes, and Company makes no representation regarding any limitation on use of its net operating losses that might apply either before or after the Closing Date under Code Section 382 or any other applicable limitations under any Tax laws, rules or regulations. All material Taxes due and owing by Company on or before the Closing Date (whether or not shown on any Tax Return) have been, or will be, paid before the Closing Date.

(b) Company has withheld and paid each Tax required to have been withheld and paid in connection with amounts paid or owing to any employee, independent contractor, creditor, customer, shareholder or other party, and complied with all information reporting and backup withholding provisions of applicable Law.

(c) No written claim has been made by any taxing authority in any jurisdiction where Company does not file Tax Returns that it is, or may be, subject to Tax by that jurisdiction.

(d) No extensions or waivers of statutes of limitations have been given or requested with respect to the collection or assessment of any Taxes of Company.

(e) The amount of Company's Liability for unpaid Taxes for all periods ending on or before the Balance Sheet Date has been properly and accurately accrued on the Balance Sheet in accordance with GAAP and consistent with past custom and practice. The Company does not have any Liability for unpaid Taxes since the Balance Sheet Date outside of the ordinary course of business; *provided, however*, that no representation is made under this Agreement with respect to any Tax liability or other costs that might arise or accrue to Company or any other Person or entity by reason of, or in connection with, any election by or on behalf of Company pursuant to Section 338 of the Code with respect to the consummation of the Mergers or any other transactions contemplated by this Agreement.

(f) All deficiencies asserted, or assessments made, against Company as a result of any examinations by any taxing authority have been fully paid.

(g) Company is not a party to any Action by any taxing authority. To Company's Knowledge, there are no written pending or threatened Actions by any taxing authority.

(h) There are no Encumbrances for Taxes, other than Permitted Encumbrances, upon the assets of Company.

(i) Company is not a party to, or bound by, any Tax indemnity, Tax-sharing or Tax allocation agreement.

(j) Company is not a party to, or bound by, any closing agreement or offer in compromise with any taxing authority.

(k) No private letter rulings, technical advice memoranda or similar agreement or rulings have been requested, entered into or issued by any taxing authority with respect to Company.

(l) Company has not been a member of an affiliated, combined, consolidated or unitary Tax group for Tax purposes. Company has no Liability for Taxes of any Person (other than Company) under Treasury Regulations Section 1.1502-6 (or any corresponding provision of state, local or foreign Law), as a transferee or successor, by contract or otherwise.

(m) Except as set forth in Section 3.22(m) of the Company Disclosure Schedules, Company has not agreed to make, nor is it required to make, any adjustment under Section 481(a) of the Code or any comparable provision of state, local or foreign Tax Laws by reason of a change in accounting method or otherwise. Company will not be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or portion thereof) ending after the Closing Date as a result of any installment sale or open transaction disposition made prior to the Closing or prepaid amount received outside of the ordinary course of business prior to the Closing.

(n) Company is not a "foreign person" as that term is used in Treasury Regulations Section 1.1445-2. Company is not, nor has it been, a "United States real property holding corporation" (as defined in Section 897(c)(2) of the Code) during the applicable period specified in Section 897(c)(1)(A)(ii) of the Code.

(o) Company has not been a "distributing corporation" or a "controlled corporation" in connection with a distribution described in Section 355 of the Code.

(p) Company is not, and has not been, a party to a "reportable transaction" within the meaning of Section 6707A(c)(1) of the Code and Treasury Regulations Section 1.6011-4(b).

(q) None of the assets of Company is property that Company is required to treat as being owned by any other person pursuant to the so-called "safe harbor lease" provisions of former Section 168(f)(8) of the Internal Revenue Code of 1954, as amended.

Section 3.23 Books and Records. The minute books and stock record books of Company, all of which have been made available to Parent, are complete (except for such redactions as are necessary to maintain privilege prior to Closing) and correct and have been maintained in accordance with sound business practices. The minute books of Company contain accurate and complete records of all meetings, and actions taken by written consent of, the stockholders, the Company Board and any committees thereof (other than records of committee meetings where such committee took no formal action), and no meeting, or action taken by written consent, of any such stockholders, the Company Board or committee thereof has been held for which minutes have not been prepared and are not contained in such minute books. At the Closing, all of those books and records will be in the possession or control of Company.

Section 3.24 Certain Payments. Neither Company nor, to Company's Knowledge, any director, officer, employee, or other Person associated with or acting on behalf of it, has, directly or indirectly, in violation of any Law made any contribution, gift, bribe, rebate, payoff, influence payment, kickback, or other payment to any Person, private or public, regardless of form, whether in money, property, or services (a) to obtain favorable treatment in securing business for Company, (b) to pay for favorable treatment for business secured by Company or (c) to obtain special concessions or for special concessions already obtained, for or in respect of Company. Without limiting the generality of the foregoing, Company (including any of its directors, officers, employees or other Persons associated with or acting on its behalf) has not, directly or indirectly, taken any action which would cause it to be in violation of the U.S. Foreign Corrupt Practices Act, as amended, or any rules or regulations thereunder (the "**FCPA**"), including by offering or conveying, directly or indirectly (such as through an agent), anything of value to obtain or retain business or to obtain any improper advantage, including any bribe, rebate, payoff, influence payment, kickback or other similar unlawful payment to a foreign government official, candidate for office, or political party or official of a political party. Company has conducted its business in compliance with the FCPA in all respects.

Section 3.25 Privacy and Data Security. Company has made available true and correct copies of all written privacy policies adopted by Company in connection with its operations. Company (i) has complied in all material respects with all applicable privacy laws and other laws regarding the disclosure of data, (ii) has not violated its applicable privacy policies in any material respect and (iii) has taken commercially reasonable steps to protect and maintain the confidential nature of the personal information provided to Company in accordance with its applicable privacy policies.

Section 3.26 Government Grants and Incentives. Section 3.26 of the Company Disclosure Schedules provides a complete list of all pending and outstanding grants, incentives, benefits, qualifications and subsidies from any Governmental Authority, granted to Company within the last three (3) years (collectively, "**Government Grants**"). Company does not have any Liability whatsoever with respect to royalties or other payments relating to, arising out of or in connection with such Government Grants. Company is in material compliance with all of the terms, conditions and requirements of the Government Grants and has fulfilled in all material respects the undertakings relating thereto. Neither Company nor any of its agents, contractors, vendors, licensors or otherwise has developed any Company Intellectual Property through the application of any financing made available by any Government Grants, and no Company Intellectual Property is subject to any assignment, grant-back, license or other right of any Governmental Authority as a result of any Government Grants.

Section 3.27 Products Liability.

(a) No claim is pending or, to Company's Knowledge, threatened in connection with the product liability of any Products, and no Governmental Authority has commenced or, to Company's Knowledge, threatened to initiate any Action or requested the recall of any Product, or commenced or, to Company's Knowledge, threatened in writing to initiate any Action to enjoin the production of any Product.

(b) Except as set forth on Section 3.27 of the Company Disclosure Schedules, no customer of Company has delivered any written complaint or written allegation of any quality, design, engineering or safety issue with respect to any Product that would reasonably be expected to have a Material Adverse Effect.

Section 3.28 State Takeover Statutes. No "moratorium," "fair price," "business combination," "control share acquisition" or similar provision of any state anti-takeover Law is, or at the Effective Time will be, applicable to this Agreement, the Mergers or any of the other transactions contemplated hereby.

Section 3.29 Related Party Transactions. Except as set forth in Section 3.29 of the Disclosures Schedules and other than Contracts entered into in connection with bona fide financings, no present or former director, executive officer, stockholder, partner, member, employee or Affiliate of Company, nor any of such Person's Affiliates or immediate family members (each of the foregoing, a "**Related Party"**), is a party to any Contract with Company that is of a type that would be required to be disclosed pursuant to Item 404 of Regulation S-K (an "**Affiliate Transaction"**) if the Company Stock was publicly traded. To Company's Knowledge, no Related Party of Company owns, directly or indirectly, on an individual or joint basis, any interest in (other than ownership of two percent (2%) or less of the outstanding voting stock of a publicly-traded entity), or serves as an officer or director or in another similar capacity of, any supplier or other independent contractor of Company, or, except for those Contracts set forth in Section 3.29 of the Company Disclosure Schedules or any Material Contract entered into in connection with bona fide financings, any organization which has a Material Contract with Company.

Section 3.30 Brokers. Except for Torreya Capital, a division of Financial West Investment Group, Inc. (the " **Company's Investment Banker"**), no broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Company. The Company represents and warrants it will pay, or otherwise make accommodation on the Distribution Schedule for, any amounts due to the Company's Investment Banker at or prior to Closing and further represent and warrant that any such amount is excluded from the definition of "Cash on Hand".

ARTICLE 4.
REPRESENTATIONS AND WARRANTIES OF PARENT

Parent represents and warrants to Company that the statements contained in this Article 4 are true and correct as of the date hereof.

Section 4.1 Organization. Parent is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Parent has full corporate power and authority to enter into this Agreement, to carry out its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery by Parent of this Agreement, the performance by Parent of its obligations hereunder and the consummation by Parent of the transactions contemplated hereby have been duly authorized by all requisite corporate action on the part of Parent. This Agreement has been duly executed and delivered by Parent and Merger Subs, and this Agreement constitutes legal, valid and binding obligations of Parent and Merger Subs, as applicable, enforceable against Parent and Merger Subs in accordance with their terms, except (i) as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights, and (ii) general principles of equity that restrict the availability of equitable remedies.

Section 4.2 **No Conflicts; Consents**. The execution, delivery and performance by Parent of this Agreement, and the consummation of the transactions contemplated hereby, do not and will not: (a) conflict with or result in a violation or breach of, or default under, any provision of the certificate of incorporation, by-laws or other organizational documents of Parent; (b) conflict with or result in a violation or breach of any provision of any Law or Governmental Order applicable to Parent; or (c) require the consent, notice or other action by or to any Person pursuant to, or result in any breach or violation of or constitute a default under, any Contract to which Parent or any of its Affiliates is a party. Except for (i) applicable requirements of the Exchange Act, including the filing of any Current Report on Form 8-K required to be filed in connection with the Mergers, (ii) any filings required under state securities Laws, (iii) any filings required by OTC Markets (or such national or foreign securities exchange on which Parent's shares are listed) and (iv) the filing of the Certificate of Merger with the Secretary of State of the State of Delaware, in each case, which have or will be made, neither Parent nor Merger Subs are required to submit any notice, report or other filing with any Governmental Authority in connection with the execution, delivery or performance by any of them of this Agreement or the consummation of the transactions contemplated hereby. Other than as stated above, no consent, approval or authorization of any governmental or regulatory authority or any other party or Person is required to be obtained by Parent or Merger Subs in connection with its execution, delivery and performance of this Agreement or the consummation of the transactions contemplated hereby.

Section 4.3 **No Stockholder Vote Required**. No vote or other action of the stockholders of Parent is required pursuant to any applicable Law, the governing documents of Parent or otherwise in order for the Parent to consummate the transactions contemplated by this Agreement.

Section 4.4 **Issuance of Parent Shares**. The issuance and delivery of Parent Shares in accordance with this Agreement has been duly authorized by all necessary corporate action on the part of Parent and, when issued as contemplated hereby, such Parent Shares shall be duly and validly issued, fully paid and nonassessable. Such Parent Shares, when so issued and delivered in accordance with the provisions of this Agreement, shall be free and clear of all Encumbrances, other than restrictions on transfer created by applicable securities Laws and will not have been issued in violation of applicable Laws, applicable OTC Markets rules or regulations, or any preemptive rights or rights of first refusal or similar rights.

Section 4.5 **Brokers**. No broker, finder or investment banker is entitled to any brokerage, finder's or other fee or commission in connection with the transactions contemplated by this Agreement based upon arrangements made by or on behalf of Parent.

Section 4.6 **Legal Proceedings**. There are no Actions pending or, to Parent's knowledge, threatened against or by Parent or any Affiliate of Parent or any of their respective properties or any of their respective officers or directors (in their capacities as such) that would challenge or would reasonably be expected to prevent, enjoin or otherwise delay the transactions contemplated by this Agreement. No event has occurred or circumstances exist that may give rise or serve as a basis for any such Action. There is no Governmental Order against Parent or any Affiliate of Parent, or any of their respective directors or officers (in their capacities as such), that could prevent, enjoin, or materially alter or delay the consummation of the transactions contemplated by this Agreement.

Section 4.7 Merger Sub. Merger Sub was organized solely for the purpose of entering into this Agreement and consummating the transactions contemplated hereby and has not engaged in any activities or business, and has incurred no liabilities or obligations whatsoever, in each case, other than those incident to its organization and the execution of this Agreement and the consummation of the transactions contemplated hereby. Merger Sub is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Merger Sub has full corporate power and authority to enter into this Agreement, to carry out its obligations hereunder and to consummate the transactions contemplated hereby. The execution and delivery by Merger Sub of this Agreement, the performance by Merger Sub of its obligations hereunder and the consummation by Merger Sub of the transactions contemplated hereby have been duly authorized by all requisite action on the part of Merger Sub.

Section 4.8 Second Merger Sub. Second Merger Sub was organized solely for the purpose of entering into this Agreement and the Second Merger and consummating the transactions contemplated hereby and has not engaged in any activities or business, and has incurred no liabilities or obligations whatsoever, in each case, other than those incident to its organization and the execution of this Agreement or the Second Certificate of Merger and the consummation of the transactions contemplated hereby. Second Merger Sub is a limited liability company duly organized, validly existing and in good standing under the Laws of the State of Delaware. Second Merger Sub has full power and authority to enter into this Agreement and the Second Certificate of Merger, to carry out its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery by Second Merger Sub of this Agreement and the Second Certificate of Merger, the performance by Second Merger Sub of its obligations hereunder and thereunder and the consummation by Second Merger Sub of the transactions contemplated hereby and thereby have been duly authorized by all requisite action on the part of Second Merger Sub. Second Merger Sub is an entity disregarded as separate from Parent for U.S. federal tax purposes and neither Parent nor Second Merger Sub intends to take any action inconsistent with such treatment.

Section 4.9 SEC Filings; Securities Law and Other Matters.

(a) Parent has filed all forms, reports, statements and documents required to be filed with the SEC for the twenty-four (24) month period preceding the Closing (collectively, the "**Parent SEC Reports**"), each of which has complied in all material respects with the applicable requirements of the Securities Act and the Exchange Act, and the rules and regulations of the SEC promulgated thereunder, as applicable, and applicable to the Parent SEC Reports. None of the Parent SEC Reports contained as of their respective dates, and as of the date of the last amendment thereof, if amended after filing, any untrue statement of a material fact or omitted or omits to state a material fact required to be stated or incorporated by reference therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(b) All of the financial statements included in the Parent SEC Reports, in each case, including any related notes thereto, as filed with the SEC (collectively, the "**Parent Financial Statements**"), have been prepared in accordance with GAAP applied on a consistent basis throughout the periods involved and fairly present the consolidated financial position of Parent and its Subsidiaries at the respective date thereof and the consolidated results of its operations and changes in cash flows for the periods indicated (except, in each case as may be indicated in the notes thereto and subject, in the case of the unaudited statements, to normal, year-end adjustments and the absence of footnotes otherwise required by GAAP). To the knowledge of Parent, there are no circumstances that would require Parent to restate any of the Parent Financial Statements.

(c) There are no material liabilities of Parent or any of its Subsidiaries, taken as a whole, of any kind whatsoever, whether or not accrued and whether or not contingent or absolute, other than (i) liabilities disclosed in Parent's consolidated balance sheet (the "**Parent Balance Sheet**") as of March 31, 2017 (the "**Parent Balance Sheet Date**"), included in Parent's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017; (ii) liabilities incurred by or on behalf of Parent in connection with this Agreement and the transactions contemplated hereby; (iii) liabilities disclosed in Parent SEC Report filed since the filing of the Parent Balance Sheet and (iv) liabilities incurred in the ordinary course of business since the Parent Balance Sheet Date, none of which, individually or in the aggregate, would reasonably be expected to result in a Material Adverse Effect with respect to Parent.

(d) Shares of Parent common stock are registered pursuant to Section 12(b) of the Exchange Act and are listed on the OTC Markets and Parent has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of its shares under the Exchange Act or delisting its shares from the OTC Markets, nor has Parent received any notification that the SEC or the OTC Markets is contemplating terminating such registration or listing.

(e) Since the Parent Balance Sheet Date, and other than in the ordinary course of business consistent with past practice, there has not been, with respect to Parent, any event, occurrence or development that has had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect.

Section 4.10 Compliance with Laws. Except as has not had and would reasonably be expected to have, individually or in the aggregate, Material Adverse Effect with respect to Parent and its Subsidiaries, taken as a whole, Parent and each of its Subsidiaries is, and since December 31, 2014 has been, in compliance with all Laws applicable to it or its business, properties or assets.

Section 4.11 Taxes. There are no material Taxes due and payable by Parent or any of its Subsidiaries which have not been duly paid. Parent and each of its Subsidiaries has duly filed all material Tax Returns required to have been filed by them and there are in effect no waivers of applicable statutes of limitations with respect to the collection or assessment of Taxes for any year. Parent is not aware of any fact or circumstance that would reasonably be expected to prevent the Integrated Transaction from qualifying as a "reorganization" within the meaning of Section 368(a) of the Code.

ARTICLE 5.
COVENANTS OF THE PARTIES

Section 5.1 Conduct of Business Prior to the Closing.

(a) During the period from the date of this Agreement until the Closing or the earlier termination of this Agreement pursuant to Section 6.1 hereof, except with the prior written consent of Parent (which consent shall not be unreasonably withheld or delayed), Company shall (i) except as set forth in Section 5.1(b) of the Company Disclosure Schedules, carry on its business according to its ordinary course of business and substantially in the same manner as heretofore conducted; provided that, the foregoing notwithstanding, Company may use all available cash to repay any Indebtedness or Securityholder Transaction Expenses prior to Closing, (ii) use commercially reasonable efforts to preserve and protect its material assets, properties, organization (including key officers and employees), goodwill and business relationships, (iii) cause all transactions with third parties to take place on arm's length terms, (iv) maintain insurance coverage on such terms and in such amounts substantially as maintained on the date hereof, and (v) comply in all material respects with all applicable Laws, orders, codes, licenses, regulations and ordinances of any Governmental Authority.

(b) During the period from the date of this Agreement until the Closing or the earlier termination of this Agreement pursuant to Section 6.1 hereof, except as otherwise expressly provided for by this Agreement or consented to in writing by Parent (which consent will not be unreasonably withheld or delayed) or as set forth on Section 5.1(b) of the Company Disclosure Schedules, Company shall not:

(i) cause or permit any amendments to the Company Charter or any of Company's organizational documents;

(ii) incur or commit to incur any Indebtedness in excess of $10,000, or guarantee any Indebtedness of others;

(iii) declare or pay any dividend or make any other distributions (whether in cash, shares or property) in respect of any of its shares, or split, combine, reclassify any of its shares or issue or authorize the issuance of any other securities in respect of, in lieu of or in substitution for its shares, or repurchase or otherwise acquire, directly or indirectly, any of its shares, other than (A) the issuance of shares of Company Stock pursuant to the exercise in accordance with their terms of options or Warrants outstanding as of the Agreement Date, or (B) the repurchase of Company Common Stock from former employees, non-employee directors and consultants in accordance with agreements providing for the repurchase of shares in connection with any termination of service as in effect on the Agreement Date;

(iv) except as contemplated by this Agreement or the acceleration of options prior to the Closing, accelerate, amend, or change the period of exercisability or vesting of any options, Warrants or any other rights to purchase securities or authorize cash payments in exchange for any such options, Warrants or other rights to purchase securities;

(v) sell, lease, license or otherwise dispose of or encumber any of its properties or assets that are material, individually or in the aggregate, to its business, taken as a whole, other than in the ordinary course of business;

(vi) enter into, terminate or amend, in a manner that will materially and adversely affect the business of Company, any agreement that is, or would be if existing on the date of this Agreement, a Material Contract, other than in the ordinary course of business;

(vii) make any capital expenditures, capital additions or capital improvements, in excess of $10,000 in the aggregate, except those that are made in the ordinary course of business;

(viii) reduce the amount of any insurance coverage provided by existing insurance policies;

(ix) amend any benefit plan of Company or adopt any plan that would constitute a benefit plan except in order to comply with applicable Law, or hire any new employee, pay any discretionary bonus, special remuneration or special noncash benefit, or increase the benefits, salaries or wage rates of its employees (except with respect to payments and benefits made pursuant to written agreements outstanding on the date of this Agreement);

(x) grant or pay any severance or termination pay or benefits (A) to any director or officer or (B) to any other employee;

(xi) commence a lawsuit other than (A) for the routine collection of bills, (B) in such cases where Company in good faith determines that failure to commence suit would result in the material impairment of Company's business, provided that it consults with Parent prior to the filing of such a suit, or (C) in connection with a breach of this Agreement;

(xii) acquire or agree to acquire by merging with, or by purchasing a material portion of the shares or assets of, or by any other manner, any business or any corporation, partnership, association or other business organization or division thereof or otherwise acquire or agree to acquire any assets that, in any such of the foregoing cases, are material individually or in the aggregate, to its business, taken as a whole;

(xiii) other than in the ordinary course of business or as may be required by applicable Law, make or change any material election in respect of material Taxes, adopt or change any material accounting method in respect of Taxes, enter into any closing agreement with respect to Taxes, settle any material claim or assessment in respect of Taxes, or consent to any extension or waiver of the limitation period applicable to any material claim with respect to the collection or assessment of Taxes;

(xiv) revalue any of its assets, including writing down the value of inventory or writing off notes or accounts receivable other than in the ordinary course of business or as required by changes in GAAP; or

(xv) take or agree in writing or otherwise to take, any of the actions described in Section 5.1(b)(i) through (xiv) above.

Section 5.2 Access to Information.

(a) From the date hereof until the Closing, Company shall, and shall cause Company to, (i) afford Parent and its Agents reasonable access during normal business hours to and the right to inspect all of the Real Property, properties, assets, premises, books and records, Contracts and other documents and data related to Company, except that the right to inspect the Real Property does not extend to the right to conduct sampling of the soil, groundwater, and/or air of the Real Property without Company's prior written consent; (ii) furnish Parent and its Agents with such financial, operating and other data and information related to Company as Parent or any of its Agents may reasonably request; and (iii) instruct the Agents of Company and Company to cooperate with Parent in its investigation of Company; provided, that such access shall be at Parent's sole expense; *provided*, *however*, that Company shall not be required to provide Parent or its Agents with access to any files, books, records or information where such access would (A) waive any privileges or protections under applicable Law, (B) violate any Law concerning privacy rights applicable to employees, (C) violate the terms of any nondisclosure or similar Contract with any third party (*provided*, that in each case, Company shall use its commercially reasonable efforts to provide Parent with access to such information to the fullest extent practicable without risking loss of privilege or protections under such Law, privacy right or Contract, including, for example, providing for such information to be reviewed by counsel for Parent on terms reasonably acceptable to counsel for Company) or (D) violate any Law, including but not limited to any antitrust Law as interpreted in the reasonable discretion of counsel to Company. Any investigation pursuant to this Section 5.2 shall be conducted in such manner as not to interfere unreasonably with the conduct of the business of Company.

(b) For a period of seven (7) years from and after the Closing, Parent will make or cause to be made available (including by electronic means, to the extent available) to the Representative all books, records, Tax Returns and documents of the Surviving Company (and the assistance of employees responsible for such books, records and documents or whose participation is reasonably necessary or desirable in connection therewith) as may be reasonably necessary for (i) investigating, settling, preparing for the defense or prosecution of, defending or prosecuting any Third Party Claim or (ii) such other purposes for which access to such documents is reasonably necessary for the Representative to conduct its duties hereunder; *provided*, *however*, that any such access or furnishing of information shall be during Parent's normal business hours, under the supervision of Parent's personnel and in such a manner as not to interfere with the normal operations of Parent or Surviving Company.

Section 5.3 No Solicitation of Other Bids .

(a) Prior to the earlier of the Closing or termination of this Agreement, Company shall not, and shall not authorize or permit any of its Affiliates or any of its or their Agents to, directly or indirectly, (i) encourage, solicit, facilitate, initiate or continue inquiries regarding an Acquisition Proposal; (ii) enter into discussions or negotiations with, or provide any information to, any Person concerning a possible Acquisition Proposal; or (iii) enter into any agreements or other instruments (whether or not binding) regarding an Acquisition Proposal. Company shall immediately cease and cause to be terminated, and shall cause its Affiliates and all of its and their Agents to immediately cease and cause to be terminated, all existing discussions or negotiations with any Persons conducted heretofore with respect to, or that could lead to, an Acquisition Proposal. For purposes hereof, "**Acquisition Proposal**" shall mean any inquiry, proposal or offer from any Person (other than Parent or any of its Affiliates) concerning (A) a merger, consolidation, liquidation, recapitalization, share exchange or other business combination transaction involving Company; (B) the issuance or acquisition of shares of capital stock or other equity securities of Company (other than (x) the issuance of shares of Company Stock pursuant to the exercise in accordance with their terms of options or Warrants outstanding as of the Agreement Date, or (y) the repurchase of Company Common Stock from former employees, non-employee directors and consultants in accordance with agreements providing for the repurchase of shares in connection with any termination of service as in effect on the Agreement Date); or (C) the sale, lease, exchange or other disposition of any significant portion of Company's properties or assets.

(b) In addition to the other obligations under this Section 5.3, Company shall promptly (and in any event within three (3) Business Days after receipt thereof by Company) advise Parent in writing of any Acquisition Proposal, any request for information with respect to any Acquisition Proposal, or any inquiry with respect to an Acquisition Proposal, the material terms and conditions of such request, Acquisition Proposal or inquiry.

(c) Company agrees that the rights and remedies for noncompliance with this Section 5.3 shall include having such provision specifically enforced by any court having equity jurisdiction, it being acknowledged and agreed that any such breach or threatened breach shall cause irreparable injury to Parent and that money damages would not provide an adequate remedy to Parent.

Section 5.4 Notice of Certain Events.

(a) From the date hereof until the Closing, Company shall promptly notify Parent, and Parent shall promptly notify Company, in writing of:

(i) any fact, circumstance, event or action the existence, occurrence or taking of which (A) has had, or could reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect with respect to such notifying party, or (B) has resulted in, or would reasonably be expected to result in, the failure of any of the conditions set forth in Section 2.2 or 2.3, as applicable, to be satisfied;

(ii) any written notice or other communication from any Person alleging that the consent of such Person is or may be required in connection with the transactions contemplated by this Agreement;

(iii) any notice or other communication from any Governmental Authority in connection with the transactions contemplated by this Agreement; and

(iv) any Actions commenced or, to Company's Knowledge or Parent's knowledge, as applicable, threatened against, relating to or involving or otherwise affecting such notifying party that, if pending on the date of this Agreement, would have been required to have been disclosed pursuant to Section 3.17 or Section 4.7 or that relates to the consummation of the transactions contemplated by this Agreement.

(b) The delivery of any notice pursuant to Section 5.4(a) (each, a "**Disclosure Update**") shall amend, modify and supplement the Company Disclosure Schedules or Parent Disclosure Schedules, as applicable, delivered upon the execution of this Agreement for all purposes hereunder but only (1) to the extent such Disclosure Update does not disclose facts, events or circumstances describing a previously undisclosed Material Adverse Effect on the Company or Parent, as applicable, or (2) if such Disclosure Update discloses facts, events or circumstances that first occurred after the date of this Agreement and the Closing occurs. For the avoidance of doubt, any disclosure in any such Disclosure Update shall not be deemed to have cured any inaccuracy or breach of any representation or warranty made and effective as of the date of this Agreement, including for purposes of the indemnification or termination rights contained in this Agreement or of determining whether or not the conditions set forth in Section 2.2 have been satisfied.

Section 5.5 Financial Statement Preparation. Company shall use its commercially reasonable efforts prior to Closing to prepare, or assist Parent in causing to be prepared, as promptly as practicable, and in any event no later than seventy (75) days following the Closing Date, any financial statements that Parent is required to file pursuant to Form 8-K, Rule 3-05 or Article 11 of Regulation S-X under the 1934 Act, and shall use its commercially reasonable efforts to obtain the consents of its auditor(s) with respect thereto as may be required by applicable SEC regulations. Company represents and warrants that it has secured the cooperation of its finance staff to assist Parent with getting audited financial statements for each of 2014, 2015 and 2016. All costs and expenses associated with this Section 5.5, including reasonable compensation for services provided by Company's finance staff and auditors, shall be paid by Parent.

Section 5.6 Resignations. Company shall deliver to Parent written resignations, effective as of the Closing Date, of the officers, directors, employees and contractors of Company prior to the Closing.

Section 5.7 **Confidentiality**. The parties hereto acknowledge that Parent and Company have entered into a confidentiality agreement, dated February 27, 2017, which shall continue in full force and effect in accordance with its terms (the "**Confidentiality Agreement**"). Without limiting the terms of the Confidentiality Agreement, except for disclosures required to obtain any consent or approval of any Person (including Company Securityholders) or other disclosures approved by the other party, neither the Company nor Parent shall disclose the terms of this Agreement or the terms of any of the transactions contemplated hereby to any other Person, other than to the directors, officers, employees, agents, attorneys, consultants or representatives of such Person in connection with any of the foregoing to assist such Person in complying with its obligations under this Agreement. Notwithstanding the foregoing, this Section 5.7 shall not prohibit any such Person from making any disclosure which is, upon the advice of counsel, (a) required to avoid a violation of applicable Law by such party or (b) required by rule or regulation of any securities exchange or market on which the securities of any party or its Affiliates are listed or quoted, and in each such case the party required to make such disclosure shall do so only to the limited extent necessary to comply with such Law, regulation, rule or obligation and shall, to the extent practicable, give advance notice thereof to the other party hereto and an opportunity to comment on any such disclosure and oppose the need therefor.

Section 5.8 **Governmental Approvals and Consents.**

(a) Each party hereto shall, as promptly as possible, (i) make, or cause or be made, all filings and submissions required under any Law applicable to such party or any of its Affiliates; and (ii) use reasonable best efforts to obtain, or cause to be obtained, all consents, authorizations, orders and approvals from all Governmental Authorities that may be or become necessary for its execution and delivery of this Agreement and the performance of its obligations pursuant to this Agreement. Each party shall cooperate fully with the other party and its Affiliates in promptly seeking to obtain all such consents, authorizations, orders and approvals. The parties hereto shall not willfully take any action that will have the effect of delaying, impairing or impeding the receipt of any required consents, authorizations, orders and approvals.

(b) If any consent, approval or authorization necessary to preserve any right or benefit under any Material Contract to which Company is a party is not obtained prior to the Closing, Company shall, subsequent to the Closing, cooperate with Parent and Company in attempting to obtain such consent, approval or authorization as promptly thereafter as practicable. If such consent, approval or authorization cannot be obtained, Company shall use its reasonable best efforts to provide Company with the rights and benefits of the affected Material Contract for the term thereof, and, if Company provides such rights and benefits, Parent shall assume all obligations and burdens thereunder.

Section 5.9 **Stockholder Approval**. Promptly after execution of this Agreement, Company shall solicit the written consent to this Agreement and the transactions contemplated hereby by the requisite number of Stockholders necessary to obtain the Required Stockholder Approval. Company shall provide the Stockholders with such Disclosure Materials as shall be required by applicable Law. Company shall submit to Parent the form of any written notice and other Disclosure Materials to be transmitted to the Stockholders pursuant to this Section 5.9 prior to delivery thereof to the Stockholders. Company shall include in such Disclosure Materials such information relating to the Parent and the Parent Shares as Parent may reasonably request in writing prior to such delivery in connection with the potential issuance of Parent Shares pursuant to this Agreement.

Section 5.10 Director and Officer Indemnification.

(a) For a period of six (6) years from and after the Closing Date, Parent agrees to indemnify (including advancement of expenses) and hold harmless, and shall cause the Surviving Company to indemnify (including advancement of expenses) and hold harmless, all past and present officers and directors of Company to the same extent such persons are indemnified by Company as of the date of this Agreement pursuant to Company's organizational documents, any applicable employment agreements and indemnification agreements and to the fullest extent under applicable Law for acts or omissions which occurred at or prior to the Effective Time. The Surviving Company's organizational documents shall contain provisions with respect to indemnification and exculpation that are at least as favorable to the past and present officers and directors of Company as those provisions contained in Company Charter and Company bylaws in effect on the date hereof, and such provisions shall not be amended, repealed or otherwise modified for a period of six (6) years in any manner that would adversely affect the rights of the past and present officers and directors of Company.

(b) Parent or the Surviving Company shall maintain in effect for a period of six (6) years from and after the Effective Time, an officers' and directors' liability insurance policy and a fiduciary liability policy with respect to acts or omissions occurring at or prior to the Effective Time covering each past and present officer and member of the Company Board who is currently covered by Company's officers' and directors' liability insurance policy. The cost of obtaining such "tail" insurance policies shall be paid by Parent.

(c) If Parent, the Surviving Company or any of Parent's or Surviving Company's successors or assigns (i) consolidates with or merges into any other person and shall not be the continuing or surviving corporation or entity of such consolidation or merger or (ii) transfers or conveys all or substantially all of its properties and assets to any person, then, and in each such case, to the extent necessary, proper provision shall be made so that the successors and assigns of Parent or the Surviving Company, as the case may be, shall assume the obligations set forth in this Section 5.10.

(d) The provisions of this Section 5.10 are intended for the benefit of, and shall be enforceable by, all past and present officers and directors of Company and his or her heirs and representatives. The rights of all past and present officers and directors of Company under this Section 5.10 are in addition to, and not in substitution for, any other rights to indemnification or contribution that any such person may have by contract, applicable Law or otherwise.

Section 5.11 Closing Conditions. From the date hereof until the Closing, each party hereto shall use reasonable best efforts to take such actions as are necessary to expeditiously satisfy the closing conditions set forth in Article 2 hereof.

Section 5.12 Intellectual Property Registrations. Prior to Closing, the Company will direct its current intellectual property counsel to forward all correspondence regarding Intellectual Property Registrations to Parent's intellectual property counsel, Sheridan Ross P.C.

Section 5.13 **Further Assurances**. Following the Closing, each of the parties hereto shall, and shall cause their respective Affiliates to, execute and deliver such additional documents, instruments, conveyances and assurances and take such further actions as may be reasonably required to carry out the provisions hereof and give effect to the Mergers or any other acts or transactions contemplated by this Agreement.

Section 5.14 **Maintenance and Prosecution of Company Intellectual Property** . During the period between the Effective Time and the Earnout Termination Date, Parent shall, at its own cost and expense, maintain all Company Intellectual Property in effect as of the date hereof and subject to protection under the Laws of the United States, including but not limited to paying any applicable filing fees, and shall prosecute any United States Patent Applications included in the Company Intellectual Property.

Section 5.15 **Compliance with Laws**. From and after the Closing, Parent will be in material compliance with all Healthcare Laws applicable to Parent and its products, including without limitation the Products (collectively, the "**Seller Products**"). The design, manufacture, testing, and distribution of the Seller Products by or on behalf of Parent will be conducted in material compliance with all applicable Healthcare Laws. Parent will be in material compliance with FDA's establishment registration and product listing requirements to the extent required by applicable Healthcare Laws. Parent will hold such Permits of the applicable government or government agencies required for the conduct of its business as will be conducted, including, without limitation, those Permits necessary based on the scope of its activities to permit such activities related to the design, development, pre-clinical and clinical testing, manufacture, labeling, sale, shipment, distribution and promotion of products in jurisdictions where it will conduct such activities with respect to each Seller Product.

ARTICLE 6.
TERMINATION

Section 6.1 **Termination**. This Agreement may be terminated at any time prior to the Closing:

(a) by the mutual written consent of Company and Parent;

(b) by Parent by written notice to Company if:

(i) Parent is not then in material breach of any provision of this Agreement and there has been a breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Company pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 2.2(a) or (b) and such breach, inaccuracy or failure has not been cured by Company within twenty-one (21) days of Company's receipt of written notice of such breach from Parent; or

(ii) any of the conditions set forth in Section 2.2 shall not have been, or if it becomes apparent that any of such conditions will not be, fulfilled by May 31, 2017, unless such failure shall be due to the failure of Parent to perform or comply with any of the covenants, agreements or conditions hereof to be performed or complied with by it prior to the Closing;

(c) by Company by written notice to Parent if:

(i) Company is not then in material breach of any provision of this Agreement and there has been a breach, inaccuracy in or failure to perform any representation, warranty, covenant or agreement made by Parent or Merger Sub pursuant to this Agreement that would give rise to the failure of any of the conditions specified in Section 2.3(a) or (b) and such breach, inaccuracy or failure has not been cured by Parent within twenty-one (21) days of Parent's receipt of written notice of such breach from Company; or

(ii) any of the conditions set forth in Section 2.3 shall not have been, or if it becomes apparent that any of such conditions will not be, fulfilled by May 31, 2017, unless such failure shall be due to the failure of Company to perform or comply with any of the covenants, agreements or conditions hereof to be performed or complied with by it prior to the Closing; or

(d) by Parent or Company by written notice to the other party in the event that:

(i) there shall be any Law that makes consummation of the transactions contemplated by this Agreement illegal or otherwise prohibited;

(ii) any Governmental Authority shall have issued a Governmental Order restraining or enjoining the transactions contemplated by this Agreement, and such Governmental Order shall have become final and non-appealable; or

(iii) any of the conditions set forth in Section 2.1 shall not have been, or if it becomes apparent that any of such conditions will not be, fulfilled by May 31, 2017, unless such failure shall be due to the failure of the notifying party to perform or comply with any of the covenants, agreements or conditions hereof to be performed or complied with by it prior to the Closing.

The party desiring to terminate this Agreement pursuant to this Section 6.1 (other than pursuant to Section 6.1(a)) shall give a notice of such termination to the other party setting forth a brief description of the basis on which such party is terminating this Agreement.

Section 6.2 Effect of Termination. In the event of the termination of this Agreement in accordance with this Article 6, this Agreement shall forthwith become void and there shall be no liability on the part of any party hereto except:

(a) as set forth in this Article 6 (Termination), and Section 5.7 (Confidentiality) and Article 10 (Miscellaneous) hereof; and

(b) that nothing herein shall relieve any party hereto from liability for any willful breach of any provision hereof.

ARTICLE 7.
OTHER COVENANTS

Section 7.1 Survival. The representations and warranties contained in Article 3 and Article 4 shall survive the Closing for twelve months. The indemnity contained in Section 7.2(a)(iv) shall survive until the expiration of the applicable statute of limitations plus sixty (60) days. All other covenants and agreements of the parties contained herein shall survive the Closing indefinitely or for the period explicitly specified therein. The period ending on each such termination date described in this Section 7.1 is referred to as the "**Survival Period**".

Section 7.2 Indemnification of Parent.

(a) From and after the Closing (but subject to the terms and conditions of this Article 7), each Company Securityholder, based upon and limited to each such Company Securityholder's Distribution Allocation, shall, in each case, severally but not jointly, indemnify and hold the Parent Indemnitees (as defined below) harmless from and against any and all losses, liabilities, claims, suits, actions, obligations, deficiencies, demands, awards, judgments, damages, interest, fines, penalties, costs and expenses (including reasonable costs of investigation and defense and reasonable attorneys' and other professionals' reasonable fees and expenses) whether or not involving a Third Party Claim, but specifically excluding consequential, special, incidental, indirect, exemplary or punitive damages (including diminution of value, loss of future revenue, lost profits or lost business opportunity as consequential or indirect damages) except to the extent actually awarded in a Third Party Claim (hereinafter individually a "**Loss**" and collectively "**Losses**") suffered or incurred by Parent, its Affiliates or any of their respective officers, directors, managers, employees, stockholders, members, partners, agents, representatives or successors and assigns (the "**Parent Indemnitees**") attributable to, or arising or resulting from:

(i) the fraud of Company;

(ii) the fraud of any Company Securityholder (but each Company Securityholder's liability shall be limited to Losses caused by its own fraud);

(iii) any breach of any covenant of Company contained in this Agreement;

(iv) any proceeding in respect of any Dissenting Shares and any payments required to be made by Parent or the Surviving Company to any Person that was a holder of Company Stock immediately prior to the Effective Time in respect of such Person's Dissenting Shares, to the extent that such payments exceed the portion of the final Aggregate Merger Consideration to which such Person would have been entitled pursuant to this Agreement in respect of such Dissenting Shares if such Person had not exercised appraisal or dissenting rights in respect thereof; and

(v) any Pre-Closing Tax Liability.

(b) The parties hereto acknowledge and agree that the Representative (solely in its capacity as the Representative) is a party to this Agreement solely to perform certain administrative functions in connection with the consummation of the transactions contemplated hereby. Accordingly, the parties hereto acknowledge and agree that other than any liability which any Company Securityholder may have hereunder, Representative shall have no additional liability to, and shall not be liable for any Losses of, any party hereto or to any Parent Indemnitee in connection with any obligations of the Representative under this Agreement or otherwise in respect of this Agreement or the transactions contemplated hereby, except to the extent such Losses are a result of gross negligence or willful misconduct by the Representative in connection with the performance of its obligations hereunder.

(c) Losses that may be recovered pursuant to Section 7.2 shall take account of and be reduced by (i) any amounts recovered by the Parent Indemnitees or the Surviving Company pursuant to any indemnification by or indemnification agreement with any third party, (ii) any refund, credit or reduction in Tax realized by such Parent Indemnitees or their Affiliates arising from the incurrence or payment of such indemnifiable Losses (based upon the maximum marginal federal, state or local tax rate applicable to such Persons), and (iii) the amount of any insurance proceeds, contribution payments or reimbursements actually received or receivable by the Parent Indemnitees in respect thereof (each Person named and source identified in clauses (i) through (iii), a "**Collateral Source**"). The Parent Indemnitees shall use commercially reasonable efforts to seek recovery from all Collateral Sources; *it being understood that* the reasonable costs and expenses of exercising such efforts shall be deemed Losses. If the amount to be netted hereunder from any payment required under Section 7.2 is determined after payment the set off of any Earnout Payment of any amount otherwise required to be paid to a Parent Indemnitee under this Article 7, the Parent Indemnitees shall repay to the Company Securityholders, promptly after such determination, any amount that the Company Securityholders would not have had to pay pursuant to this Section 7.2(c) had such determination been made at the time of such payment.

(d) Amounts payable by any Company Securityholder to Parent pursuant to this Section 7.2 shall, to the extent reasonably practicable, be satisfied by returning to Parent an amount of Parent Shares equal to (x) the dollar value of such Company Securityholder's indemnification obligation under this Section 7.2 divided by (y) the dollar value per Parent Share used to determine the amount of Parent Shares to be issued to such Company Securityholder pursuant to this Agreement, determined as if the Parent Shares having the highest dollar value per Parent Share were returned first. Notwithstanding anything to the contrary contained herein, in no event shall any Company Securityholder be liable under 7.2(a)(iv) for any amounts in excess of the consideration actually received by such Company Securityholder hereunder.

(e) All payments under this Section 7.2 shall be treated by the parties as an adjustment to the proceeds received by the Company Securityholders pursuant to Article 1, to the extent permitted by applicable Law.

Section 7.3 Indemnification of Company Securityholders.

(a) From and after the Closing (but subject to the provisions of this Article 7), Parent shall indemnify and hold each Company Securityholder, each Company Securityholder's Affiliates and each of their respective officers, directors, managers, employees, stockholders, members, partners, agents, representatives, successors and assigns (the "**Securityholder Indemnitees**") harmless from and against, and pay to the applicable Securityholder Indemnitees the amount of, any and all Losses based upon, attributable to or resulting from (a) the fraud, criminal activity, or intentional misconduct of the Parent or Merger Sub, (b) any breach of any covenant of Parent or Merger Sub contained in this Agreement, including, without limitation, Annex 1 hereof, and (c) any design, sale, manufacture and any other activities primarily associated with Parent Products. All payments under this Section 7.3 shall be treated by the parties as an adjustment to the proceeds received by the Company Securityholders pursuant to Article 1.

(b) Notwithstanding anything to the contrary set forth in this Agreement or otherwise, from and after the Closing (but subject to the terms and conditions of this Article 7), any indemnification of the Securityholder Indemnitees for which the Parent is liable hereunder shall be paid promptly to the Company Securityholders pursuant to the Distribution Schedule and any such payments shall be payable pursuant to an allocation of 60% in cash and 40% in Parent Shares (valued at the average closing price of Parent Shares as reported on OTC Markets (or such national or foreign securities exchange on which Parent's shares are listed) for the ten (10) trading days immediately prior to the date of issuance), unless otherwise agreed by Parent and the Representative in writing.

Section 7.4 Expiration of Claims. The ability of any Parent Indemnitee or Securityholder Indemnitee to receive indemnification pursuant to Section 7.2 or Section 7.3, respectively, shall terminate upon expiration of the applicable Survival Period (as set forth in Section 7.1), unless such Parent Indemnitee or Securityholder Indemnitee, as applicable, has made, in good faith, a proper claim (as described in Sections 7.5(a) and 7.6(a) below) for indemnification pursuant to Section 7.2 or Section 7.3, respectively, subject to the terms and conditions of this Article 7, prior to such termination date, as applicable. If a Parent Indemnitee or an Securityholder Indemnitee has made, in good faith, a proper claim for indemnification pursuant to Section 7.2 or Section 7.3, respectively, prior to such termination date, then such claim, if then unresolved, shall not be extinguished by the passage of the deadlines set forth in Section 7.1 (it being understood that any and all Losses arising after the expiration of the Survival Period shall be recoverable (subject to the limitations set forth herein) only upon notice specifically with respect to such Losses properly given prior to the expiration of the Survival Period in accordance with this Article 7).

Section 7.5 Inter-Party Claims.

(a) In order for a Parent Indemnitee or Securityholder Indemnitee to be entitled to seek any indemnification provided for under this Agreement (such party, the "**Claiming Party**"), such Claiming Party must notify the other party or parties from whom such indemnification is sought (the " **Defending Party**"), in writing promptly after the Claiming Party becomes aware of the occurrence of the event giving rise to such Claiming Party's claim for indemnification, specifying in reasonable detail the basis and, if available, the amount of Loss with respect to, such claim (each, a "**Demand**"); provided, that failure to give such notification shall not affect the indemnification provided hereunder except to the extent the Defending Party is materially prejudiced as a result of such failure or the indemnification obligations are materially increased as a result of such failure.

(b) Upon receipt of a Demand by the Defending Party, such Defending Party shall have thirty (30) days (the " **Indemnity Notice Period**"), to review and respond by written notice to such Demand (the "**Return Notice**") to the Claiming Party. If the Return Notice does not contest the Demand, or if no Return Notice is delivered to the Claiming Party by the expiration of the Indemnity Notice Period, then, (i) with respect to a Demand made by Parent, payment shall be made in the order and priority set forth in Section 7.2, and (ii) with respect to a Demand made by the Securityholder Indemnified Parties, payment shall be made in accordance with Section 7.3(b).

(c) If the Return Notice given by the Defending Party disputes the claim or claims asserted in a Demand or the amount of Losses thereof (a "**Disputed Claim**"), then the Claiming Party and the Defending Parties shall make a reasonable good faith effort to resolve their differences for a period of thirty (30) days following the receipt by the Claiming Party of the Return Notice asserting a Disputed Claim. If the Claiming Party and the Defending Party are unable to resolve the Disputed Claims through negotiations prior to the expiration of such thirty (30) day period, such Disputed Claims shall, subject to the terms of this Agreement, be resolved by litigation in an appropriate court of competent jurisdiction. The Claiming Party shall have the burden of proof in establishing the amount of Losses it has suffered.

Section 7.6 Third Party Claims.

(a) In order for a Claiming Party to seek any indemnification provided for under this Agreement in respect of a claim or demand made by any third party Person against the Claiming Party (a "**Third Party Claim**"), such Claiming Party must notify the Defending Party in writing, specifying in reasonable detail the basis and, if available, the amount of Losses with respect to the Third Party Claim promptly after receipt by such Claiming Party of notice of the Third Party Claim (a "**Notice of Third Party Claim**"); *provided* that failure to give such notification on a timely basis shall not affect the indemnification provided hereunder except to the extent the Defending Party is materially prejudiced as a result of such failure or the indemnification obligations are materially increased as a result of such failure. Such Notice of Third Party Claim shall be accompanied by copies of all relevant documentation with respect to such Third Party Claim, including any summons, complaint or other pleading that may have been served, any written demand or any other document or instrument.

(b) If a Third Party Claim is made against a Claiming Party, the Defending Party shall, at its expense, be entitled to participate in the defense thereof and, if it so chooses, to assume the defense thereof with counsel selected by the Defending Party and reasonably satisfactory to the Claiming Party (i) if within thirty (30) days of the receipt of the Notice of Third Party Claim, the Defending Party gives notice to the Claiming Party stating the Defending Party's intention to do so and acknowledging that the Defending Party shall indemnify the Claiming Party from and against all Losses (to the extent finally determined to be required by, and subject to any applicable limits provided in, this Article 7), that the Claiming Party suffers from the Third Party Claim, or (ii) if the Defending Party does not assume the defense of a Third Party Claim pursuant to clause (i) of this sentence, at any time that the Defending Party reasonably believes that the Claiming Party has ceased to actively and diligently prosecute the defense of such Third Party Claim. Should a Defending Party so elect to assume the defense of a Third Party Claim, the Defending Party shall under no circumstances be liable to the Claiming Party for legal expenses subsequently incurred by the Claiming Party in connection with the defense thereof; *provided*, that in the case that (A) there exists or is reasonably likely to exist a conflict of interest that would make it unethical under applicable rules of professional responsibility for the same counsel to represent both the Claiming Party and the Defending Party, (B) the Defending Party fails to actively and diligently prosecute the defense of such Third Party Claim, (C) such Third Party Claim relates to or otherwise arises in connection with any criminal or material regulatory enforcement action, or (D) such Third Party Claim is reasonably likely to result in an injunction or other equitable relief against the Claiming Party or, in the reasonable discretion of the Claiming Party, result in a Loss in excess of the dollar amount available for indemnification pursuant to this Article 7 (the scenarios described in clauses (A) – (D) are collectively referred to as "**Conflicts**"), then the Defending Party shall be liable to the Claiming Party for reasonable legal expenses of one legal counsel selected by the Claiming Party and reasonably satisfactory to the Defending Party subsequently incurred by the Claiming Party in connection with the defense thereof (to the extent finally determined to be required by, and subject to any applicable limits provided in this Article 7). If the Defending Party assumes such defense, the Claiming Party shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Defending Party, it being understood, however, that the Defending Party shall control such defense so long as the Third Party Claim does not involve a Conflict, in which case the Claiming Party shall control such defense. If the Defending Party chooses to defend any Third Party Claim, then all the parties shall cooperate in the defense or prosecution of such Third Party Claim, including by retaining and, upon the Defending Party's request, providing to the Defending Party all records and information which are reasonably relevant to such Third Party Claim, and making employees available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder. If the Defending Party assumes the defense of any Third Party Claim, the Defending Party shall obtain the prior written consent of the Claiming Party (which shall not be unreasonably conditioned, withheld or delayed) before entering into any settlement or consenting to the entry of a judgment with respect to such claim unless such settlement or judgment (1) involves no finding or admission of any violation of Law or the rights of any Person and has no effect on any other claims that may be made against the Claiming Party, and (2) expressly and unconditionally provides a full and general release of the Claiming Party from all liabilities and obligations with respect to such claim. If the Claiming Party assumes the defense of any Third Party Claim, then the Claiming Party shall obtain the prior written consent of the Defending Party (which shall not be unreasonably conditioned, withheld or delayed) before entering into any settlement or consenting to the entry of a judgment with respect to such claim.

Solely for purposes of calculating indemnifiable Losses hereunder (but not for purposes of determining whether a breach of any representation, warranty, covenant or agreement has occurred), any materiality or Material Adverse Effect qualifications in the representations, warranties, covenants and agreements shall be disregarded.

Section 7.7 Limitation. Each of the parties understands, acknowledges and agrees that this Article 7 shall be the sole and exclusive remedy for claims made after the Effective Time with respect to the subject matter of this Agreement or the transactions contemplated hereby, and that the parties hereto shall have no other remedy or recourse with respect to any such claims other than pursuant to, and subject to the terms and conditions of, this Article 7, except for claims of or arising out of fraud, in which case each Company Securityholder shall be liable on a several but not joint basis for its pro rata portion of its Distribution Allocation of such losses in an aggregate amount not to exceed such Company Securityholder's Distribution Allocation of the Aggregate Merger Consideration actually paid and/or issued or otherwise deemed earned under the terms of this Agreement. The parties hereto acknowledge and agree that no party hereto may avoid such limitation on liability by (x) seeking damages for breach of contract, tort or pursuant to any other theory of liability, all of which are hereby waived or (y) asserting or threatening any claim against any Person (other than a Company Securityholder in a claim pursuant to Article 7) that is not a party (or a successor to a party) for breaches of the representations, warranties and covenants contained in this Agreement. PARENT, ON BEHALF OF ITSELF AND EACH OF THE PARENT INDEMNITEES EXPRESSLY WAIVES ALL RIGHTS AFFORDED BY ANY STATUTE WHICH LIMITS THE EFFECT OF A RELEASE WITH RESPECT TO UNKNOWN CLAIMS. EACH OF THE PARENT INDEMNITEES UNDERSTANDS THE SIGNIFICANCE OF THIS RELEASE OF UNKNOWN CLAIMS AND WAIVER OF STATUTORY PROTECTION AGAINST A RELEASE OF UNKNOWN CLAIMS. EACH PARENT INDEMNITEE ACKNOWLEDGES AND AGREES THAT THIS WAIVER IS AN ESSENTIAL AND MATERIAL TERM OF THIS AGREEMENT. Notwithstanding anything to the contrary in this Agreement, no term or provision of this Agreement shall limit any potential claims or remedies based on fraud and nothing herein shall limit any claim that a Company Securityholder may have as a stockholder of Parent whether or not the Company Securityholder's status as a stockholder of Parent arose out of the receipt of the Parent Shares.

Section 7.8 Tax Matters.

(a) **Responsibility for Filing Tax Returns**.

(i) Parent shall prepare or cause to be prepared and timely file or cause to be timely filed all Tax Returns for the Company and the Surviving Company that have not yet been filed as of the Closing Date, in a manner consistent with past practice, except as otherwise required by applicable Law. Parent shall deliver to Representative all income Tax Returns for any Pre-Closing Tax Periods (including Tax Returns for Straddle Periods) that are to be filed after the Closing Date for review and comment no less than fifteen (15) days before the applicable due date. Except to the extent that an amendment or election would not result in an increase in liabilities for a Pre-Closing Tax Period, Parent shall not, without the Representative's prior written consent, cause or permit the Surviving Company to (i) amend any Tax Return that relates in whole or in part to any Pre-Closing Tax Period or (ii) make any election that has retroactive effect to any Pre-Closing Tax Period.

(ii) Except to the extent that such refund is attributable to the carryback of a Tax attribute attributable to a Post-Closing Tax Period, the Company Securityholders shall be entitled to any Tax refunds that are received by Parent or the Surviving Company, and any amounts credited against Taxes to which Parent or the Surviving Company become entitled in any Post-Closing Tax Period of Company, that relate to any Pre-Closing Tax Period, including Taxes paid with respect to a Pre-Closing Tax Period of Company. Parent shall pay or cause to be paid over to the Company Securityholders (in accordance with each Company Securityholder's Distribution Allocation) any such refund or the amount of any such credit within twenty (20) days after receipt of such refund or after becoming entitled to such credit against Taxes. Any payment under this Section 7.8(a) shall be considered a purchase price adjustment.

(b) **Cooperation**. The parties shall reasonably cooperate with each other to provide each other with such assistance as may be reasonably requested by them in connection with the preparation of any Tax Returns, any Tax audit or other examination in connection with an administrative or judicial proceeding involving a taxing authority relating to Taxes, and the enforcement of the provisions of this Section 7.8(b). Such cooperation shall include, including upon Representative's request, providing records and information that are reasonably relevant to any such matters and making employees available on a mutually convenient basis to provide additional information.

(c) **Transfer Taxes**. Parent, on the one hand, and the Company Securityholders, on the other hand, will each pay fifty percent (50%) of any real property transfer or gains tax, stamp tax, stock transfer tax, or other similar Tax imposed on the Surviving Company or any Company Securityholder as a result of the transactions contemplated by this Agreement (collectively, "**Transfer Taxes**"), and any penalties or interest with respect to the Transfer Taxes. Parent shall file all necessary Tax Returns and other documentation with respect to Transfer Taxes (except to the extent such Tax Returns are required by Law to be filed by a Company Securityholder), and Representative agrees to cooperate with Parent in the filing of any such Tax Returns, including promptly supplying any information in its possession that is reasonably necessary to complete such returns. Each party shall use commercially reasonable efforts to minimize any applicable Transfer Taxes.

(d) **Reorganization**. Each of Company and Parent will report the Mergers as a "reorganization" within the meaning of Section 368(a) of the Code. Neither Company nor Parent shall take or cause to be taken any action that could prevent the Mergers from qualifying as a "reorganization" within the meaning of Section 368(a) of the Code, including by paying or issuing any consideration pursuant to this Agreement that would result in the aggregate consideration paid in Parent Shares pursuant to this Agreement, including pursuant to Annex 1, being less than forty percent (40%) by value of the overall aggregate consideration paid pursuant to this Agreement (provided that the value of any Parent Shares shall be determined solely for this purpose as the average of the high and low trading values of Parent Shares for the day immediately before the date on which the applicable portion of such aggregate consideration is issued or paid).

(e) **Tax Covenants of Parent and Second Merger Sub.**

(i) Parent, either directly or through a member of Parent's "qualified group" within the meaning of Treasury Regulations Section 1.368-1(d)(4)(ii) (the "**Qualified Group**"), will continue at least one significant historic business line of Company, or use at least a significant portion of the historic business assets of Company in a business, in each case within the meaning of Treasury Regulations Section 1.368-1(d), except that the historic business assets of Company may be transferred (i) to a corporation that is another member of Parent's Qualified Group, or (ii) to an entity subject to federal income Tax as a partnership if (A) one or more members of Parent's Qualified Group have active and substantial management functions as a partner with respect to such historic business or historic business assets of Company, or (B) members of Parent's Qualified Group in the aggregate own an interest in the partnership representing a significant interest in the historic business or historic business assets of Company, in each case within the meaning of Treasury Regulations Section 1.368-1(d)(4)(iii).

(ii) In connection with the Mergers, Parent will not reacquire, and will not permit any Person that is a "related person" (as defined in Treasury Regulations Section 1.368-1(e)(4)) to Parent to acquire, any Parent Shares issued in connection with the Mergers, in exchange for any consideration other than Parent Shares.

(iii) Parent will not sell or otherwise dispose, and will not cause or permit Surviving Company or any of Parent's other Affiliates to sell or otherwise dispose, of any of the assets of Company acquired in the Mergers, except for dispositions made in the ordinary course of business or transfers described in Section 368(a)(2)(C) of the Code or described and permitted in Treasury Regulations Section 1.368-2(k).

Section 7.9 Further Assurances. From time to time, as and when requested by any party and at such requesting party's expense, any other party shall execute and deliver, or cause to be executed and delivered, all such documents and instruments and shall take, or cause to be taken, all such further or other actions as the requesting party may reasonably deem necessary or desirable to evidence and effectuate the transactions contemplated by this Agreement.

ARTICLE 8.
REPRESENTATIVE

Section 8.1 Representative.

(a) Effective upon and by virtue of the Required Stockholder Approval and his, her or its acceptance of the consideration payable under the terms and conditions of this Agreement, and without any further act of any of the Company Securityholders, each Company Securityholder hereby appoints the Representative as his, her or its attorney-in-fact and agent for and on behalf of such Company Securityholder for purposes of this Agreement and any other agreements and documents executed or delivered in connection with this Agreement. The Representative shall take such actions to be taken by the Representative under this Agreement and any other agreements and documents executed or delivered in connection with this Agreement and such other actions on behalf of such Company Securityholder as it may deem necessary or appropriate in connection with or to consummate the transactions contemplated hereby or thereby, including, without limitation, (i) accepting service of process on the Company Securityholders, (ii) executing and delivering this Agreement, and any other ancillary documents and negotiating and executing such amendments, modifications, waivers or changes thereto as to which the Representative, in its sole discretion, shall have consented (provided that any waiver or amendment that shall adversely and disproportionately affect the rights or obligations of any Company Securityholder as compared to other Company Securityholders shall require the prior written consent of such Company Securityholder), (iii) receiving or providing notices on behalf of the Company Securityholders with respect to any matter or Actions arising out of or relating to this Agreement, or the transactions contemplated hereby, (iv) taking all actions and making all filings on behalf of such Company Securityholders with any Governmental Authority or other Person necessary to effect the consummation of the transactions contemplated by this Agreement, (v) agreeing to, negotiating, entering into settlements and compromises of, complying with orders of courts with respect to, and otherwise administering and handling any claims under this Agreement on behalf of such Company Securityholders, (vi) interpreting all terms of this Agreement; (vii) instituting, prosecuting and/or defending lawsuits; (viii) in connection with any of the foregoing actions, engaging and hiring accountants, auditors, appraisers, legal counsel and other legal and financial experts as may be necessary and appropriate properly to discharge the Representative's duties and obligations hereunder and (ix) taking all other actions that are either necessary or appropriate in the judgment of the Representative for the accomplishment of the foregoing or contemplated by the terms of this Agreement. The Representative hereby accepts such appointment. The appointment of the Representative as each Company Securityholder's attorney-in-fact revokes any power of attorney heretofore granted that authorized any other Person to represent such Company Securityholder with regard to this Agreement and any other agreements or documents executed or delivered in connection with this Agreement. The Representative is the sole and exclusive representative of each of the Company Securityholders for any purpose provided for by this Agreement. Representative shall be bound by the same confidentiality restrictions binding Company pursuant to Section 5.7 provided, however, that the Representative shall use commercially reasonable efforts based on contact information available to the Representative to keep the Company Securityholders reasonably informed with respect to actions of Representative pursuant to the authority granted Representative under this Agreement which actions have a material impact on the amounts payable to the Company Securityholders. Each Company Securityholder shall promptly provide written notice to the Representative of any change of address of such Company Securityholder.

(b) A decision, act, consent or instruction of the Representative hereunder shall constitute a decision, act, consent or instruction of all Company Securityholders and shall be final, binding and conclusive upon each such Company Securityholder, and Parent and the Surviving Company may rely upon any such decision, act, consent or instruction of the Representative as being the decision, act, consent or instruction of each and every such Company Securityholder. Parent, the Surviving Company shall be relieved from any liability to any Person for any acts done by them in accordance with such decision, act, consent or instruction of the Representative.

(c) Certain Company Securityholders have entered into a letter agreement with the Representative to provide direction to the Representative in connection with the performance of its services under this Agreement (such Company Securityholders, included their individual representatives, hereinafter referred to as the "**Advisory Group**"). Neither the Representative and its members, managers, directors, officers, contractors, agents and employees) nor any member of the Advisory Group (collectively, the "**Representative Group**") shall incur liability with respect to any action taken or suffered by any Company Securityholder in reliance upon any notice, direction, instruction, consent, statement or other document believed by such Representative to be genuine and to have been signed by such Company Securityholder (and shall have no responsibility to determine the authenticity thereof), nor for any other action or inaction, except the gross negligence, bad faith or willful misconduct of the Representative Group. In all questions arising under this Agreement, the Representative may rely on the advice of outside counsel, and the Representative shall not be liable to any Company Securityholder for anything done, omitted or suffered in good faith by Representative based on such advice. No provision of this Agreement shall require the Representative to expend or risk its own funds or otherwise incur any financial liability in the exercise or performance of any of its powers, rights, duties or privileges under this Agreement on behalf of any Company Securityholders.

(d) Each Company Securityholder shall severally, but not jointly (based on such Company Securityholder's Distribution Allocation), indemnify the Representative Group and hold the Representative Group harmless against any loss, liability or expense incurred without gross negligence, bad faith or willful misconduct on the part of the Representative Group and arising out of or in connection with the acceptance or administration of the Representative's duties hereunder, including the reasonable fees and expenses of any legal counsel or other advisors reasonably retained by the Representative. Notwithstanding the foregoing, the Representative's standard hourly rates and all out-of-pocket fees and expenses incurred by the Representative in performing its duties shall be borne by the Company Securityholders paid in accordance with their respective Distribution Allocations of such fees and expenses out of any Earnout Payment otherwise distributable to the Company Securityholders, and, thereafter, directly from the Company Securityholders, in accordance with their respective Distribution Allocations.

(e) At any time Stockholders representing at least a majority of the equity securities of the Company outstanding immediately prior to the Effective Time may, by written consent, appoint another Person as Representative. Notice together with a copy of the written consent appointing such Person and bearing the signatures of such Stockholders must be delivered to Parent not less than ten (10) days prior to such appointment. Such appointment shall be effective upon the later of the date indicated in the consent or the date ten (10) days after such consent is received by Parent.

(f) In the event that the Representative becomes unable or unwilling to continue in his or its capacity as the Representative, or if the Representative resigns as a Representative, Stockholders representing at least a majority of the equity securities of the Company outstanding immediately prior to the Effective Time may, by written consent, appoint a new representative as the Representative. Notice and a copy of the written consent appointing such new representative and bearing the signatures of such Stockholders must be delivered to Parent. Such appointment shall be effective upon the later of the date indicated in the consent or the date ten (10) days after such consent is received by Parent.

(g) The immunities and rights to indemnification shall survive the resignation or removal of Representative or any member of the Advisory Group and the Closing and/or any termination of this Agreement. The Representative shall be entitled to: (i) rely upon the Distribution Schedule, (ii) rely upon any signature believed by it to be genuine, and (iii) reasonably assume that a signatory has proper authorization to sign on behalf of the applicable Company Securityholder or other party. The grant of authority provided for herein (A) is coupled with an interest and shall be irrevocable and survive the death, incompetency, bankruptcy or liquidation of any Company Securityholder, (B) shall survive the delivery of an assignment by any Company Securityholder of the whole or any fraction of his, her or its interest in any post-Closing consideration and (C) shall survive the consummation of the Mergers. The provisions of this Section 8.1 shall be binding upon the executors, heirs, legal representatives, successors and assigns of each Company Securityholder, and any references in this Agreement to any Company Securityholder or the Company Securityholders shall mean and include the successors to such Company Securityholder's rights hereunder, whether pursuant to testamentary disposition, the laws of descent and distribution or otherwise.

ARTICLE 9.
DEFINITIONS

Section 9.1 Certain Defined Terms. The following terms have the meanings:

"**Action**" means any claim, action, cause of action, demand, lawsuit, arbitration, inquiry, audit, notice of violation, proceeding, litigation, citation, summons, subpoena or investigation of any nature, civil, criminal, administrative, regulatory or otherwise, whether at law or in equity.

"**Affiliate**" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

"**Agents**" means, with respect to any Person, any and all directors, officers, employees, consultants, financial advisors, counsel, accountants and other agents of such Person.

"**Aggregate Merger Consideration**" means, collectively, the rights of the Company Securityholders to receive (i) the Closing Merger Consideration, (ii) the Earnout Payments, if any, and (iii) any amounts payable under Sections 7.3 and 7.8(a)(ii).

"**Business Day**" means any day except Saturday, Sunday or any other day on which commercial banks located in New York, New York are authorized or required by Law to be closed for business.

"**Cash on Hand**" means, with respect to Company, as of the close of business on the Closing Date all unrestricted cash, cash equivalents and freely marketable securities but not including any restricted cash (including all cash posted to support letters of credit, performance bonds or other similar obligations or deposits with third parties, including landlords), in each case determined in accordance with GAAP and expressed in United States dollars. For the avoidance of doubt, Cash on Hand shall be calculated net of issued but uncleared checks and drafts and shall include checks, other wire transfers and drafts deposited or available for deposit for the account of Company.

"**CERCLA**" means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. §§ 9601 et seq.

"**Closing Merger Consideration**" means an amount equal to 2,500,000 Parent Shares.

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Company Charter**" means the Amended and Restated Certificate of Incorporation of Company, as amended.

"**Company Common Stock**" means Company's Common Stock, par value $0.001 share.

"**Company Disclosure Schedules**" means the Company Disclosure Schedules delivered by Company to Parent concurrently with the execution and delivery of this Agreement as modified by any Disclosure Updates.

"**Company Preferred Stock**" means the Company's Series A Preferred Stock and the Company's Series A-1 Preferred Stock.

"**Company Securityholders**" means collectively, the holders of Preferred Stock and Convertible Debt of the Company.

"**Company Stock**" means Company Preferred Stock and Company Common Stock.

"**Company's Knowledge**" or "**Knowledge of Company**" or any other similar knowledge qualification, means the actual knowledge of Earl Bright and Karen Long.

"**Contracts**" means all contracts, leases, deeds, mortgages, licenses, instruments, notes, commitments, undertakings, indentures, joint ventures and all other agreements, commitments and legally binding arrangements, whether written or oral.

"**Convertible Debt**" means those certain Secured Convertible Promissory Notes issued pursuant to that certain Note Purchase Agreement dated March 30, 2016, as well as that certain Convertible Promissory Note dated as of September 27, 2012 issued to ExploraMed NC6, LLC.

"**Company Creditor**" shall mean ExploraMed NC6, LLC and Torreya Capital Partners, each as related to the Unpaid Contractual Obligations.

"**Dataroom**" means the electronic dataroom hosted by SecureDocs.com at https://nuelle.securedocs.com.

"**Disclosure Materials**" means the documents, materials and notices prepared or to be prepared by Company pursuant to the DGCL or otherwise in connection with obtaining the approval by the Stockholders of this Agreement and the Merger or notifying any Company Securityholders of the approval of the Agreement and the Merger and the availability of appraisal rights under the DGCL.

"**Distribution Allocation**" means the allocation of Parent Shares or cash a Company Securityholder will receive at Closing or as part of an Earnout Payment pursuant to this Agreement.

"**Dollars or $**" means the lawful currency of the United States.

"**Earnout Payments**" means any amounts payable to Company Securityholders pursuant to Annex 1 hereto.

"**Earnout Termination Date**" means the last date on which any Earnout Payments may become due and payable to the Company Securityholders in accordance with Annex 1.

"**Encumbrance**" means any charge, claim, community property interest, pledge, condition, equitable interest, lien (statutory or other), option, security interest, mortgage, easement, encroachment, right of way, right of first refusal, or restriction of any kind, including any restriction on use, voting, transfer, receipt of income or exercise of any other attribute of ownership.

"**Environmental Claim**" means any Action, Governmental Order, lien, fine, penalty, or, as to each, any settlement or judgment arising therefrom, by or from any Person alleging liability of whatever kind or nature (including liability or responsibility for the costs of enforcement proceedings, investigations, cleanup, governmental response, removal or remediation, natural resources damages, property damages, personal injuries, medical monitoring, penalties, contribution, indemnification and injunctive relief) arising out of, based on or resulting from: (a) the presence, Release of, or exposure to, any Hazardous Materials; or (b) any actual or alleged non-compliance with any Environmental Law or term or condition of any Environmental Permit.

"**Environmental Law**" means any applicable Law, and any Governmental Order or binding agreement with any Governmental Authority: (a) relating to pollution (or the cleanup thereof) or the protection of natural resources, endangered or threatened species, human health or safety, or the environment (including ambient air, soil, surface water or groundwater, or subsurface strata); or (b) concerning the presence of, exposure to, or the management, manufacture, use, containment, storage, recycling, reclamation, reuse, treatment, generation, discharge, transportation, processing, production, disposal or remediation of any Hazardous Materials. The term "**Environmental Law**" includes, without limitation, the following (including their implementing regulations and any state analogs): the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. §§ 9601 et seq.; the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984, 42 U.S.C. §§ 6901 et seq.; the Federal Water Pollution Control Act of 1972, as amended by the Clean Water Act of 1977, 33 U.S.C. §§ 1251 et seq.; the Toxic Substances Control Act of 1976, as amended, 15 U.S.C. §§ 2601 et seq.; the Emergency Planning and Community Right-to-Know Act of 1986, 42 U.S.C. §§ 11001 et seq.; the Clean Air Act of 1966, as amended by the Clean Air Act Amendments of 1990, 42 U.S.C. §§ 7401 et seq.; and the Occupational Safety and Health Act of 1970, as amended, 29 U.S.C. §§ 651 et seq.

"**Environmental Notice**" means any written directive, notice of violation or infraction, or notice respecting any Environmental Claim relating to actual or alleged non-compliance with any Environmental Law or any term or condition of any Environmental Permit.

"**Environmental Permit**" means any Permit, letter, clearance, consent, waiver, closure, exemption, decision or other action required under or issued, granted, given, authorized by or made pursuant to Environmental Law.

"**ERISA**" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations promulgated thereunder.

"**ERISA Affiliate**" means, with respect to any Person, any other Person that, together with such first Person, would be treated as a single employer within the meaning of Section 414(b), (c), (m) or (o) of the Code.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended, or any successor federal statute thereto and the rules and regulations of the SEC promulgated thereunder.

"**Excluded Contracts**" means (i) non-exclusive Contracts concerning "off-the-shelf" or similar software that is available on commercially reasonable terms, (ii) standard non-disclosure, confidentiality and material transfer Contracts, in each case entered into in the ordinary course of business, (iii) Contracts that have expired on their own terms or were terminated, and (iv) purchase orders and associated terms and conditions for which the underlying goods or services have been delivered or received.

"**GAAP**" means, with respect to any Person, United States generally accepted accounting principles in effect from time to time, as consistently applied by such Person across its operations.

"**Governmental Authority**" means any federal, state, local or foreign government or political subdivision thereof, or any agency or instrumentality of such government or political subdivision, or any self-regulated organization or other non-governmental regulatory authority or quasi-governmental authority (to the extent that the rules, regulations or orders of such organization or authority have the force of Law), or any arbitrator, court or tribunal of competent jurisdiction.

"**Governmental Order**" means any order, writ, judgment, injunction, decree, stipulation, determination or award entered by or with any Governmental Authority.

"**Hazardous Materials**" means: (a) any material, substance, chemical, waste, product, derivative, compound, mixture, solid, liquid, mineral or gas, in each case, whether naturally occurring or manmade, that is hazardous, acutely hazardous, toxic, infectious, or words of similar import or regulatory effect under Environmental Laws; and (b) any petroleum or petroleum-derived products, radioactive materials or wastes, asbestos in any form, lead or lead-containing materials, urea formaldehyde foam insulation, and polychlorinated biphenyls.

"**Healthcare Laws**" means, to the extent related to the conduct of a Person's business as of the date hereof, Federal, state, and foreign Laws in jurisdictions where such Person operates relating to health care products and services, including (each as amended from time to time): the FDCA, Medicare (Title XVIII of the Social Security Act) and Medicaid (Title XIX of the Social Security Act), the federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b)), the Stark Anti-Self-Referral Law (42 U.S.C. §§ 1395nn), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§ 3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.) and the exclusion laws (42 U.S.C. § 1320a-7), the Affordable Care Act (Public Law 111-148), all regulations or guidance promulgated pursuant to such Laws, and any other federal, or state Law that regulates the design, development, testing, studying, manufacturing, processing, storing, importing or exporting, licensing, labeling or packaging, advertising, distributing or marketing of medical device products, or that is related to kickbacks, patient or program charges, recordkeeping, claims process, documentation requirements, medical necessity, referrals, the hiring of employees or acquisition of services or supplies from those who have been excluded from government health care programs, quality, safety, privacy, security, licensure, accreditation or any other aspect of providing health care services.

"**Indebtedness**" means, with respect to any Person, without duplication: (a) the principal, accreted value, accrued and unpaid interest, fees and prepayment premiums or penalties, unpaid fees or expenses and other monetary obligations in respect of (i) indebtedness of such Person for borrowed money and (ii) indebtedness evidenced by notes, debentures, bonds, or other similar instruments for the payment of which such Person is liable; (b) all obligations of such Person for the reimbursement of any obligor on any letter of credit, banker's acceptance or similar credit transaction; (c) all obligations of such Person under capital leases; and (d) all obligations of the type referred to in clauses (a) through (c) of any Persons for the payment of which such Person is responsible or liable as obligor, guarantor or surety, including guarantees of such obligations (but solely to the extent of such responsibility or liability).

"**Law**" means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement or rule of law of any Governmental Authority.

"**Liability**" means, with respect to any Person, any liability or obligation of that Person of any kind, character or description, whether known or unknown, absolute or contingent, accrued or unaccrued, asserted or unasserted, disputed or undisputed, liquidated or unliquidated, secured or unsecured, joint or several, due or to become due, vested or unvested, executory, determined, determinable or otherwise.

"**Material Adverse Effect**" means, with respect to a party, any change, effect, event, occurrence or development, which individually or in the aggregate, with all other changes, effects, events and developments, that has or would reasonably expected to have a material adverse effect (a) on the ability of Company to consummate the transactions contemplated by this Agreement or perform its obligations under this Agreement; provided, that any effect on Company's ability to consummate the transactions contemplated by this Agreement or perform its obligations under this Agreement, to the extent resulting from Parent's or Merger Sub's material breach or failure to consummate the Closing on or before the date for Closing set forth in Section 1.2 (assuming all conditions to such obligations have been satisfied or duly waived) for any reason shall not be considered a "Material Adverse Effect" under this subsection (a), or (b) upon the business, assets, liabilities, financial condition, or operating results of such party, except any adverse effect related to or resulting from (i) general business or economic conditions affecting the economy or the industry or markets in which such party operates; (ii) any natural disaster, or national or international political or social conditions, including the engagement by the United States in hostilities or the escalation thereof, whether or not pursuant to the declaration of a national emergency or war, or the occurrence or the escalation of any military or terrorist attack upon the United States, or any of its territories, possessions, or diplomatic or consular offices or upon any military installation, equipment or personnel of the United States; (iii) financial, banking, or securities markets (including any disruption thereof and any decline in the price of any security or any market index); (iv) changes in GAAP or other similar accounting requirements in foreign countries which are not specific to the affected party, (v) changes in Laws, rules, regulations, orders, or other binding directives issued by any Governmental Authority, (vi) the taking of any action explicitly contemplated by this Agreement, the other agreements contemplated hereby or at the request of the affected party other party hereto or the announcement of this Agreement, or the other agreements contemplated hereby or the transactions contemplated hereby or thereby, (vii) the negotiation, execution, announcement or pendency of this Agreement or the transactions contemplated hereby or any communication by Parent or any of its Affiliates of its plans or intentions (including with respect to employees) with respect to any of the business of such party, including losses or threatened losses of, or any adverse change in the relationship with employees, customers, suppliers, distributors, financing sources, joint venture partners, licensors, licensees, or others having relationships with such party, (viii) any adverse change in or effect on the business of such party that is cured by or on behalf of such party before the earlier of the Closing Date and the date on which this Agreement is terminated pursuant to Article 6, or (ix) any failure to meet internal projections relating to such party (it being understood that the underlying causes of, or factors contributing to, the failure to meet such projections may be taken into account in determining whether a Material Adverse Effect has occurred), but only in the case of (i), (ii) or (iii), to the extent such change or effect does not disproportionately affect such party relative to other industry participants.

"**OTC Markets**" means OTC Market Group.

"**Parent Disclosure Schedules**" means the Parent Disclosure Schedules delivered by Parent to Company concurrently with the execution and delivery of this Agreement as modified by any Disclosure Updates.

"**Parent Product**" means any product that Parent has manufactured, distributed, marketed or sold, or is manufacturing, distributing, marketing or selling and any products currently under preclinical or clinical development by Parent.

"**Parent Shares**" means shares of common stock, par value $0.0001 per share, of Parent. All references to a number of Parent Shares shall be subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting the Parent Shares.

"**Permits**" means all permits, licenses, franchises, approvals, authorizations, registrations, certificates, variances and similar rights obtained, or required to be obtained, from Governmental Authorities.

"**Person**" means an individual, corporation, partnership, joint venture, limited liability company, Governmental Authority, unincorporated organization, trust, association or other entity.

"**Pre-Closing Tax Liability**" means all unpaid Taxes of Company for all taxable periods ending on or before the Closing Date and, for any Straddle Period, the Straddle Period Prorated Taxes for the portion of any such taxable period up to and including the Closing Date.

"**Post-Closing Tax Period**" means any taxable period ending after the Closing Date.

"**Pre-Closing Tax Period**" means any taxable period ending on or before the Closing Date.

"**Preferred Stockholders**" means collectively, the holders of Company Preferred Stock.

"**Products**" means any product that Company has manufactured, distributed, marketed or sold, or is manufacturing, distributing, marketing or selling, and/or any products currently under preclinical or clinical development by Company at Closing, including in each case any modifications or improvements thereto, including but not limited to Fiera® personal care devices, Sofsense™ rings, chargers, and including improvements, derivatives, and the like.

"**Real Property**" means the real property owned, leased or subleased by Company, together with all buildings, structures and facilities located thereon.

"**Release**" means any actual release, spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, abandonment, disposing or allowing to escape or migrate into or through the environment (including, without limitation, ambient air (indoor or outdoor), surface water, groundwater, land surface or subsurface strata or within any building, structure, facility or fixture), including the abandonment or discarding of barrels, containers and other closed receptacles containing any Hazardous Materials.

"**SEC**" means the United States Securities and Exchange Commission.

"**Securities Act**" means the Securities Act of 1933, as amended, or any successor federal statute thereto and the rules and regulations of the SEC promulgated thereunder.

"**Securityholder Transaction Expenses**" means, without duplication, all (i) unpaid third party fees and expenses, including any fees expenses payable to counsel, accountants, investment bankers and consultants, payable by Company arising from, incurred in connection with or incident to this Agreement, the Merger and the transactions contemplated hereby, including the drafting, negotiation, execution and delivery of this Agreement and all of the other agreements and documents contemplated hereby, and (ii) fifty percent (50%) of any Transfer Taxes; provided, for the avoidance of doubt, that Securityholder Transaction Expenses shall not include any severance, change of control or other similar payments, including accrued vacation and accrued bonuses and other similar compensation paid or payable in connection with the termination of any employee of the Company in connection with or as a result of the Merger and the transactions contemplated hereby.

"**Stockholder**" means a holder of Company Stock immediately prior to the Effective Time.

"**Straddle Period**" means any Tax period that includes but does not end on the Closing Date.

"**Straddle Period Prorated Taxes**" as of the Closing Date means (a) for any (i) income, payroll or other Taxes measured by net income or receipts, (ii) Taxes imposed in connection with the sale, transfer, or assignment of property, or (iii) Taxes required to be withheld, the liability for Taxes that would arise upon a deemed "closing of the books" on the Closing Date if the Closing Date is not otherwise the last day of a taxable period (provided that any deduction or allowance for depreciation or amortization shall be allocated on a per diem basis), and (b) for any other Taxes, including ad valorem Taxes or other Taxes determined with respect to a period of time, the portion of such Taxes that are accrued on the Closing Date based on the applicable number of days in the taxable period arising on or before the Closing Date as compared to the total taxable days in the applicable taxable period.

"**Subsidiary**" means, with respect to any Person, any corporation, partnership, association, limited liability company, unlimited liability company or other business entity of which (a) if a corporation, a majority of the total voting power of shares of stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person or a combination thereof, or (b) if a partnership, association, limited liability company, or other business entity, a majority of the partnership or other similar ownership interests thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more Subsidiaries of that Person or a combination thereof. For purposes hereof, a Person or Persons shall be deemed to have a majority ownership interest in a partnership, association, limited liability company, or other business entity if such Person or Persons are allocated a majority of partnership, association, limited liability company, or other business entity gains or losses or otherwise control the managing director, managing member, general partner or other managing Person of such partnership, association, limited liability company, or other business entity.

"**Unpaid Contractual Obligations**" means those amounts due to each of ExploraMed NC6, LLC under than certain Business Services Agreement dated September 27, 2012 and Torreya Capital Partners under that certain Engagement Letter dated July 27, 2016.

"**Tax**" or "**Taxes**" means (a) any federal, provincial, territorial, state, municipal, school board, school, local or non-U.S. taxes, like charges, levies, like fees or assessments imposed by any Governmental Authority, including income, gross receipts, business, capital, capital gains, goods and services, provincial sales, registration, value added, escheat, excise (including medical device excise), severance, premium, windfall profit, customs, duties, land transfer, personal property, employment, payroll, license, employee, capital stock, franchise, profits, withholding, social security, unemployment, health, employment insurance, governmental pension plan premiums or contributions, disability, real property, ad valorem/personal property, stamp, occupation, sales, use, transfer, value added, alternative minimum, estimated or other similar tax, and (b) any interest, penalty or addition thereto imposed by any Governmental Authority whether disputed or not.

"**Tax Return**" means any return, declaration, report, claim for refund, information return or statement or other document relating to Taxes that is filed or required to be filed with a Governmental Authority responsible for Tax administration, including any schedule or attachment thereto, and including any amendment thereof.

"**Treasury Regulations**" means the final or temporary regulations promulgated under the Code, as such regulations may be amended from time to time.

"**WARN Act**" means the federal Worker Adjustment and Retraining Notification Act of 1988, and similar state, local and foreign laws related to plant closings, relocations, mass layoffs and employment losses.

"**Warrant Holder**" means a holder of one or more Warrants.

"**Warrants**" means warrants issued by Company to purchase Company Stock.

Section 9.2 Other Defined Terms. The following terms have the meanings defined for such terms in the Sections set forth below

Term	Section
Accelerated Payment	Annex 1
Acquisition Proposal	Section 5.3(a)
Advisory Group	Section 8.1(c)
Affiliate Transaction	Section 3.29
Agreement	Preamble
Agreement Date	Preamble
Appraisal Demands	Section 1.5
Balance Sheet	Section 3.6
Balance Sheet Date	Section 3.6
Benefit Plan	Section 3.20(a)
Certificates of Merger	Section 1.2
Claiming Party	Section 7.5(a)
Closing	Section 1.2
Closing Date	Section 1.2
Company	Preamble
Company Board	Recitals
Company Intellectual Property	Section 3.12(a)
Company's Investment Bank	Section 3.30
Conflicts	Section 7.6(b)
Defending Party	Section 7.5(a)
Dissenting Shares	Section 1.5
Distribution Schedule	Section 1.4(c)
Divestiture Consideration	Annex 1

Term	Section
Earnout Accounting Firm	Annex 1
Earnout Objection Statement	Annex 1
Earnout Payments	Section 9.1
Earnout Share Amount	Annex 1
Earnout Statement	Annex 1
Effective Time	Section 1.2
FCPA	Section 3.24
Financial Statements	Section 3.6
First Certificate of Merger	Section 1.2
Government Grants	Section 3.26
Initial Surviving Corporation	Section 1.1
Insurance Policies	Section 3.16
Integrated Transaction	Recitals
Intellectual Property	Section 3.12(a)
Intellectual Property Registrations	Section 3.12(b)
Interim Balance Sheet	Section 3.6
Interim Balance Sheet Date	Section 3.6
Interim Financial Statements	Section 3.6
Letters of Transmittal	Section 1.4(b)
Licensed Intellectual Property	Section 3.12(a)
Loss or Losses	Section 7.2(a)
Material Contracts	Section 3.9(a)
Material Customers	Section 3.15(a)
Material Suppliers	Section 3.15(a)
Merger	Recitals
Merger Sub	Preamble
Mergers	Recitals
Milestone Payment	Annex 1
Multiemployer Plan	Section 3.20(c)
Parent	Preamble
Parent Balance Sheet	Section 4.9(c)
Parent Balance Sheet Date	Section 4.9(c)
Parent Financial Statements	Section 4.9(b)
Parent Indemnitees	Section 7.2(a)
Parent SEC Reports	Section 4.9(a)
Paying Agent	Section 1.4(a)
Paying Agent Agreement	Section 1.4(a)
Permitted Encumbrances	Section 3.10
Qualified Benefit Plan	Section 3.20(c)
Related Party	Section 3.29
Representative	Preamble
Representative Group	Section 8.1(c)
Required Stockholder Approval	Recitals
Revenue Earnout Payments	Annex 1
Second Certificate of Merger	Section 1.2
Second Merger	Recitals
Second Merger Sub	Recitals
Securityholder Indemnitees	Section 7.3
Seller Products	Section 5.15
Stockholders	Recitals

Term	Section
Surviving Company	Section 1.1(b)
Third Party Claim	Section 7.6(a)
Trademarks	Section 3.12(a)(i)
Transfer Taxes	Section 7.8(c)
Union	Section 3.21(b)
Year-End Financial Statements	Section 3.6

ARTICLE 10.
MISCELLANEOUS

Section 10.1 **Press Releases and Communications**. Prior to issuing any press release relating to this Agreement, Parent will submit such press release to Representative for its consent, which will not be unreasonably withheld; *provided* that Parent shall use its best efforts to exclude any financial deal terms from any such press release or public filing. Company and the Representative shall not, without the prior written consent of Parent, issue any press release or otherwise make any public statements with respect to this Agreement or the transactions contemplated; *provided, however,* that the foregoing will not restrict or prohibit Company from making any announcement to its employees, customers and other business relations with the prior approval of Parent, such approval not to be unreasonably withheld or delayed.

Section 10.2 **Expenses**. Except as otherwise expressly provided herein, all costs and expenses, including, without limitation, fees and disbursements of counsel, financial advisors and accountants, incurred in connection with this Agreement and the transactions contemplated hereby shall be paid by the party incurring such costs and expenses, whether or not the Closing shall have occurred.

Section 10.3 **Notices**. All notices, requests, consents, claims, demands, waivers and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand; (b) two (2) Business Days following deposit with a nationally recognized overnight courier (receipt requested); (c) on the date sent by facsimile or e-mail of a PDF document (with confirmation of transmission) if sent during normal business hours of the recipient, and on the next Business Day if sent after normal business hours of the recipient or (d) on the third day after the date mailed, by certified or registered mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the following addresses (or at such other address for a party as shall be specified in a notice given in accordance with this Section 10.3):

If to Parent or Merger Sub:

Aytu BioScience, Inc.
373 Inverness Parkway, Suite 206
Englewood, CO 80112
E-mail:
Attention:

with a copy to:	Wyrick Robbins Yates & Ponton LLP 4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607 Facsimile: (919) 781-4865 E-mail: dmannheim@wyrick.com Attention: W. David Mannheim and Zachary R. Bishop
If to Representative:	
with a copy to:	
If to Company:	Nuelle, Inc. 2570 W. El Camino Real Suite 310 Mountain View, CA 94040 Facsimile: E-mail: ebright@nuelle.com Attention: Earl Bright
with a copy to:	Wilson Sonsini Goodrich & Rosati P.C. 650 Page Mill Road Palo Alto, CA 94304 E-mail: poettinger@wsgr.com Attention: Philip Oettinger

Section 10.4 **Interpretation**. For purposes of this Agreement, (a) the words “include,” “includes” and “including” shall be deemed to be followed by the words “without limitation”; (b) the word “or” is not exclusive; (c) the words “herein,” “hereof,” “hereby,” “hereto” and “hereunder” refer to this Agreement as a whole; (d) the word “will” shall be construed in the imperative having the same meaning as the word “shall”; (e) the word “day”, “quarter” or “year” means a calendar day, quarter or year (except where a fiscal day, quarter or year is expressly referenced); (f) the word “notice” requires notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (g) provisions that require that a party or the parties “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (h) words of any gender include the other gender; and (i) words using the singular or plural number also include the plural or singular number, respectively. Unless the context otherwise requires, references herein: (x) to Articles, Sections, Company Disclosure Schedules, Parent Disclosure Schedules and Exhibits mean the Articles and Sections of, and Company Disclosure Schedules, Parent Disclosure Schedules and Exhibits attached to, this Agreement; (y) to an agreement, instrument or other document means such agreement, instrument or other document as amended, supplemented and modified from time to time to the extent permitted by the provisions thereof and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted.

Section 10.5 **Headings**. The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

Section 10.6 **Severability**. If any term or provision of this Agreement is invalid, illegal or unenforceable in any jurisdiction, such invalidity, illegality or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

Section 10.7 **Entire Agreement**. This Agreement (including the Exhibits and Schedules hereto) constitute the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein and therein, and supersede all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event of any inconsistency between the statements in the body of this Agreement, the Exhibits, Company Disclosure Schedules (other than an exception expressly set forth as such in the Company Disclosure Schedules) Parent Disclosure Schedules (other than an exception expressly set forth as such in the Parent Disclosure Schedules), and other Schedules hereto, the statements in the body of this Agreement will control.

Section 10.8 **Successors and Assigns**. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither party may assign its rights or obligations hereunder without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed. No assignment shall relieve the assigning party of any of its obligations hereunder.

Section 10.9 **No Third-party Beneficiaries**. Except as provided in Article 7 or Section 5.10, this Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

Section 10.10 **Amendment and Modification; Waiver**. This Agreement may only be amended, modified or supplemented by an agreement in writing signed by each party hereto; provided that after the Effective Time, Parent and the Representative may cause this Agreement to be amended by execution of an instrument in writing signed on behalf of Parent and the Representative. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. No waiver by any party shall operate or be construed as a waiver in respect of any failure, breach or default not expressly identified by such written waiver, whether of a similar or different character, and whether occurring before or after that waiver. No failure to exercise, or delay in exercising, any right, remedy, power or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power or privilege.

Section 10.11 Governing Law; Submission to Jurisdiction; Waiver of Jury Trial .

(a) This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware any other jurisdiction).

(b) ANY LEGAL SUIT, ACTION OR PROCEEDING ARISING OUT OF OR BASED UPON THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY MAY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF DELAWARE IN EACH CASE LOCATED IN THE CITY OF RALEIGH, COUNTY OF WAKE, AND EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING. SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT BY MAIL TO SUCH PARTY'S ADDRESS SET FORTH HEREIN SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUIT, ACTION OR OTHER PROCEEDING BROUGHT IN ANY SUCH COURT. THE PARTIES IRREVOCABLY AND UNCONDITIONALLY WAIVE ANY OBJECTION TO THE LAYING OF VENUE OF ANY SUIT, ACTION OR ANY PROCEEDING IN SUCH COURTS AND IRREVOCABLY WAIVE AND AGREE NOT TO PLEAD OR CLAIM IN ANY SUCH COURT THAT ANY SUCH SUIT, ACTION OR PROCEEDING BROUGHT IN ANY SUCH COURT HAS BEEN BROUGHT IN AN INCONVENIENT FORUM.

(c) EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY. EACH PARTY TO THIS AGREEMENT CERTIFIES AND ACKNOWLEDGES THAT (A) NO REPRESENTATIVE OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT SEEK TO ENFORCE THE FOREGOING WAIVER IN THE EVENT OF A LEGAL ACTION, (B) SUCH PARTY HAS CONSIDERED THE IMPLICATIONS OF THIS WAIVER, (C) SUCH PARTY MAKES THIS WAIVER VOLUNTARILY, AND (D) SUCH PARTY HAS BEEN INDUCED TO ENTER INTO THIS AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 10.11(C).

Section 10.12 Specific Performance. The parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the parties shall be entitled to specific performance of the terms hereof, in addition to any other remedy to which they are entitled at law or in equity.

Section 10.13 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, e-mail or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first written above by their respective officers thereunto duly authorized.

COMPANY:

NUELLE, INC.

By /s/ Karen Long
Name: Karen Long
Title: President and CEO

PARENT:

AYTU BIOSCIENCE, INC.

By /s/ Joshua Disbrow
Name: Joshua Disbrow
Title: Chief Executive Officer

MERGER SUB:

AYTU ACQUISITION CORPORATION, INC.

By /s/ Joshua Disbrow
Name: Joshua Disbrow
Title: President

SECOND MERGER SUB:

AYTU HOLDINGS, LLC

By /s/ Joshua Disbrow
Name: Joshua Disbrow
Title: President

REPRESENTATIVE:

Earl Bright, solely in his capacity as the Representative

By /s/ Earl Bright
Name: Earl Bright
Title: Representative

ANNEX 1.
EARNOUT CALCULATION

A. Certain Defined Terms.

"**Bundled Product**" means a Company Product and other products that are not such Company Product either (a) packaged together for sale or shipment as a single unit or (b) sold together.

"**Commercially Reasonable Best Efforts**" shall mean, for the purposes of this Annex 1, with respect to the efforts and resources to be expended, or considerations to be undertaken, by Parent such reasonable, good faith best efforts and resources as a device company of a similar size and with similar revenues as Parent would normally use to accomplish a similar objective, activity or decision under similar circumstances.

"**Company Product**" means (i) any product that incorporates any portion of Company Intellectual Property existing as of the Closing or Licensed Intellectual Property existing as of the Closing, and that is being acquired by Parent through the Merger, but for any ownership or license thereof, would infringe a Valid Claim with respect to any Company Intellectual Property existing as of the Closing or Licensed Intellectual Property existing as of the Closing, and/or (ii) any Product that is being acquired by Parent through the Merger.

"**Divestiture**" (and other correlative terms) shall mean any transaction in which any Company Product or any intellectual property or regulatory assets related to the same are divested or transferred by any means, directly or indirectly, including by way of merger, consolidation, asset acquisition or sale, license, sublicense, purchase, sale, assignment or other similar transfer; *provided, however,* that a Divestiture shall not include (i) any transfer to a member of Parent Group, or (ii) sales of any Company Product in the ordinary course of business of Parent or the Company.

"**Earnout Period**" means the period from the date hereof until all of the payments have been made pursuant to Sections B and C below.

"**Earnout Year**" means each of the twelve months periods commencing on June 1 of the Earnout Period.

"**Licensee**" means, with respect to Parent Group, any licensee of a member of Parent Group, any sublicensee of any such licensee (ad infinitim), and any distributor of a member of Parent Group or any such licensee or sublicensee.

"**Net Sales**" means gross amounts invoiced, deemed invoiced or otherwise received for sales of Company Products by Parent Group and any Licensees (each, a "**Selling Party**"), less the sum of the following, solely to the extent related to the sale of such Company Products: (1) sales, value added, use, excise, and similar taxes; (2) amounts allowed or credited on returns of Company Products; (3) freight, shipping, handling, and insurance charges; (4) import or export duties, tariffs, or similar charges incurred with respect to the import or export of Company Products into or out of any country; (5) any coupons, discounts or rebates; and (6) third party licensing fees. Such amounts shall be determined from the books and records of the Selling Party maintained in accordance with GAAP as consistently applied by the Selling Party across its operations. Parent shall cause each Licensee to maintain all necessary books and records and to provide reports and otherwise grant access to such books and records to Parent and its Agents in order for Parent to satisfy its record maintenance and reporting obligations hereunder. Company Products are considered "sold" when billed out or invoiced or, in the event such Company Products are not billed out or invoiced, Products are considered "deemed invoiced" when the consideration for sale of the Company Products is received or when the Product is shipped to any third party, with or without consideration. If a sale, transfer or other disposition of Company Products involves consideration other than cash or is not at arm's length, then the Net Sales from such sale, transfer or other disposition shall be the arm's length fair market value, which generally will mean the Selling Party's Per Unit Average Selling Price. Whenever any Company Product is sold as part of a Bundled Product, the "Net Sales" for such Company Product resulting from such sale of such Bundled Product shall be the product of (i) the number of units of such Bundled Product sold by one or more members of Parent Group and any Licensees multiplied by (ii) the Per Unit Average Selling Price of such Company Product. For the avoidance of doubt, Net Sales does not include sales of products of Parent, any Affiliate of Parent, or of any other party that are not Company Products, as such term is defined above.

"**Parent Group**" means Parent and its direct and indirect Subsidiaries and Affiliates including, after the Effective Time, the Surviving Corporation.

"**Parent Trading Price at Date of Accelerated Payment**" means the mean of the average of the closing price of Parent Shares as reported on OTC Markets (or such national or foreign securities exchange on which Parent's shares are listed) for the ten (10) trading days immediately prior to the earlier of (i) the date of closing of the Divestiture or (ii) any public announcement relating to the Divestiture (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting the Parent Shares).

"**Parent Trading Price at Delivery of Earnout Statement**" means the mean of the average of the closing price prices of Parent Shares as reported on OTC Markets (or such national or foreign securities exchange on which Parent's shares are listed) for the ten (10) trading days immediately prior to the earlier of (i) the date of Parent's delivery of an Earnout Statement reflecting the amount of any Revenue Earnout Payment or Milestone Payment (as defined below), or (ii) any public announcement by Parent Group that it owes any Revenue Earnout Payment or Milestone Payment (subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting the Parent Shares).

"**Per Unit Average Selling Price**" means, with respect to a Company Product in a given Earnout Year, an amount equal to the greater of (1) the price per unit at which the Company sold such Company Product immediately preceding the Closing Date, and (2) the quotient of (x) the total amount of annual Net Sales of such Company Product, not including any such Company Products that are sold as a Bundled Product, divided by (y) the total number of units of such Company Products sold during such year, not including any such Company Products that are sold as a Bundled Product.

"**Valid Claim**" means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing to be invalid or unenforceable or of a scope not covering a particular technology, product, services, process, or method through reissue, disclaimer or otherwise.

B. Revenue Earnout Payments

During the Earnout Period, Parent shall pay the Company Securityholders an amount equal to the following (the " **Revenue Earnout Payments**"):

[*]% of Net Sales of Company Products for cumulative Net Sales between $0 and $[*] (this payment to be made in Parent Shares).

[*]% of Net Sales of Company Products for cumulative Net Sales between $[*] and $[*].

[*]% of Net Sales of Company Products for cumulative Net Sales between $[*] and $[*].

[*]% of Net Sales of Company Products for cumulative Net Sales between $[*] and $[*].

[*]% of Net Sales of Company Products for cumulative Net Sales between $[*] and $[*].

All of the payments set forth in this Section B above: (i) will be made for the preceding twelve month period ended June 30; and (ii) are due and payable within 90 days of June 30.

C. Milestone Earnout Payments

In addition to the amounts payable under B above, during the Earnout Period, Parent shall pay the Company Securityholders an amount equal to the following (each a "**Milestone Payment**"):

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

Upon achieving the first occurrence of Net Sales of $[*] over any sequential four calendar quarter period, Parent will make a one-time payment to the Company Securityholders of an amount equal to $[*].

All of the payments set forth in this Section C above are due and payable within 90 days of achieving the applicable milestone. For clarity, the Milestone Payments set forth above are one-time payments only, but if more than one milestone event occurs in any sequential four calendar quarter period, all corresponding Milestone Payments for such milestone events so occurring in such period shall be due as described in this Annex 1.

For example, if Net Sales reach $[*] for the sequential four calendar quarters ending December 31, 2018 (and no previous Milestone Payments have been made), Parent will make a Milestone Payment to the Company Securityholders in an amount equal to $[*], which will be paid on or before March 31, 2019, but no additional Milestone Payments will be payable to the Company Securityholders unless and until Net Sales reaches $[*] over any sequential four calendar quarter period.

D. Reporting

Parent shall provide the Representative (1) within ninety (90) days after the end of each calendar year, a written report indicating, on a product-by-product basis, Parent's calculation of Net Sales of Company Products and each component thereof, including total gross invoiced amounts and amounts deducted by category from gross invoiced amounts to calculate Net Sales, and (2) as soon as reasonably practicable following the due date for Parent Group's release of earnings for each Earnout Year, but no later than ten (10) Business Days after such release, Parent's calculation of the applicable Revenue Earnout Payment or Milestone Payment, if any, and information and data reflecting and demonstrating the Net Sales for such Earnout Year. All such amounts shall be expressed in U.S. dollars, and such reports shall include the rates of exchange used to convert to U.S. dollars from the currency in which such sales were made or payments received.

E. Payment

On or before the tenth (10^{th}) Business Day following the date on which the Representative accepts Parent's calculation of the Revenue Earnout Payments or Milestone Payment (either by delivering written notice of acceptance to Parent or deemed acceptance under Section F below) or the Revenue Earnout Payment or Milestone Payment is finally determined under Section F below, Parent shall (i) pay to the Paying Agent, who shall in turn pay to each Company Securityholder such Company Securityholder's Distribution Allocation of the cash portion of such Revenue Earnout Payment or Milestone Payment, by wire transfer of immediately available funds, and (ii) deliver to each Company Securityholder a number of Parent Shares (rounded to the nearest share) equal to (A) such Company Securityholder's Distribution Allocation of the Parent Share portion of such Revenue Earnout Payment or Milestone Payment divided by (B) the Parent Trading Price at Delivery of Earnout Statement.

To the extent payment of any Accelerated Payment (as defined below), Revenue Earnout Payment or Milestone Payment in cash would disqualify the Mergers from being a reorganization under Section 368 of the Code and the Treasury Regulations promulgated thereunder as determined pursuant to the second sentence of Section 7.8(d), each party hereto agrees to such payment will be made in Parent Shares at the Parent Trading Price at Date of Accelerated Payment or Parent Trading Price at Delivery of Earnout Statement, as applicable.

F. Objections

Parent shall, and shall cause its Parent Group to, keep complete, true and accurate books of account and records showing the derivation of the amounts of all Revenue Earnout Payments or Milestone Payments, including, without limitation, on a product-by-product basis, Parent's calculation of Net Sales and each component thereof, including total gross invoiced amounts and amounts deducted by category from gross invoiced amounts to calculate Net Sales. Parent shall, and shall cause the Parent Group to provide Representative and its Agents with reasonable access during normal business hours to the books, records (including work papers, schedules, memoranda and other documents), supporting data and employees of Parent Group to the extent reasonably necessary to verify any Revenue Earnout Payment or Milestone Payment. If the Representative has any objections to the statements described in Section D above (each, an "**Earnout Statement**"), the Representative shall deliver to Parent a statement setting forth, in reasonable detail, its objections thereto (each, an " **Earnout Objection Statement**"). If an Earnout Objection Statement is not delivered to Parent within thirty (30) days after delivery of an Earnout Statement, such Earnout Statement as prepared by Parent shall be deemed irrevocably accepted by the Representative on behalf of the Company Securityholders and be final, binding and non-appealable by the parties and the Company Securityholders. The Representative and Parent shall negotiate in good faith to resolve the objections raised in any Earnout Objection Statement, but if they do not reach a final resolution within thirty (30) days after the delivery of an Earnout Objection Statement to Parent, any unresolved disputes shall be submitted to an independent national accounting firm mutually selected by Parent and the Representative (the "**Earnout Accounting Firm**"). In the event any such dispute is submitted to the Earnout Accounting Firm, each party shall be permitted to submit a statement setting forth its calculation of the applicable Revenue Earnout Payment or Milestone Payment, together with such supporting documentation as it deems appropriate, to the Earnout Accounting Firm. The Representative and Parent shall use their respective commercially reasonable efforts to cause the Earnout Accounting Firm to resolve such dispute as soon as practicable, but in any event within thirty (30) days after the date on which the Earnout Accounting Firm receives the applicable statements prepared by the Representative and Parent. The calculation of any Revenue Earnout Payment or Milestone Payment as finally determined by the Earnout Accounting Firm (which such determination shall be made in a manner consistent with the terms of this Agreement and shall not, for any Revenue Earnout Payment or Milestone Payment, be less than the amount set forth in the applicable Earnout Statement nor exceed the amount set forth in the applicable Earnout Objection Statement) shall be final, binding and non-appealable among the parties. Each party shall bear its own costs and expenses in connection with the resolution of such dispute by the Earnout Accounting Firm. All costs and expenses of the Earnout Accounting Firm, if any, shall be paid by the parties proportionately based on the difference of each party's calculation of the applicable Revenue Earnout Payment or Milestone Payment as compared to the final determination of the Earnout Accounting Firm. For example, if Parent proposes a Revenue Earnout Payment or Milestone Payment of $100, the Representative proposes a Revenue Earnout Payment or Milestone Payment of $200, and the final determination of the Earnout Accounting Firm is $160, then 60% of the costs of the Earnout Accounting Firm's review would be borne by Parent and 40% of such costs would be borne by the Representative (on behalf of the Company Securityholders). Notwithstanding the foregoing, in the event that the Earnout Accounting Firm determines that the actual amount of any Revenue Earnout Payment or Milestone Payment exceeds Parent's determination of such Revenue Earnout Payment or Milestone Payment by five percent (5%) or more, then Parent shall pay all costs and expenses of the Earnout Accounting Firm and Representative (with respect to its resolution of the corresponding dispute.

G. Divestiture

1. If Parent (a) does not make all of the payments to the Company Securityholders under Sections B or C of this Annex 1 before May 3, 2022, and (b) closes a Divestiture before May 3, 2022, Parent shall make the Accelerated Payment (as defined below) to the Company Securityholders. Parent shall pay and deliver to the Paying Agent, who shall in turn (i) pay to each Company Securityholder such Company Securityholder's Distribution Allocation of the cash portion of such Accelerated Payment, by wire transfer of immediately available funds, and/or (ii) deliver to each Company Securityholder a number of Parent Shares (rounded to the nearest share) equal to (A) such Company Securityholder's Distribution Allocation of the Parent Share portion of such Accelerated Payment divided by (B) the Parent Trading Price at Date of Accelerated Payment.

"**Accelerated Payment**" means an amount equal to ten percent (10%) of the Divestiture Consideration (as defined below).

"**Divestiture Consideration**" means:

(i) in the case of an asset sale or license (or sublicense) transaction , the sum of all cash and the fair market value of all securities or other property payable to Parent Group in consideration of the transaction at any time, less all current and long-term liabilities (but not contingent liabilities) of Parent Group that are not discharged or assumed by the buyer or licensee (or its affiliates) in connection with the transaction; or

(iii) in the case of a merger or stock sale, the sum of all cash, and the fair market value of all securities and other property payable to the stockholders of Parent Group (and any option holders or warrant holders) in return for their stock (or options or warrants) in Parent Group at any time.

The valuation of any securities or other property shall be determined by reference to the operative transaction agreement for a respective merger, stock sale or asset sale, provided that, if no such valuation is readily determinable from such operative transaction agreement, then for securities for which there is an active public market;

(a) if traded on a securities exchange or the NASDAQ Stock Market, the value shall be deemed to be the average of the closing prices of the securities on such exchange or market over the 10 day period ending three days prior to the closing of such transaction; or

(b) if actively traded over-the-counter, the value shall be deemed to be the average of the closing bid prices over the 10 day period ending three days prior to the closing of such transaction.

The method of valuation of securities subject to investment letters or other similar restrictions on free marketability shall take into account an appropriate discount from the market value as determined pursuant to clause (a) or (b) above so as to reflect the approximate fair market value thereof.

For securities for which there is no active public market, the value shall be the fair market value thereof as either (i) determined in good faith by the Board of Directors of Parent, (ii) approved by the Representative, such approval not to be unreasonably withheld, or (iii) determined by a third party appraiser appointed and paid for by the Parent Group.

2. Upon the closing of the Divestiture, all Revenue Earnout Payments and Milestone Payments shall immediately cease, and the provisions of Sections B and C above shall be thereafter null and void and of no effect, and no more Earnout Payments of Milestone Payments will be paid, except for those that are due and payable prior to the closing of the Divestiture.

I. Miscellaneous.

1. All payments required pursuant to this Annex 1 shall be deemed to be adjustments for Tax purposes to the aggregate consideration paid by Parent pursuant to this Agreement (in the case of Parent, in respect of the shares in the Surviving Company held by Parent as a result of the Mergers), unless otherwise required by applicable Law.

1. Parent shall, and shall cause its Affiliates to, make an appropriate number of sales calls on not less than 75% of the clinicians identified in Attachment A to this Annex 1 for a period of no less than eighteen months, commencing on the Closing Date, and use Commercially Reasonable Best Efforts to sell the Company Products, which includes, without limitation, Parent engaging an appropriately incentivized sales force for the Company Products for a period of no less than eighteen months, commencing on the Closing Date. Notwithstanding the foregoing, the obligation of Parent to use, or cause its Affiliates to use, such Commercially Reasonable Best Efforts shall not be deemed a guarantee or assurance of any kind that any Net Sales will be earned. Except as specifically provided in this paragraph, from and after the Effective Time, all decisions and efforts with respect to the operation or conduct of business of the Surviving Company shall be in Parent's sole and absolute discretion without any express or implied warranty or covenant of any kind to any Stockholder or anyone else. The parties acknowledge and agree that Parent and its Affiliates owe no fiduciary duty to the Company, the Surviving Company or the Stockholders with respect any payment under this Annex A.

2. At any time following the day that is eighteen months after any Earnout Payment is due hereunder, the Surviving Company shall be entitled to require the Paying Agent to deliver to it any funds (including any earnings received with respect thereto) and any Parent Shares that had been made available to the Paying Agent with respect to such Earnout Payment and that have not been disbursed to Company Securityholders and thereafter such Company Securityholders shall be entitled to look only to Parent and the Surviving Company (subject to abandoned property, escheat or other similar Laws) and only as general creditors thereof with respect to the applicable portion of the Earnout Payment payable to them, without any interest thereon.

Exhibit A

CERTIFICATE OF INCORPORATION
OF
AYTU ACQUISITION CORPORATION, INC.

FIRST: The name of the corporation is Aytu Acquisition Corporation, Inc. (the "***Corporation***").

SECOND: The address of the Corporation's registered office in the State of Delaware is 3500 South DuPont Highway, in the City of Dover, Kent County, Delaware 19901. The name of its registered agent at such address is Incorporating Services, Ltd.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.

FOURTH: The total number of shares that the Corporation shall have authority to issue is two million (2,000,000) shares, $0.0001 par value per share. The Corporation is authorized to issue one class of stock to be designated Common Stock.

FIFTH: The name and mailing address of the incorporator are as follows:

Zachary R. Bishop	4101 Lake Boone Trail, Suite 300 Raleigh, NC 27607

SIXTH: Unless and except that the bylaws of the Corporation shall so require, the election of directors of the Corporation need not be by written ballot.

SEVENTH: To the fullest extent permitted by the Delaware General Corporation Law as the same exists or as may hereafter be amended, no present or former director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article, nor the adoption of any provision of this Certificate of Incorporation inconsistent with this Article, shall eliminate or reduce the effect of this Article in respect of any matter occurring, or any cause of action, suit or claim that, but for this Article, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

EIGHTH: The Corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to, or testifies in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature, by reason of the fact such person is or was a director, officer or employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, employee benefit plan, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding to the full extent permitted by law, and the Corporation may adopt bylaws or enter into agreements with any such person for the purpose of providing for such indemnification.

NINTH: The Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, and other provisions authorized by the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this Article.

TENTH: In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized to make, alter and repeal the bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw whether adopted by them or otherwise.

The undersigned incorporator hereby acknowledges that the foregoing Certificate of Incorporation is his act and deed.

Dated: May ___, 2017

Zachary R. Bishop, Incorporator

Exhibit B

Paying Agent Agreement

PAYING AGENT AGREEMENT

This Paying Agent Agreement (this "**Agreement**") is entered into as of _____, 2017, by and among AYTU BIOSCIENCE, INC., a Delaware corporation ("**Parent**"), EARL BRIGHT (the "**Representative**"), and VSTOCK TRANSFER, LLC, a California limited liability company (the "**Paying Agent**").

RECITALS

A. Pursuant to a Merger Agreement dated as of May ___, 2017 (the "**Merger Agreement**"), by and among Parent, Nuelle, Inc., a Delaware corporation ("**Company**"), AYTU ACQUISITION CORPORATION, INC., a Delaware corporation ("**Merger Sub**"), AYTU HOLDINGS, LLC, a Delaware limited liability company ("**Second Merger Sub**"), and the Representative, Merger Sub will merge with and into Company, leaving Company as the initial surviving corporation (the "**Initial Surviving Corporation**"). The Initial Surviving Corporation will then merge with and into Second Merger Sub, leaving Second Merger Sub as the surviving company (the "**Surviving Company**"). Capitalized terms used but not expressly defined in this Agreement shall have the meanings ascribed to them in the Merger Agreement.

B. The Merger Agreement describes an amount of shares of Parent common stock (the "**Paying Agency Shares**") which Parent is required to deliver to the Paying Agent at the Closing for further distribution to the Company Securityholders and Creditors (each a "**Payee**").

C . Annex 1 of the Merger Agreement describes an amount of shares of Parent common stock (the "**Paying Agency Earnout Shares**") and amounts of cash (the "**Paying Agency Earnout Fund**") that Parent may be required to deliver to the Paying Agent for further distribution to the Payees.

D . Annex 1 of the Merger Agreement additionally describes an amount of shares of Parent common stock (the "**Paying Agency Acceleration Shares**") and amounts of cash (the "**Paying Agency Acceleration Fund**") that Parent may be required to deliver to the Paying Agent for further distribution to the Payees.

E. Through this Agreement, Parent and the Representative desire to appoint the Paying Agent as the "Paying Agent" under the Merger Agreement, and the Paying Agent desires to accept such appointment and to distribute the Paying Agency Shares, Paying Agency Earnout Shares, Paying Agency Earnout Fund, Paying Agency Acceleration Shares and Paying Agency Acceleration Fund and other materials discussed herein to the Payees pursuant to the terms of this Agreement.

AGREEMENT

NOW, THEREFORE, the parties agree as follows:

ARTICLE 11.APPOINTMENT OF PAYING AGENT. PAYING AGENT HEREBY ACCEPTS APPOINTMENT BY PARENT AND THE REPRESENTATIVE AS THE "PAYING AGENT" UNDER THE MERGER AGREEMENT AND, IN SUCH CAPACITY, SHALL BE AUTHORIZED AS THE PAYING AGENT TO ACT ON BEHALF OF THE SURVIVING COMPANY AND PARENT FOR THE PURPOSE OF DELIVERING THE PORTION OF THE AGGREGATE MERGER CONSIDERATION TO BE PAID TO COMPANY CREDITORS AS WELL AS IN EXCHANGE FOR SHARES OF THE COMPANY'S STOCK AND CONVERTIBLE DEBT (THE "COMPANY SECURITIES") AND PAY THE SAME TO THE PAYEES UPON SATISFACTION OF THE CONDITIONS SET FORTH HEREIN. PAYING AGENT HEREBY ACKNOWLEDGES THAT ITS DUTIES, LIABILITIES AND RIGHTS AS PAYING AGENT ARE AS SET FORTH HEREIN AND IN THE LETTER OF TRANSMITTAL.

ARTICLE 12.RECEIPT OF COMPANY SECURITIES AND RELATED MATERIALS. IN CONNECTION WITH THE RECEIPT OF COMPANY SECURITIES AND RELATED MATERIALS:

Section 12.1 Documents To Be Received. With respect to an exchange of Company Securities, the Paying Agent shall receive (i) a Letter of Transmittal (or facsimiles thereof), properly executed in accordance with the instructions therein, (ii) subject to Section 3(i) hereof, a Company stock certificate(s) or convertible note (the "**Certificate(s)**") from the Payees listed on the Distribution Schedule attached hereto as Exhibit A representing the Company Securities, and (iii) all other instruments and communications submitted to the Paying Agent in connection with the exchange of the Certificate(s), and the Paying Agent shall preserve the same, and upon request will deliver a copy of the same to Parent or otherwise disposed of them in accordance with the written instructions of the Parent.

Section 12.2 Examination of Documents. The Paying Agent shall examine the Letters of Transmittal and Certificate(s) and other documents received to ascertain whether: (i) the Letters of Transmittal and/or other documents appear to the Paying Agent to have been completed and executed in accordance with the instructions set forth in the Letter of Transmittal and (ii) the Certificate(s) appear to be properly surrendered and are in proper form for transfer in accordance with the instructions set forth in the Letter of Transmittal.

Section 12.3 Irregularities in Documents. In the event the Paying Agent determines that any Letter of Transmittal or other document has been improperly completed or executed, that any of the Certificate(s) are not in proper form, or some other irregularity exists, the Paying Agent shall follow its regular procedures to attempt to cause such irregularity to be corrected. As to any irregular item that the Paying Agent cannot resolve through its regular procedures, the Paying Agent shall consult with Parent and the Representative for instructions.

Section 12.4 Tax Documents. To the extent not included with the materials submitted with the Letter of Transmittal, the Paying Agent shall request and obtain from each Payee, before issuing any payment hereunder, tax identification numbers by means of a completed appropriate IRS Form W-9 or original W-8 and other forms and documents that the Paying Agent may reasonably request. The parties hereto understand that if such tax reporting documentation is not so certified to the Paying Agent, the Paying Agent may be required by the Internal Revenue Code of 1986, as amended, to withhold a portion of any interest and other earnings, if any, on the Paying Agency Earnout Fund and Paying Agency Acceleration Fund. To the extent that the Paying Agent becomes liable for the payment of any taxes in respect of income derived from the investment of funds held or payments made hereunder, the Parent and the Representative (solely on behalf of the Payees and not in its individual capacity) agree, jointly and severally, to indemnify the Paying Agent (and its officers, directors, employees, agents, attorneys and affiliates) (the "**Paying Agent Indemnitees**") for, and hold the Paying Agent Indemnitees harmless against any taxes, additions for late payment, interest, penalties and other expenses that may be assessed against the Paying Agent Indemnitees, unless any such tax, addition for late payment, interest, penalties and other expenses shall arise out of or be caused by the actions or failure to act of the Paying Agent Indemnitees.

ARTICLE 13.DISBURSEMENT OF PAYING AGENCY SHARES, PAYING AGENCY EARNOUT SHARES, PAYING AGENCY EARNOUT FUND, PAYING AGENCY ACCELERATION SHARES AND PAYING AGENCY ACCELERATION FUND.

Section 13.1 Deposit of Paying Agency Shares. On the Closing Date, Parent will deliver issuance instructions to the Paying Agent with respect to the Paying Agency Shares, and will deposit with the Paying Agent, or cause a third party to deposit, in electronic or book-entry form evidence of the Paying Agency Shares.

Section 13.2 Disbursement of Paying Agency Shares to Payees. The Paying Agent agrees, promptly after notice from Parent of the closing of the transaction contemplated by the Merger Agreement (which such notice may be by e-mail) (the "**Effective Time**"), to deliver, to each Payee who has completed a Letter of Transmittal and returned it to the Paying Agent, together with Certificates representing outstanding Company Securities (or an affidavit of lost stock certificate in form reasonably acceptable to Parent and Paying Agent), that portion of the Paying Agency Shares payable to such Payee promptly after receipt of such documentation but in any event within three (3) Business Days thereafter.

Section 13.3 Deposit of Paying Agency Earnout Shares and Paying Agency Earnout Fund. If Revenue Earnout Payments or Milestone Payments are required by Annex 1 of the Merger Agreement, Parent will deliver issuance instructions to the Paying Agent with respect to the Paying Agency Earnout Shares, and will deposit with the Paying Agent in a special account immediately available funds the portion of the Paying Agency Earnout Fund and will deposit with the Paying Agent, or cause a third party to deposit, in electronic or book-entry form evidence of the portion of the Paying Agency Earnout Shares collectively equal to such Revenue Earnout Payment or Milestone Payment; provided that Parent shall provide to the Paying Agent and the Representative no later than forty-eight (48) hours prior to making such deposit notice of, and a disbursement schedule for, the Revenue Earnout Payment or Milestone Payment. The funds on deposit in the Paying Agency Earnout Fund shall remain uninvested. The wire transfer instructions for the transfer of all funds to be delivered to the Paying Agent hereunder are:

VStock Transfer, LLC

ABA No.:
Acct No.:
Attention:
As the Paying Agent for:
For further credit to account number:

Section 13.4 Disbursement of Paying Agency Earnout Shares and Paying Agency Earnout Fund to Payees . Subject to any applicable withholding or backup withholding requirements of Section 5 hereof, the Paying Agent agrees to make the appropriate payment to each Payee of such Payee's portion of the Paying Agency Earnout Shares and Paying Agency Earnout Fund as set forth on a disbursement schedule provided by Parent and approved by the Representative in writing on the terms and conditions set forth herein, and in no event later than three (3) Business Days, after receiving all proper documentation from such Payee as described herein and approval of the Representative in writing.

Section 13.5 Deposit of Paying Agency Acceleration Shares and Paying Agency Acceleration Fund. If and only if Parent delivers to Representative written notice of a proposed Divestiture occurring on or before May 3, 2022 in accordance with the terms and conditions of Annex 1 of the Merger Agreement, then on or before the later of (a) closing of a Divestiture and (b) May 3, 2022, Parent will deliver issuance instructions to the Paying Agent with respect to the Paying Agency Acceleration Shares, will deposit with the Paying Agent in a special account immediately available funds the Paying Agency Acceleration Fund and will deposit with the Paying Agent, or cause a third party to deposit, in electronic or book-entry form evidence of the Paying Agency Acceleration Shares; provided that Parent shall provide to the Paying Agent and the Representative no later than forty-eight (48) hours prior to making such deposit notice of, and a disbursement schedule for, the Accelerated Payment. The funds on deposit in the Paying Agency Earnout Fund shall remain uninvested. The wire transfer instructions for the transfer of all funds to be delivered to the Paying Agent hereunder are:

VStock Transfer, LLC

ABA No.:
Acct No.:
Attention:
As the Paying Agent for:
For further credit to account number:

Section 13.6 Disbursement of Paying Agency Acceleration Shares and Paying Agency Acceleration Fund to Payees . Subject to any applicable withholding or backup withholding requirements of Section 5 hereof, the Paying Agent agrees to make the appropriate payment to each Payee of such Payee's portion of the Paying Agency Acceleration Shares and Paying Agency Acceleration Fund as set forth on a disbursement schedule provided by Parent and approved by the Representative in writing on the terms and conditions set forth herein, and in no event later than three (3) Business Days, after receiving all proper documentation from such Payee as described herein and approval of the Representative in writing.

Section 13.7 Delivery and Cancellation of Certificate(s). A Payee will not receive any consideration for his, her or its shares of Company Securities unless and until such Payee delivers the Letter of Transmittal or a facsimile thereof, duly completed and signed, to the Paying Agent, together with the Certificate(s) representing such Company Securities and any required accompanying evidences of authority in form satisfactory to the Paying Agent, who may request direction from the Parent as to whether or not such documentation and evidences of authority are deemed satisfactory. If the Certificate(s) have been lost, destroyed or wrongfully taken, the Payee will not receive any consideration for his, her or its Company Securities unless and until such Payee delivers the documents referred to in Section 3(i). Upon making payment for Company Securities, the Paying Agent shall physically cancel the Certificate(s) and retain them on behalf of the Surviving Company.

Section 13.8 Payment in Another Name. If payment is to be made by the Paying Agent to a person other than the person in whose name a surrendered Certificate(s) is/are registered, the Paying Agent shall make no payment until the Certificate(s) so surrendered has/have been properly endorsed (or otherwise put in proper form for transfer), including, without limitation, a Medallion Signature Guaranty if necessary, and the person requesting such payment has paid any transfer or other taxes or governmental charges required by reason of such payment in a name other than that of the registered holder of the Certificate(s) or has established to the Paying Agent's reasonable satisfaction that such tax or charge either has been paid or is not payable. Any tax information with respect to such payment which the Paying Agent is required to report pursuant to Section 5 of this Agreement shall list the registered holder of the Certificate(s) as the payee.

Section 13.9 Lost, Stolen or Mutilated Certificates. In the event a Payee claims a Certificate has been lost, stolen or destroyed, the Paying Agent shall mail to such Payee documentation and instructions necessary to be completed in order to effectively surrender the Company Securities represented by such Certificate, including instructions relating to the payment to secure an indemnity/surety bond. Upon its receipt of such items (in lieu of surrender of the lost, stolen or destroyed Certificate), accompanied by a duly executed Letter of Transmittal, the Paying Agent shall promptly make payment to the related holder in accordance with Sections 3(b), 3(d) and 3(f) hereof.

ARTICLE 14.INFORMATION AND REPORTS.

Section 14.1 Monthly Report. Upon written request, the Paying Agent shall deliver to the Representative and Parent, at the addresses listed in Section 12(b) hereof, and to such other persons as the Representative or Parent may designate, a monthly report of the items presented for exchange. Each such report shall include: the number of shares of Company stock or Convertible Debt and, Paying Agency Earnout Shares, Paying Agency Acceleration Shares and cash paid in exchange therefore (previous period, current period and total).

Section 14.2 Maintaining Records. The Paying Agent shall keep and maintain complete and accurate ledgers showing all shares of Company stock and Convertible Debt. The Paying Agent is authorized to cooperate with and furnish information to any organization or its legal representatives designated from time to time by the Representative or Parent in any manner reasonably requested by either of them in connection with the Mergers and share exchange pursuant thereto.

ARTICLE 15.TAX REPORTING.

Section 15.1 The Paying Agent shall prepare and mail to each Payee, other than Payee who demonstrate their status as nonresident aliens in accordance with United States Treasury Regulations, a Form 1099-B reporting any cash payments, in accordance with United States Treasury Regulations; the Paying Agent shall also prepare and electronically file copies of such Forms 1099-B with the Internal Revenue Service, in accordance with United States Treasury Regulations.

Section 15.2 If the Paying Agent has not received notice from the surrendering Payee of that Payee's certified Taxpayer Identification Number, the Paying Agent shall deduct and withhold backup withholding tax from any cash payment made pursuant to Internal Revenue Code regulations.

Section 15.3 Upon Paying Agent's request, Company agrees to consult with Paying Agent regarding Paying Agency's tax inquiries.

ARTICLE 16.DELIVERY OF PAYING AGENCY SHARES, , PAYING AGENCY EARNOUT SHARES, PAYING AGENCY EARNOUT FUND, PAYING AGENCY ACCELERATION SHARES AND PAYING AGENCY ACCELERATION FUND. ALL DISTRIBUTIONS OF PAYING AGENCY SHARES, PAYING AGENCY EARNOUT SHARES AND PAYING AGENCY ACCELERATION SHARES SHALL BE MADE DIRECTLY TO THE PAYEES IN ACCORDANCE WITH THE DISBURSEMENT SCHEDULE AS SET FORTH ON EXHIBIT A. THE TRANSFER OF SUCH PAYING AGENCY SHARES, PAYING AGENCY EARNOUT SHARES AND PAYING AGENCY ACCELERATION SHARES SHALL BE EVIDENCED IN ELECTRONIC OR BOOK-ENTRY FORM AND NOT BY DELIVERY OF STOCK CERTIFICATES. ALL PAYMENTS FROM THE, PAYING AGENCY EARNOUT FUND AND PAYING AGENCY ACCELERATION FUND SHALL BE MADE BY WIRE TRANSFER OF IMMEDIATELY AVAILABLE FUNDS TO THE ACCOUNT DESIGNATED BY THE RECEIVING PAYEE IN THE APPLICABLE LETTER OF TRANSMITTAL (PROVIDED THAT WIRE INSTRUCTIONS HAVE BEEN INCLUDED IN THE APPLICABLE LETTER OF TRANSMITTAL).

ARTICLE 17.COMPENSATION. PARENT AGREES TO PAY UPON DEMAND THE FEES OF THE PAYING AGENT AND THE REASONABLE EXPENSES AND DISBURSEMENTS INCURRED BY THE PAYING AGENT UNDER THIS AGREEMENT AS SET FORTH ON EXHIBIT B.

ARTICLE 18.DUTIES OF THE PAYING AGENT. IN THE EXECUTION OF ITS DUTIES HEREUNDER, THE PAYING AGENT:

Section 18.1 shall have no duties or obligations other than those specifically set forth herein, all of which are ministerial and non-fiduciary in nature, or as may be subsequently agreed to in writing by the Paying Agent, the Representative and Parent, and no implied duties or obligations shall be read into this Agreement against the Paying Agent;

Section 18.2 shall not be regarded as making any representation as to, and shall have no responsibility for the validity, sufficiency, value or genuineness of any Certificate(s), and the Paying Agent shall not be required to make any representations as to the validity, sufficiency, value or genuineness of the Mergers;

Section 18.3 shall not be obligated to expend any of its own funds or to take any legal action hereunder which might in the Paying Agent's sole judgment require it to risk the Paying Agent's own funds or incur any liability;

Section 18.4 may rely on and be protected in acting in reliance upon any stock certificate, stock power, affidavit, instrument, opinion, notice, letter, facsimile transmission, telex, telegram, electronic transmission or other document or security delivered to the Paying Agent and believed by the Paying Agent in good faith to be genuine and to have been signed by the proper party or parties;

Section 18.5 may rely on and be protected in acting in reliance upon the written instructions of the Representative, Parent or any other employee or representative designated by either of the Representative or Parent in accordance with this Agreement with respect to any matter relating to the Paying Agent's actions hereunder;

Section 18.6 shall have no obligation to make any payment as the Paying Agent unless Parent shall have provided the necessary available funds to make such payments;

Section 18.7 shall not be liable or responsible for any failure of the Representative, Parent or the Surviving Company to comply with any of their respective obligations relating to the Mergers, including, without limitation, obligations under applicable securities laws;

Section 18.8 shall not be liable for any error in judgment made or action taken or omitted by Paying Agent in good faith in the course of performance or administration under this Agreement. The Paying Agent shall not be liable for any action taken or omitted by it in good faith except to the extent that a court of competent jurisdiction determines that the Paying Agent's gross negligence or willful misconduct in breach of this Agreement was the sole cause of any loss to Parent. Under no circumstances shall the Paying Agent be liable for special, indirect, incidental, punitive or consequential loss or damage of any kind (including, without limitation, lost profits), even if Paying Agent has been advised in advance of the possibility of such loss or damage;

Section 18.9 may consult with counsel satisfactory to it (including in-house counsel) and shall be held harmless in relying on the advice or opinion of such counsel in respect of any action taken, suffered or omitted by it hereunder in good faith and in accordance with such advice or opinion of such counsel; and

Section 18.10 is authorized, in its sole discretion, to comply with final orders issued or process entered by any court with respect to the Paying Agency Shares, Paying Agency Earnout Shares, Paying Agency Earnout Fund, Paying Agency Acceleration Shares and Paying Agency Acceleration Fund or this Agreement, without determination by the Paying Agent of such court's jurisdiction in the matter. If any portion of the Paying Agency Shares, Paying Agency Earnout Shares, Paying Agency Earnout Fund, Paying Agency Acceleration Shares or Paying Agency Acceleration Fund is at any time attached, garnished or levied upon under any court order, or in case the payment, assignment, transfer, conveyance or delivery of any such property shall be stayed or enjoined by any court order, or in case any order, judgment or decree shall be made or entered by any court affecting such property or any part thereof, then and in any such event, the Paying Agent is authorized, in its sole discretion, to rely upon and comply with any such order, writ, judgment or decree which it is advised by legal counsel selected by it is binding upon it without the need for appeal or other action; and if the Paying Agent complies with any such order, writ, judgment or decree, it shall not be liable to any of the parties hereto or to any other person or entity by reason of such compliance even though such order, writ, judgment or decree may be subsequently reversed, modified, annulled, set aside or vacated.

The provisions of this Section 8 shall survive the termination of this Agreement or the resignation or removal of the Paying Agent.

ARTICLE 19.INDEMNIFICATION OF PAYING AGENT. FROM AND AT ALL TIMES AFTER THE DATE OF THIS AGREEMENT, PARENT AND REPRESENTATIVE (SOLELY ON BEHALF OF THE PAYEES AND NOT IN ITS INDIVIDUAL CAPACITY), JOINTLY AND SEVERALLY, SHALL, TO THE FULLEST EXTENT PERMITTED BY LAW, INDEMNIFY AND HOLD HARMLESS EACH PAYING AGENT INDEMNITEE AGAINST ANY AND ALL ACTIONS, CLAIMS (WHETHER OR NOT VALID), LOSSES, DAMAGES, LIABILITIES, PENALTIES, COSTS AND EXPENSES OF ANY KIND OR NATURE (INCLUDING WITHOUT LIMITATION REASONABLE ATTORNEYS' FEES, COSTS AND EXPENSES) INCURRED BY OR ASSERTED AGAINST ANY OF THE PAYING AGENT INDEMNITEES, WHETHER DIRECT, INDIRECT OR CONSEQUENTIAL, AS A RESULT OF OR ARISING FROM OR IN ANY WAY RELATING TO ANY CLAIM, DEMAND, SUIT, ACTION OR PROCEEDING (INCLUDING ANY INQUIRY OR INVESTIGATION) BY ANY PERSON, INCLUDING WITHOUT LIMITATION PARENT, REPRESENTATIVE AND ANY PAYEE, WHETHER THREATENED OR INITIATED, ASSERTING A CLAIM FOR ANY LEGAL OR EQUITABLE REMEDY AGAINST ANY PERSON UNDER ANY STATUTE OR REGULATION, INCLUDING, BUT NOT LIMITED TO, ANY FEDERAL OR STATE SECURITIES LAWS, OR UNDER ANY COMMON LAW OR EQUITABLE CAUSE OR OTHERWISE, ARISING FROM OR IN CONNECTION WITH THE NEGOTIATION, PREPARATION, EXECUTION, PERFORMANCE OR FAILURE OF PERFORMANCE IN CONNECTION WITH THIS AGREEMENT OR ANY TRANSACTIONS CONTEMPLATED HEREIN, WHETHER OR NOT ANY SUCH PAYING AGENT INDEMNITEE IS A PARTY TO ANY SUCH ACTION, PROCEEDING, SUIT OR THE TARGET OF ANY SUCH INQUIRY OR INVESTIGATION; PROVIDED, HOWEVER, THAT NO PAYING AGENT INDEMNITEE SHALL HAVE THE RIGHT TO BE INDEMNIFIED HEREUNDER FOR ANY LIABILITY FINALLY DETERMINED BY A COURT OF COMPETENT JURISDICTION, SUBJECT TO NO FURTHER APPEAL, TO HAVE RESULTED SOLELY FROM THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF SUCH PAYING AGENT INDEMNITEE IN BREACH OF THIS AGREEMENT. PARENT AND REPRESENTATIVE (SOLELY ON BEHALF OF THE PAYEES AND NOT IN ITS INDIVIDUAL CAPACITY) FURTHER AGREE, JOINTLY AND SEVERALLY, TO INDEMNIFY EACH PAYING AGENT INDEMNITEE FOR ALL COSTS, INCLUDING WITHOUT LIMITATION REASONABLE ATTORNEY'S FEES, INCURRED BY SUCH PAYING AGENT INDEMNITEE IN CONNECTION WITH THE ENFORCEMENT OF PARENT'S AND REPRESENTATIVE'S INDEMNIFICATION OBLIGATIONS HEREUNDER. THE PROVISIONS OF THIS SECTION 9 SHALL SURVIVE THE TERMINATION OF THIS AGREEMENT OR THE RESIGNATION OR REMOVAL OF THE PAYING AGENT.

ARTICLE 20.TERMINATION OF AGREEMENT. THIS AGREEMENT SHALL TERMINATE EITHER:

Section 20.1 upon the exchange of all shares of Company Securities and distribution in full of the Paying Agency Shares, Paying Agency Earnout Shares, Paying Agency Earnout Fund, Paying Agency Acceleration Shares and Paying Agency Acceleration Fund;

Section 20.2 following the date that no further Revenue Earnout Payment, Milestone Payment, or Accelerated Payment can become due and payable by Parent, upon the distribution of all amounts remaining of the Paying Agency Shares, Paying Agency Earnout Shares, Paying Agency Earnout Fund, Paying Agency Acceleration Shares and Paying Agency Acceleration Fund in accordance with the provisions of Sections 3(b), 3(d) and 3(f) hereof; or

Section 20.3 at the option of the Representative and Parent, on the one hand, or the Paying Agent, on the other hand, with thirty (30) days' prior written notice.

Upon any termination of this Agreement pursuant to subsection (c) of this Section 10, the Paying Agent shall promptly deliver to Parent any Certificate(s), funds or other property not permitted to be retained by the Paying Agent. After such time, any party entitled to such Certificate(s), funds or property shall look solely to Parent, not to the Paying Agent or Representative, and any liability of the Paying Agent with respect thereto shall cease.

ARTICLE 21.FORCE MAJEURE. NO PARTY SHALL BE LIABLE TO ANY OTHER, OR HELD IN BREACH OF THIS AGREEMENT, IF PREVENTED, HINDERED, OR DELAYED IN PERFORMANCE OR OBSERVANCE OF ANY PROVISION CONTAINED HEREIN BY REASON OF ACT OF GOD, RIOTS, ACTS OF WAR, ACTS OF TERRORISM, EPIDEMICS, GOVERNMENTAL ACTION OR JUDICIAL ORDER, EARTHQUAKES, OR SIMILAR CAUSE (INCLUDING, BUT NOT LIMITED TO, MECHANICAL, ELECTRONIC OR COMMUNICATIONS INTERRUPTIONS, DISRUPTIONS OR FAILURES).

ARTICLE 22.MISCELLANEOUS.

Section 22.1 Governing Law; Jurisdiction. This Agreement will be construed under and governed by the laws of the State of New York without regard to the conflicts of law principles of any jurisdiction. Except as otherwise provided in the Merger Agreement, each of the parties submits to the jurisdiction of any state or federal court sitting in New York, New York, in any action or proceeding arising out of or relating to this Agreement and agrees that all claims in respect of the action or proceeding may be heard and determined in any such court. Each party also agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. Each of the parties waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety, or other security that might be required of any other party with respect thereto.

Section 22.2 Notices. All notices required or permitted to be given under this Agreement will be in writing and will be deemed given (i) when delivered in person, (ii) on the next business day after being deposited with a nationally recognized overnight courier service addressed as set forth below or (iii) upon dispatch if sent by facsimile with telephonic confirmation of receipt from the intended recipient to the facsimile number set forth below (or to such other respective addresses as may be designated by notice given in accordance with the provisions of this Section, except that any notice of change of address will not be deemed given until actually received by the party to whom directed):

If to Representative:

Earl Bright
2570 W. El Camino Real
Suite 310
Mountain View, CA 94040
Attention: Earl Bright
E-mail: ebright@nuelle.com

with a copy to:

Wilson Sonsini Goodrich & Rosati P.C.
650 Page Mill Road
Palo Alto, CA 94304
E-mail: poettinger@wsgr.com
Attention: Philip Oettinger

If to Parent:

Aytu BioScience, Inc.
373 Inverness Parkway, Suite 206
Englewood, CO 80112
E-mail:
Attention:

with a copy to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Facsimile: (919) 781-4865
E-mail: dmannheim@wyrick.com
Attention: David Mannheim

If to the Paying Agent:

VStock Transfer, LLC, a California limited liability company
_____
Attention:

Section 22.3 Entire Agreement. This Agreement supersedes all prior agreements between the parties with respect to the subject matter of this Agreement. This Agreement constitutes a complete and exclusive statement of the terms of the agreement between the parties with respect to its subject matter.

Section 22.4 Amendments and Waivers. This Agreement may not be amended, modified, altered or supplemented without the prior written consent of all parties to the Agreement. No failure or delay by any party to exercise any right or remedy under this Agreement will constitute as a waiver of such right or remedy.

Section 22.5 Severability of Invalid Provision. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable.

Section 22.6 Successors and Assigns. This Agreement is enforceable by, and inures to the benefit of, the parties to this Agreement and their respective successors and assigns. Neither this Agreement nor any right, interest or obligation under this Agreement may be assigned by any party to this Agreement without the prior written consent of the other parties hereto and any attempt to do so will be void.

Section 22.7 Status of Parties. The relationship of the parties to each other in the execution and performance of this Agreement shall be that of independent contractors.

Section 22.8 Rules of Construction. Section headings contained in this Agreement are inserted only as a matter of convenience and in no way define, limit, extend or describe the scope of this Agreement or the intent of any of the provisions of this Agreement. This Agreement has been negotiated on behalf of the parties with the advice of legal counsel and no general rule of contract construction requiring an agreement to be more stringently construed against the drafter or proponent of any particular provision may be applied in the construction or interpretation of this Agreement. Unless otherwise expressly provided, the word “including” does not limit the preceding words or terms. Except as otherwise indicated, all references in this Agreement to “Sections” and “Exhibits” are intended to refer to Sections of this Agreement and Exhibits to this Agreement.

Section 22.9 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. The exchange of copies of this Agreement and of signature pages by facsimile transmission will constitute effective execution and delivery of this Agreement as to the parties and may be used in lieu of the original Agreement for all purposes. Signatures of the parties transmitted by facsimile will be deemed to be their original signatures for all purposes.

Section 22.10 Cumulative Remedies. The powers, rights, privileges and remedies provided in this Agreement are cumulative and not exclusive or alternative and are in addition to any and all other powers, rights, privileges and remedies granted by law, rule, regulation or instrument.

Section 22.11 Further Assurances. Each of the parties shall execute and deliver such additional instruments and other documents and shall take such further actions as may be necessary or appropriate to effectuate, carry out and comply with all of the terms of this Agreement.

Section 22.12 Patriot Act. To help the government fight the funding of terrorism and money laundering activities, Federal law requires all financial institutions to obtain, verify and record information that identifies each person who opens an account. For a non-individual person such as a business entity, a charity, a Trust or other legal entity the Paying Agent will ask for documentation to verify its formation and existence as a legal entity. The Paying Agent may also ask to see financial statements, licenses, identification and authorization documents from individuals claiming authority to represent the entity or other relevant documentation.

Section 22.13 Third Party Beneficiaries. This Agreement is not intended to be for the benefit of or to be enforceable by any third party; and no third party shall be entitled to claim that it is a third party beneficiary hereof. Neither party shall make any commitments with third parties that are binding on the other party without the other party's prior written consent.

IN WITNESS WHEREOF, this Agreement has been duly executed by the parties hereto as of the day and year first above written.

PAYING AGENT:

VSTOCK TRANSFER, LLC, a California limited liability company

By _____
Name: _____
Title: _____

PARENT:

AYTU BIOSCIENCE, INC., a Delaware corporation

By _____
Name:
Title:

REPRESENTATIVE:

EARL BRIGHT

By _____

[Signature page of Paying Agent Agreement]

Exhibit A

Distribution Schedule

As provided to Paying Agent on _____, 2017.

Exhibit B

Schedule of Fees for Services as

Paying Agent

Exhibit C

Form of Letter of Transmittal

LETTER OF TRANSMITTAL

for Securities

of

NUELLE, INC.

The Paying Agent for the Merger is: **VStock Transfer, LLC**

DELIVERY INSTRUCTIONS
VStock Transfer, LLC
Attn: _____
18 Lafayette Place
Woodmere, NY 11598
For information please email info@vstock.com or call (212) 828-8436

THE INSTRUCTIONS ACCOMPANYING THIS LETTER OF TRANSMITTAL SHOULD BE READ CAREFULLY BEFORE THIS LETTER OF TRANSMITTAL IS COMPLETED. IF CERTIFICATES ARE REGISTERED IN DIFFERENT NAMES, A SEPARATE LETTER OF TRANSMITTAL MUST BE SUBMITTED FOR EACH DIFFERENT REGISTERED HOLDER. SEE INSTRUCTION 4.

Ladies and Gentlemen:

In connection with the merger (the "**Merger**") of Aytu Acquisition Corporation, Inc. ("**Merger Sub**"), a wholly owned subsidiary of Aytu Bioscience, Inc. ("**Buyer**"), with and into Nuelle, Inc. (the "**Company**"), and immediately following the Merger, the surviving corporation's merger with and into Aytu Holdings, LLC, a wholly-owned subsidiary of Buyer ("**Second Merger Sub**"), all in accordance with that certain Merger Agreement dated as of May ___, 2017 (the " **Merger Agreement**"), by and among Buyer, Merger Sub, Second Merger Sub, the Company, and Earl Bright as "Representative," the undersigned herewith surrenders the below described Secured Convertible Promissory Notes of the Company, Securities of Company Common Stock, par value $.001 per share, and/or Securities of Company Preferred Stock, par value $.001 per share (collectively, the "**Securities**"), as applicable, and the certificate(s) (the "**Certificate(s)**") representing such Securities (collectively, the Certificate(s) are referred to herein as the "**Exchange Documentation**") to be exchanged for the consideration payable pursuant to the Merger Agreement, without interest (and subject to applicable withholding and other adjustments) as contemplated by the Merger Agreement. Capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Merger Agreement.

By delivery of this Letter of Transmittal to VStock Transfer, LLC (the "Paying Agent"), the undersigned hereby (i) forever waives all appraisal rights under applicable Delaware law, (ii) withdraws all written objections to the Merger and/or demands for appraisal, if any, with respect to the Securities owned by the undersigned, (iii) appoints and irrevocably constitutes, effective as of the date of the Merger Agreement, Earl Bright as the Representative (and any successor Representative appointed in accordance with the terms of the Merger Agreement), with all power and authority set forth in and contemplated by the Merger Agreement, (iv) acknowledges and agrees that the Securities (and the Exchange Documentation representing such Securities, where applicable) will be cancelled as of the Effective Time in exchange for the consideration payable pursuant to the terms of the Merger Agreement, (v) acknowledges that the undersigned shall be bound by all actions taken by the Representative in connection with or related to the matters set forth in or reasonably contemplated by the Merger Agreement, including, without limitation, Section 8.1 thereof, and hereby adopts, ratifies, confirms and approves in all respects all such actions, and (v) acknowledges, agrees and confirms that, by his, her or its execution of this Letter of Transmittal, the undersigned hereby accepts that portion of the Aggregate Merger Consideration to which he, she or it is entitled under the Merger Agreement subject to, from and after the Closing, the indemnification obligations, and related limitations on such indemnification obligations, of a "Company Securityholder" under the Merger Agreement for his, her or its applicable share of any Losses under Article VII of the Merger Agreement, including, among other things, that except in the event of fraud, the undersigned's indemnification obligations shall be limited as described in Section 7.2(b) of the Merger Agreement.

This Letter of Transmittal should be completed and returned to the Paying Agent by all Company Securityholders surrendering Securities with all other documents required by this Letter of Transmittal to be delivered to the Paying Agent in exchange for the Merger Consideration payable in respect of such Securities. The undersigned understands that surrender is not made in acceptable form until the receipt by the Paying Agent of this Letter of Transmittal duly completed and signed, and of the appropriate Exchange Documentation, together with all accompanying evidences of authority in form satisfactory to Buyer (which may delegate power in whole or in part to the Paying Agent). All questions as to validity, form and eligibility of any surrender of Securities hereby will be determined by Buyer (which may delegate power in whole or in part to the Paying Agent) and such determination shall be final and binding. The undersigned understands that payment for surrendered Securities delivered to the Paying Agent will be made as promptly as practicable after the later of the Closing Date or the surrender of the Securities is made in acceptable form. The undersigned understands that by surrendering the Securities, the undersigned also surrenders Securities that may be issued, acquired or granted to the undersigned after the Securities are surrendered and prior to the closing of the Merger.

By signing this Letter of Transmittal, (i) the undersigned acknowledges and agrees that the Representative shall not have any liability to the Stockholders, Buyer, Merger Sub, Second Merger Sub, the Company or their respective affiliates for any act done or omitted under the Merger Agreement or under any other related agreement as Representative (except in the case of willful misconduct or fraud), and (ii) the undersigned agrees to indemnify, hold harmless and defend the Representative from and against all losses arising out of or in connection with (A) the Representative's actions taken, or omissions to act, arising out of, in connection with, or otherwise with respect to the Merger Agreement, and (B) actions taken with respect to the Merger Agreement believed by the Representative to be within the scope of its authority; provided that such Losses do not arise out of the willful misconduct or fraud of the Representative.

By signing this Letter of Transmittal the undersigned hereby represents and warrants to Buyer, Merger Sub, Second Merger Sub, the Company and Paying Agent that (a) the undersigned has received a copy of the Merger Agreement and understands the terms, conditions and transactions (including any obligations of the Company Securityholders or payments that may be adjusted, offset or made from the Aggregate Merger Consideration) described therein, (b) the undersigned has full power, authority, and legal capacity to execute and deliver this Letter of Transmittal and to consummate the transactions contemplated by this Letter of Transmittal and the Merger Agreement, (c) this Letter of Transmittal has been duly executed and delivered and constitutes a legal, valid, and binding obligation of the undersigned, enforceable in accordance with its terms, (d) the undersigned is the record and beneficial owner of the Securities shown in the box on page four of this Letter of Transmittal, free and clear of all encumbrances or other obligations under any contract to sell, dispose or transfer such Securities (other than pursuant to the Merger Agreement), and possesses full legal right, power, and authority to deliver and surrender all right, title, and interest in and to such Securities (and the Exchange Documentation representing such Securities, where applicable), for cancellation at the Effective Time pursuant to the terms of the Merger Agreement, without the consent of any third party that has not also executed this Letter of Transmittal, and (e) the undersigned has no, and has no right or obligation to acquire any, other Securities or other securities of any type or nature of the Company. The undersigned hereby understands, acknowledges and agrees that all of the representations, warranties and agreements contained in this Letter of Transmittal shall survive the Merger.

This Letter of Transmittal shall be governed by and construed in accordance with the internal substantive laws of the State of North Carolina applicable to contracts executed in and to be performed in that state, without regard to the conflicts of laws principles thereof to the extent the same would require the application of the laws of another jurisdiction. No authority herein conferred or agreed to be conferred shall be affected by, and all such authority shall survive, the death or incapacity of the undersigned. All obligations of the undersigned hereunder shall be binding upon the heirs, executors, administrators, legal representatives, successors and assigns of the undersigned. The surrender of the Securities hereby made is irrevocable. The undersigned will, upon request, execute and deliver any additional documents reasonably deemed appropriate or necessary by Buyer or Paying Agent in connection with the surrender of the Securities.

For and in consideration of the right to receive the applicable portion of the Aggregate Merger Consideration, the undersigned hereby releases, acquits and forever discharges Buyer, the Company, each of Buyer's and the Company's respective subsidiaries and affiliates and each of Buyer's, the Company's and Buyer's and the Company's respective subsidiaries' and affiliates' present, former and future officers, directors, attorneys, agents, representatives, trustees, affiliates and employees and each of their respective heirs, executors, administrators, successors and assigns (each, a "**Released Party**"), of and from any and all manner of action or actions, cause or causes of action, demands, rights, damages, debts, dues, sums of money, accounts, reckonings, costs, expenses, responsibilities, covenants, contracts, controversies, agreements and claims whatsoever, whether known or unknown, of every name and nature, both in law and in equity (each, a "**Claim**"), which the undersigned or any of the undersigned's heirs, executors, administrators, successors or assigns (collectively, " **Releasing Party**") ever had, now has, or which the undersigned or the undersigned's heirs, executors, administrators, successors or assigns hereafter may have or shall have against the Company or any other Released Party arising out of any matters, causes, acts, conduct, claims, circumstances or events occurring or failing to occur or conditions existing at or prior to the Effective Time; provided, however, that the foregoing release shall not cover or otherwise in any way affect (i) the right to receive the payments due to the undersigned pursuant to or any other rights of the undersigned arising under the Merger Agreement and any document contemplated by the Merger Agreement, whether as of the date hereof or following the date hereof, (ii) if the undersigned is a present or former employee or consultant of Company, rights to earned but unpaid cash compensation, including any bonuses, or unreimbursed business expenses incurred as of the Effective Time and reimbursable pursuant to the Company's business expense policy, (iii) unreimbursed claims under employee health, welfare and pension plans, consistent with the terms of coverage, and (iv) rights of indemnification, advance of expenses, reimbursement and other coverage for liability pursuant to the Company Charter, the Company's Bylaws and any indemnification agreement with the Company or any directors' and officers' liability insurance policy. Neither the undersigned nor any of the undersigned's heirs, executors, administrators, successors or assigns has heretofore assigned, and shall not hereafter sue any Released Party upon, any Claim released, acquitted or discharged or purported to be released, acquitted or discharged under this paragraph.

The undersigned acknowledges and agrees that, as set forth in Section 1.4(f) of the Merger Agreement, at Closing the Parent Securities to be issued pursuant to the Merger Agreement will not be registered under the Securities Act, or under any state securities laws. Under the Securities Act, such securities will be not be eligible for transfer except in accordance with applicable law and the provisions of the Merger Agreement. Prior to transfer, such Securities must be (i) registered under the Securities Act or (ii) otherwise be eligible to be transferred without restriction in accordance with Rule 144 or another exemption from registration under the Securities Act.

Please issue the payment to which the undersigned is entitled in the name set forth and deliver such payment by the method set forth, unless otherwise indicated.

PLEASE CAREFULLY READ THE ACCOMPANYING INSTRUCTIONS

DO NOT USE WHITEOUT OR CORRECTION TAPE – DO NOT CROSS OUT INCORRECT INFORMATION
CONTACT VSTOCK TRANSFER, LLC, TEL _____ FOR ADDITIONAL COPIES OF THE LETTER OF TRANSMITTAL

DESCRIPTION OF CERTIFICATES AND SURRENDERED SECURITIES

Name(s) and Address of Registered Holder(s) (Please fill in, exactly as name(s) appear(s) on Share Certificate(s))	Security Position(s) Surrendered (Attach additional signed list if necessary)			
Type of Interest	Class/Series of Share(s)/Notes (e.g., Common Stock, Series A Preferred Stock or Series A-1 Preferred Stock)	Certificate Number(s)	Check Box if Lost/Misplaced (See Instruction 10)	Number of Securities or Principal Amount Represented by Certificate(s)
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	
			¨	

COMPLETE ONLY ONE OF THE PAYMENT INSTRUCTION SECTIONS BELOW

CHECK PAYMENT INSTRUCTIONS

If you wish to have cash consideration to be issued to you in the Merger (as defined herein) sent by **check**, please complete the remainder of this Letter of Transmittal and provide mailing address instructions below.

Address _____

City, State, Zip _____

Country _____

WIRE PAYMENT INSTRUCTIONS

If you wish to have cash consideration to be issued to you in the Merger (as defined herein) sent by **wire transfer**, please complete the remainder of this Letter of Transmittal and provide wire instructions below or include such instructions herewith. ***For international wires, please provide the SWIFT code (BIC) in the Fedwire ABA Number field and the complete IBAN in the Account Number field, if available.***

Bank Name _____

Fedwire ABA Number* _____

Account Name** _____

Account Number _____

FFC Account Name (if applicable) _____

FFC Account Number (if applicable) _____

Bank Contact/Telephone Number _____

*Please provide valid Fedwire ABA (Check validity here: http://www.fedwiredirectory.frb.org/search.cfm)

**Please provide the name on the account not the type of account

(If wire is to be issued to an account in a name other than that set forth in the description of Securities surrendered box above, See Instructions 3, 4, 5 and 7)

SPECIAL PAYMENT/DELIVERY INSTRUCTIONS

(See Instructions 3, 4, 5, 7 and 11)

If you wish to have cash consideration to be issued in a name other than that of the registered holder and sent by check, please complete the remainder of this Letter of Transmittal and provide the payment instructions below.***

Payee Name _____

Address _____

City, State, Zip _____

Country _____

Tax Identification Number**** _____

***Requires signature guarantee. See Instruction No. 3 to this Letter of Transmittal.

****Fill in Taxpayer Identification Number of Payee. See Instruction 11 to this Letter of Transmittal.

IMPORTANT – COMPANY SECURITYHOLDER SIGNATURE PAGE

Must be signed by registered holder(s) exactly as name(s) appear(s) on stock certificate(s), a security position listing or by person(s) authorized to become registered holder(s) by certificates and documents transmitted herewith. Signature below certifies that no language alterations have been made in any way to this form of Letter of Transmittal. If signature is by a trustee, executor, administrator, guardian, attorney-in-fact, officer of a corporation or other person acting in a fiduciary or representative capacity, please set forth full title. See Instruction 4. (For information concerning signature guarantees see Instruction 3.)

Dated _____

Sign Here X_____

(Signature(s) of Owner(s))

Name(s) _____

(Please Print)

Capacity _____

(See Instruction 4)

Address _____

Area Code & Telephone No. _____

Email Address _____

(Complete the attached Form W-9. See instruction 11.)

STOP – CAREFULLY REVIEW INSTRUCTION 3 PRIOR TO COMPLETING REMAINDER OF PAGE

Securities need not be endorsed and transfer powers and signature guarantees are unnecessary unless (a) the Securities are registered in a name other than that of the person surrendering the Securities or (b) such registered holder completes the Special Payment/Delivery Instructions or requests payment to a name other than the registered holder.

SIGNATURE GUARANTEE

(This section should be completed by the individual applying the MSG Stamp)

(Apply Medallion Signature Guarantee Stamp Here)

Authorized Signature _____

Name _____

(Please Print)

Title _____

(Please Print)

Name of Firm _____

Area Code & Telephone No. _____

Address _____

INSTRUCTIONS

1. *Delivery of Letter of Transmittal and Surrender of Exchange Documentation*. This Letter of Transmittal, filled in and signed, must be used in connection with the delivery and surrender of the Exchange Documentation. A Letter of Transmittal and Exchange Documentation must be received by Paying Agent in satisfactory form in order to make an effective surrender. Delivery of the Exchange Documentation and other documents, as applicable, shall be effected, and the risk of loss and title to the Exchange Documentation shall pass, only upon proper surrender of the Exchange Documentation to Paying Agent. The method of surrender of the Exchange Documentation and other documents is at the election and risk of the holder. If such surrender is by mail, registered mail with return receipt requested, properly insured, is recommended. Surrender may be made by mail, by hand or by overnight courier to VStock Transfer, LLC, as Paying Agent, at one of the addresses shown above. Upon surrender of the Exchange Documentation, any Securities issued subsequent to such surrender and prior to the closing of the Merger shall be deemed to be surrendered for payment.

2. *Terms of Conversion of the Securities*. Each Equity Interest (as shown in the box on the second page of this Letter of Transmittal) will be converted at the Effective Time of the Merger into the right to receive the consideration payable pursuant to the Merger Agreement, without interest (and subject to applicable withholding contemplated by the Merger Agreement).

3. *Guarantee of Signature*. Securities need not be endorsed and transfer powers and signature guarantees are unnecessary unless (a) the Securities are registered in a name other than that of the person surrendering the Securities or (b) such registered holder completes the Special Payment/Delivery Instructions or requests payment to a name other than the registered holder. In the case of (a) above, any such Securities must be duly endorsed or accompanied by a properly executed transfer power with the signature on the endorsement or transfer power and on the Letter of Transmittal guaranteed by a participant in the Security Transfer Agents Medallion Program, the New York Stock Exchange Medallion Signature Guarantee Program or the Stock Exchange Medallion Program (each, an “Eligible Institution”). In the case of (b) above, only the signature on the Letter of Transmittal should be similarly guaranteed.

4. *Signatures on Letter of Transmittal and Endorsements*. If this Letter of Transmittal is signed by the registered holder(s) of the Securities surrendered hereby, the signature(s) must correspond with the name(s) as written on the face of the Exchange Documentation, without alteration, enlargement or any change whatsoever. If any of the Securities surrendered hereby are registered in different names, it will be necessary to complete, sign and submit as many separate Letters of Transmittal as there are different registrations of Exchange Documentation.

   If any of the Securities surrendered hereby are held of record by two or more joint owners, all such owners must sign this Letter of Transmittal. If this Letter of Transmittal or any Exchange Documentation or transfer power is signed by a trustee, executor, administrator, guardian, attorney-in-fact, officer of a corporation or other person acting in a fiduciary or representative capacity, such person should so indicate when signing, and proper evidence satisfactory to the Company of the authority of such person so to act must be submitted.

   If this Letter of Transmittal is signed by the registered holder(s) of the Securities listed and surrendered hereby, no endorsements of Exchange Documentation or separate transfer powers, as applicable, are required unless payment is to be issued in the name of a person other than the registered holder(s). Signatures on any such Exchange Documentation or transfer powers, as applicable, must be guaranteed by an Eligible Institution.

   If this Letter of Transmittal is signed by a person other than the registered holder(s) of the Securities listed and surrendered hereby, the Securities must be endorsed or accompanied by appropriate transfer powers, in either case signed exactly as the name(s) of the registered holder(s) appear(s) on the Equity Documentation. Signature(s) on any such Exchange Documentation or transfer powers must be guaranteed by an Eligible Institution.

5. *Transfer Taxes*. The registered holder(s) of the Securities surrendered hereby will bear liability for any state stock transfer taxes applicable to the delivery of checks in payment for surrendered Securities; provided, however, that if any such check is to be issued to any person(s) other than the registered holder(s) of the surrendered Securities, it shall be a condition of the issuance and delivery of such check that the amount of any stock transfer taxes (whether imposed on the registered holder(s) or such person(s)) payable on account of the transfer (or transfers) of the surrendered Securities shall be delivered to Paying Agent or satisfactory evidence of the payment of such taxes or nonapplicability thereof shall be submitted to Paying Agent before such check will be issued.

6. *Validity of Surrender, Irregularities*. All questions as to validity, form and eligibility of any surrender of Exchange Documentation hereby will be determined by Buyer (which may delegate power in whole or in part to Paying Agent), and such determination shall be final and binding. Buyer reserves the right to waive any irregularities or defects in the surrender of any Exchange Documentation and its interpretations of the terms and conditions of the Merger Agreement and of this Letter of Transmittal (including these instructions) with respect to such irregularities or defects shall be final and binding. A surrender will not be deemed to have been made until all irregularities have been cured or waived. Parties entitled to payment may be contacted by Buyer or Paying Agent and requested to provide any missing or incomplete information.

7. *Special Payment and Delivery Instructions*. Indicate the name and address to which payment for the Securities is to be sent if different from the name and/or address of the person(s) signing this Letter of Transmittal.

8. *Requests for Information or Additional Copies*. Information and additional copies of this Letter of Transmittal may be obtained by contacting Vstock Transfer, LLC at _____.

9. *Inadequate Space*. If the space provided on this Letter of Transmittal is inadequate, the Share certificate numbers, if applicable, and number of Securities should be listed on a separate signed schedule affixed hereto.

10. *Letter of Transmittal Required; Surrender of Exchange Documentation; Lost Exchange Documentation*. You will not receive any cash for your Securities unless and until you deliver this Letter of Transmittal duly completed and signed to Paying Agent, together, as applicable, with the Exchange Documentation and any required accompanying evidences of authority in form satisfactory to the Buyer. If any Exchange Documentation has been lost or destroyed, such fact should be indicated on the face of this Letter of Transmittal

11. *Form W-9*. Each holder surrendering Securities for payment is required to provide Paying Agent with a correct Taxpayer Identification Number (“TIN”) and certain other information on a Form W-9, or an appropriate IRS Form W-8. For more information, see “Important Tax Information” below.

Important Tax Information:

In order to avoid backup withholding of United States federal income tax, United States federal income tax law generally requires that if your Securities are accepted for payment, you or your assignee (in either case, the "Payee") must provide the Paying Agent (the "Payor") with the Payee's correct Taxpayer Identification Number ("TIN"), which, in the case of a Payee who is an individual, is the Payee's social security number. If the Payor is not provided with the correct TIN or an adequate basis for an exemption, the Payee may be subject to a $50 penalty imposed by the Internal Revenue Service ("IRS") and backup withholding of a portion (currently 28%) of the gross proceeds received pursuant to the Merger. Backup withholding is not an additional tax. Rather, the tax liability of a person subject to backup withholding will be reduced by the amount withheld. If withholding results in an overpayment of taxes, a refund may generally be obtained from the IRS provided that the required information is timely furnished to the IRS.

To prevent backup withholding, each Payee must provide such Payee's correct TIN by completing the Form W-9 set forth herein, certifying that (i) the TIN provided is correct, (ii) (a) the Payee is exempt from backup withholding, (b) the Payee has not been notified by the IRS that such Payee is subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified the payee that such Payee is no longer subject to backup withholding, and (iii) the Payee is a U.S. Person (including a U.S. resident alien).

Certain Payees (including, among others, certain corporations and certain foreign individuals) are not subject to these backup withholding and reporting requirements. To prevent possible erroneous backup withholding, an exempt Payee that is a U.S. person should check the "Exempt payee" box on the Form W-9. In order for a nonresident alien individual or foreign entity to establish its exemption from backup withholding, such person must submit an appropriate and properly completed Form W-8BEN, W-8ECI, W-8EXP or W-8IMY, as the case may be, signed under penalties of perjury attesting to such exempt status. Such forms may be obtained from the Paying Agent or the IRS at its Internet website: www.irs.gov.

PAYEES ARE URGED TO CONSULT THEIR TAX ADVISOR REGARDING BACKUP WITHHOLDING. FAILURE TO COMPLETE AND RETURN THE FORM W-9 MAY RESULT IN BACKUP WITHHOLDING OF A PORTION (CURRENTLY 28%) OF ANY PAYMENTS MADE TO YOU PURSUANT TO THE MERGER.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Aytu BioScience, Inc.'s Registration Statements on Form S-8 (File No. 333-205462) and Form S-1 (File Nos. 333-207421, 333-205414, 333-209874, 333-210144, 333-212100, and 333-213738) of our report dated August 31, 2017, relating to the consolidated financial statements that appear in this Annual Report on Form 10-K.

/s/ EKS&H LLLP

August 31, 2017
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, 2017 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: August 31, 2017

/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, 2017 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: August 31, 2017

/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, 2017, 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: August 31, 2017

/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)