SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 10-K

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2018

☐ 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 ☒

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 ☒

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 ☒ 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 ☒ 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	☒
		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 ☒

The aggregate market value of common stock held by non-affiliates of the Registrant as of December 31, 2017 was $7.9 million based on the closing price of $44.60 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 31, 2018, there were 1,801,411 shares of common stock outstanding and 0 shares of preferred stock outstanding.

TABLE OF CONTENTS

This Annual Report on Form 10-K refers to trademarks, such as Aytu, Natesto, ZolpiMist, 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

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.

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 pharmaceutical company focused on global commercialization of novel products addressing significant medical needs. We have multiple approved products on the market, and we seek to build a portfolio of novel therapeutics that serve large medical needs, across a range of conditions, through our in-house commercial team. Our commercial infrastructure consists of a U.S.-based specialty sales force and an international distribution network with presence in approximately fifty countries. We are currently concentrating on hypogonadism, male infertility and, recently, insomnia and plan to expand into other 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 U.S. 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 $1.8 billion market accounting for over 6.8 million prescriptions annually. 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 system that is currently CE marked (which generally enables it to be sold within the European Economic Area), Health Canada cleared, and Australian TGA and Mexican COFEPRAS-approved, and for which we intend to initiate a 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 (the core biological component measured by the MiOXSYS system) is widely implicated in its pathophysiology. MiOXSYS was developed from our previously developed oxidation-reduction potential research platform known as RedoxSYS®. We are advancing MiOXSYS toward FDA clearance as an aid in the assessment of male infertility.

In June 2018 we acquired an exclusive U.S. license to ZolpiMist™. ZolpiMist is an FDA-approved prescription product that is indicated for the short-term treatment of insomnia, and is the only oral spray formulation of zolpidem tartrate - the most widely prescribed prescription sleep aid in the U.S. ZolpiMist is commercially available and competes in the non-benzodiazepine prescription sleep aid category, a $1.8 billion prescription drug category with over 43 million prescriptions written annually. Thirty million prescriptions of zolpidem tartrate (Ambien®, Ambien® CR, Intermezzo®, Edluar®, ZolpiMist™, and generic forms of immediate-release, controlled release, and orally dissolving tablet formulations) are written each year in the U.S., representing almost 70% of the non-benzodiazepine sleep aid category. Approximately 2.5 million prescriptions are written for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets). We intend to integrate ZolpiMist into our sales force's promotional efforts as an adjunct product to Natesto as there is substantial overlap of physician prescribers of both testosterone and prescription sleep aids.

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

Natesto® (testosterone) nasal gel

On April 22, 2016, we entered into an agreement to acquire the exclusive U.S. rights, which rights we acquired on July 1, 2016, to Natesto (testosterone) nasal gel, from Acerus Pharmaceuticals Corporation, or Acerus. Natesto is a patented, FDA-approved testosterone replacement therapy, or TRT, and is the only nasally-administered formulation of testosterone available in the U.S. 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. Rather, Natesto 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. Natesto is also positioned for men who have previously been prescribed a TRT, including Androgel, and want a product with a different clinical profile available in a convenient, easy-to-use, effective therapeutic option.

MiOXSYS®

MiOXSYS is a rapid *in vitro* diagnostic system that performs a semen analysis test used to measure static oxidation-reduction potential, or sORP, in human semen. MiOXSYS is a CE marked system (that is also Health Canada, Australian TGA and Mexican COFEPRAS approved) and is an accurate, easy to use, and fast infertility assessment tool that directly measures oxidative stress in semen though the direct measurement of oxidation-reduction potential. It is estimated that 72.4 million couples worldwide experience infertility problems. In the U.S., 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 may 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 compound annual growth rate, or 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 without easy, accurate assessment methods available for initial evaluation and subsequent response to antioxidant intervention. 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. The product subsequently received Australian TGA approval in November of 2017 and clearance in Mexico in March of 2018. We expect to advance MiOXSYS into clinical trials in the U.S. in order to enable 510k de novo clearance.

ZolpiMist™ (zolpidem tartrate oral spray)

On June 11, 2018, the Company acquired an exclusive license for ZolpiMist from Magna Pharmaceuticals, Inc. This agreement allows for Aytu's exclusive commercialization of ZolpiMist in the U.S. and Canada, and the ability to sublicense the product for commercialization in Canada. The ZolpiMist license adds another unique, commercial-stage product to the Company's product portfolio and provides our U.S. sales force with another novel product to sell to their already-called-on primary care (family medicine, internal medicine, general practice) physician targets. More than half of our sales force's Natesto physician targets are primary care physicians, so there is a significant overlap in targets and opportunity to enable them to efficiently sell both Natesto and ZolpiMist to these prevalent, high-prescribing clinicians. The Company expects to formally launch ZolpiMist through its U.S. sales force in late 2018.

ZolpiMist is an FDA-approved prescription product that is indicated for the short-term treatment of insomnia, and is the only oral spray formulation of zolpidem tartrate - the most widely prescribed prescription sleep aid in the U.S. ZolpiMist is commercially available and competes in the non-benzodiazepine prescription sleep aid category, a $1.8 billion prescription drug category with over 43 million prescriptions written annually. Thirty million prescriptions of zolpidem tartrate (Ambien®, Ambien® CR, Intermezzo®, Edluar®, ZolpiMist™, and generic forms of immediate-release, controlled release, and orally dissolving tablet formulations) are written each year in the U.S., representing almost 70% of the non-benzodiazepine sleep aid category. Approximately 2.5 million prescriptions are written for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets).

ZolpiMist (5 mg per dose and available in both a 30-dose and 60-dose canister) was approved for marketing by the FDA in December of 2008 and was shown to be bioequivalent to Ambien® 5 mg and 10 mg tablets. ZolpiMist is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation and is contraindicated in patients with a known hypersensitivity to zolpidem tartrate.

Key elements of our business strategy include:

- Expanding the commercialization of Natesto in the U.S. for the treatment of hypogonadism with our direct sales force.
- Relaunching ZolpiMist, a prescription sleep aid that will be a complementary product to Natesto, in primary care physician offices sold through our U.S. sales force**.** Establishing MiOXSYS as a leading in vitro diagnostic system around the world in the assessment of male infertility through ex-US partnering; and progressing MiOXSYS through the FDA's 510k de novo clearance pathway.
- Acquiring additional marketed products and late-stage development assets that can be efficiently marketed through our growing commercial organization.

We plan to augment our core in-development and commercial assets through efficient identification of complementary products. 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 (including co-promotions and co-marketing arrangements).

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 U.S. and abroad. Through an assertive product and business development approach, we expect that we will build a substantial portfolio of complementary commercial and near-commercial-stage 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.

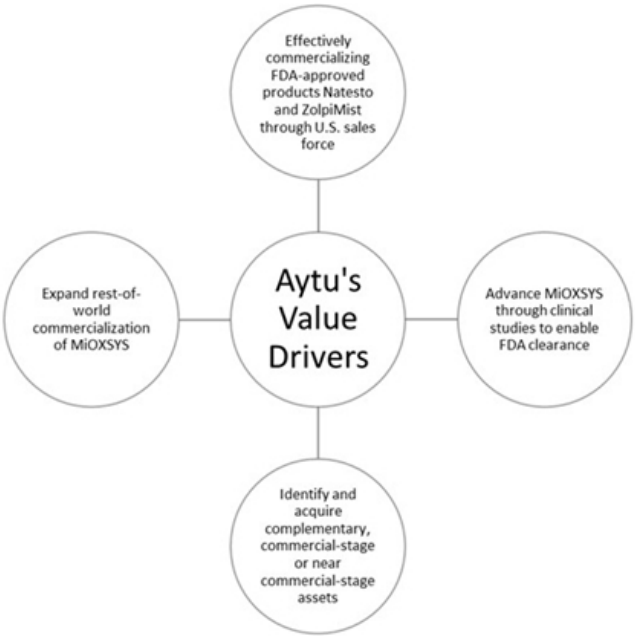
On March 20, 2015, Rosewind formed Rosewind Merger Sub V, Inc. and Rosewind Merger Sub L, Inc., each a wholly-owned subsidiary formed for the purpose of the Merger. On April 16, 2015, Rosewind Merger Sub V, Inc. merged with and into Vyrix and Rosewind Merger Sub L, Inc. merged with and into Luoxis, and 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, solely to pursue the specialty pharmaceuticals, devices, and diagnostics markets, focusing on large areas of medical need, 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. At our annual meeting of shareholders held on June 27, 2018, our shareholders approved another reverse stock split at a ratio of 1-for-20 which became effective on August 10, 2018. All share and per share amounts in this report have been adjusted to reflect the effect of these reverse stock splits (hereafter referred to collectively as the "Reverse Stock Splits").

Our Strategy

In the near-term, we expect to create value for shareholders by implementing a focused, four-pronged strategy. Our primary focus is on growing sales of Natesto in the U.S. and relaunching ZolpiMist through our sales force, expanding the MiOXSYS business both inside and outside the U.S., advancing MiOXSYS toward FDA clearance, and continuing to build a product pipeline through efficient business development. Upon achieving growth of our current, revenue-generating products, we intend to build a complementary portfolio of aligned assets that can be efficiently commercialized through our specialty sales force and, when appropriate, aligned distribution partners outside the U.S. In just over three years since our formation through the merger, we have acquired or in-licensed four FDA-approved, marketed assets (and have since divested one asset – Primsol® Solution and have discontinued another, ProstaScint®), launched a U.S.-based specialty sales force, advanced our lead diagnostic asset MiOXSYS to CE marking, Health Canada clearance, Australian TGA approval, and Mexican COFEPRAS clearance, engaged in asset purchase and licensing discussions for products aligned to our strategy, launched Natesto in the U.S. through our own sales force, licensed ZolpiMist in the U.S. and Canada, and are now preparing for ZolpiMist's re-launch through our sales force.

Aytu BioScience's Strategic Value Drivers



The primary elements of our strategy are:

- **Effectively commercializing Natesto and ZolpiMist, our FDA-approved products through our U.S. sales force**

Natesto

Low testosterone is a condition affecting approximately 13 million U.S. men, with U.S. revenues reaching $1.8 billion for the twelve months ending December of 2017. 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 gross revenues in excess of $90.0 million.

Natesto is a novel, 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) as required with the market-leading product AndroGel and other topically-applied gels. 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. Additionally, with Natesto's unique pharmacokinetic profile including rapid time to C_{max} and clearance in 6-8 hours, we believe Natesto may present an improved safety profile over the currently marketed TRT formulations.

ZolpiMist

ZolpiMist is commercially available and competes in the non-benzodiazepine prescription sleep aid category, a $1.8 billion prescription drug category with over 43 million prescriptions written annually. Thirty million prescriptions of zolpidem tartrate (Ambien®, Ambien® CR, Intermezzo®, Edluar®, ZolpiMist™, and generic forms of immediate-release, controlled release, and orally dissolving tablet formulations) are written each year in the U.S., representing almost 70% of the non-benzodiazepine sleep aid category. Approximately 2.5 million prescriptions are written for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets).

ZolpiMist is a novel, FDA-approved prescription product that is indicated for the short-term treatment of insomnia, and is the only oral spray formulation of zolpidem tartrate - the most widely prescribed prescription sleep aid in the U.S. Because of ZolpiMist's oral spray delivery, patients achieve rapid increases in zolpidem tartrate blood levels with a low 5 mg dose per spray. Due to the rapid absorption through the mucosa and increase in blood levels, patients may achieve quicker sleep onset while avoiding first-pass liver metabolism.

We have launched a commercial infrastructure in the U.S. in order to support increased sales and distribution of Natesto, and now ZolpiMist. We have a highly experienced sales force including over thirty full-time sales representatives, and this team is distinctly focused on impacting the prescribing of physicians throughout the U.S. Through this efficient, dedicated sales channel we believe we will be able to increase prescribing of our unique commercial assets.

- **Expanding rest-of-world commercialization of MiOXSYS for male infertility**

The MiOXSYS System is our proprietary *in vitro* diagnostic system that measures oxidation-reduction potential (ORP) in semen as an aid in the diagnosis of male infertility. MiOXSYS is CE Marked, Health Canada, Australian TGA and Mexico COFEPRIS approved. Through the measurement of oxidation-reduction potential, oxidative stress is directly assessed in that ORP incorporates all known and unknown oxidants and antioxidants in semen.

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, monitor patients' responses to antioxidant therapy and improve diagnosis of male infertility.

Oxidative stress is recognized as a cause of DNA damage, which results in higher rates of sperm dysfunction and infertility. The MiOXSYS System is the only system that directly measures oxidation-reduction potential to provide a comprehensive measurement of oxidative stress, and multiple studies have demonstrated the predictive value of ORP as it relates to both predicting semen quality (sperm motility, sperm concentration, sperm morphology) and correlates to infertility rates.

MiOXSYS has now been sold into 29 countries around the world through a distribution network comprised of companies who are active in the infertility market. We support the commercialization of MiOXSYS through active development of clinical and scientific data, promotion to key opinion leaders in the field of infertility, and active work with our distributor partners to promote the benefits of MiOXSYS and its key diagnostic output, static oxidation-reduction potential (sORP). Prominent centers around the world have utilized MiOXSYS in both clinical and research environments, and these include Cleveland Clinic in Cleveland, Ohio, Tulane University in New Orleans, Louisiana, Hamad Medical Corporation in Doha, Qatar, Dokkyo University Hospital in Tokyo, Japan, Singapore General Hospital in Singapore, Invicta Clinic in Poland, Zech Clinic in Austria, and many others.

In November 2017, the European Society for Human Reproduction and Embryology (ESHRE) published clinical guidelines surrounding Recurrent Pregnancy Loss. This notable organization specifically recommended testing for DNA damage in sperm for men whose female partners have suffered recurrent pregnancy loss. The MiOXSYS System is capable of performing this test. Additionally, oxidative stress is implicated as a cause of DNA damage and testing and potential treatment to improve seminal oxidative stress levels is recommended. This publication highlights the growing base of support for advanced semen testing in the context of oxidative stress testing to further assess sperm damage and help further identify potential underlying causes of damage. We expect this guideline, along with the increasing body of evidence supporting oxidation-reduction potential as a strongly correlated marker in male infertility, to further drive awareness of the clinical utility of MiOXSYS and accelerate adoption for the MiOXSYS System.

- **Advance MiOXSYS through clinical studies to enable FDA clearance.**

With MiOXSYS now CE marked, Health Canada, Australian TGA and Mexican COFEPRAS approved, and available for sale in many markets outside the U.S., we believe we are positioned to initiate our clinical studies in the U.S. to enable 510k de novo clearance in the near future. We expect to receive guidance from the 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.

We have engaged with the FDA initially and submitted a pre-submission around the concept of oxidation-reduction potential measurement as an aid in the assessment of male infertility and believe that, with further development of a specific male infertility intended use, we can re-approach the FDA with a clinical study plan and specific protocol developed that would enable us to progress with a pivotal clinical trial, thus enabling 510k de novo clearance.

- **Identifying and acquiring complementary commercial-stage or near commercial-stage 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 commercial stage products or near-commercial stage product candidates for large, underserved conditions. We will opportunistically consider products or product candidates based on their ability to create value and complement our infrastructure's focus and expertise. 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 months from the Company's merger in April 2015, we began generating revenue from the acquisition of ProstaScint, we later launched Natesto in July 2016, and will launch ZolpiMist through its U.S. sales force in late 2018. We expect to continue to identify and acquire additional, complementary assets in the future as part of our expansion plan.

Our FDA – Approved Products

Our two primary therapeutic products have received FDA approval for marketing in the U.S.: Natesto and ZolpiMist.

Natesto for Testosterone Replacement

On April 22, 2016, we entered into a license and supply agreement to acquire the exclusive U.S. rights, which rights we acquired on July 1, 2016, to Natesto ® (testosterone) nasal gel from Acerus Pharmaceuticals Corporation, or Acerus. Natesto is a patented, FDA-approved testosterone replacement therapy, or TRT, and is the only nasally-administered formulation of testosterone available in the U.S. 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 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 and patches (such as Androderm®) 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® (pellets), Aveed® (injectable testosterone undecanoate) or testosterone cypionate injections.

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 a nasally-administered 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 significantly increase revenue with Natesto in the U.S. as Natesto competes in a large, growing market. The U.S. TRT market is large, with annual revenues in the U.S. of $1.8 billion for the 12-month period ending December 2017. At the current market size of $1.8 billion, a product with 5% market penetration could achieve sales in excess of $90 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, injections, and patches. Testopel, an implantable pellet implanted directly under the skin by a physician, is also FDA-approved and marketed by Endo International plc.

The 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 International	1972	No
Vogelxo®	Gel	Upsher-Smith	2014	Yes

AndroGel®, marketed by AbbVie, is the leading TRT and had 2017 revenues of over $1.0 billion and over 1.3 million prescriptions.

Importantly, however, AndroGel is now facing generic competition with the expiration of key patents for its 1.0% formulation, and it is expected that generic equivalents to its 1.62% formulation will soon be introduced.

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 U.S., 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 undertreated.

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 and was approved by the FDA in May 2014.The details of the U.S.-based pivotal trial are as follows:

In its pivotal clinical trial, Natesto was evaluated for efficacy in a 90-day, open-label, multicenter study of 306 hypogonadal men. Eligible patients were 18 years of age and older (mean age 54 years) and had morning serum total testosterone concentrations less than 300 ng/dL. Patients were Caucasian (89%), African-American (6%), Asian (5%), or of other ethnicities (less than 1%).

Patients were instructed to self-administer Natesto (11 mg of testosterone) intranasally either two or three times daily.

The primary endpoint was the percentage of patients with an average serum total testosterone concentration (C_{avg}) within the normal range (300 to 1050 ng/dL) on Day 90.

The secondary endpoint was the percentage of patients with a maximum total testosterone concentration (C_{max}) above three predetermined limits: greater than 1500 ng/dL, between 1800 and 2500 ng/dL, and greater than 2500 ng/dL.

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

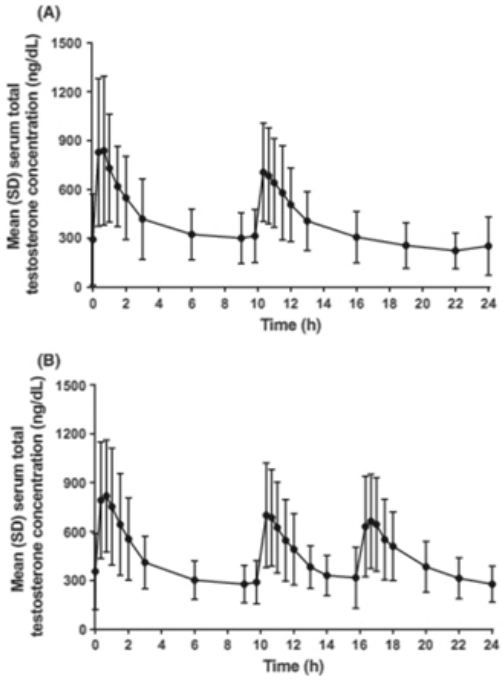
The table below (Table 3 from the Natesto Prescribing Information) summarizes the mean (SD) serum total testosterone concentrations on Day 90 in 69 patients who had a full pharmacokinetic sampling profile and were treated with Natesto (11 mg of testosterone) three times daily for 90 days.

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

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

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

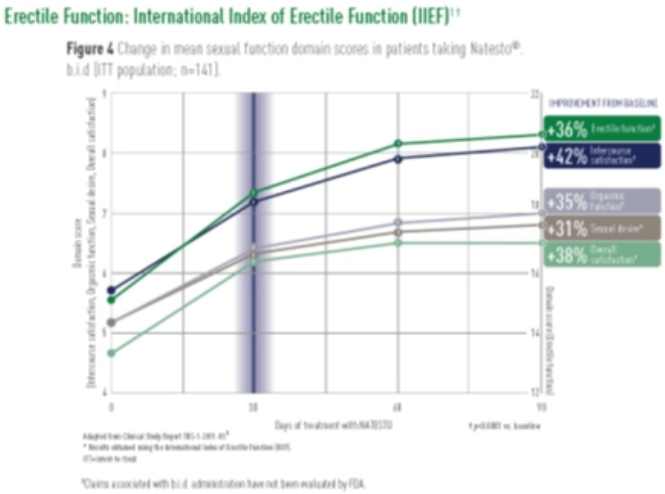
Figure 3 Plot of 24-h total testosterone concentration-time curves by treatment regimen and time point at Day 90 in the intent-to-treat population. Data are shown for the b.i.d. dosing ($n = 141$) (A), and the t.i.d. dosing ($n = 77$) (B).



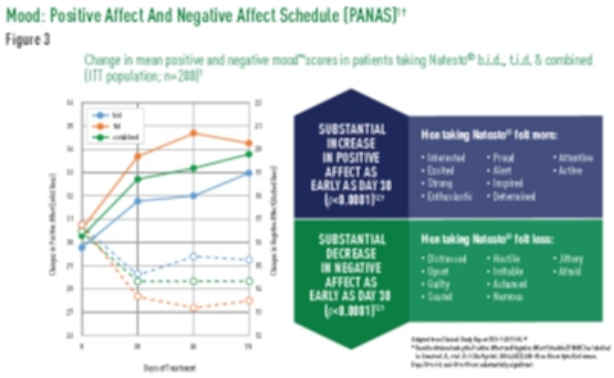
Recently Presented Natesto Safety and Efficacy Data

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:

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



In addition to demonstrating a significant improvement in erectile function, Natesto also exhibits a substantial impact on mood as measured by the 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.



In addition to efficacy parameters, safety parameters have also been examined and recently reported. Safety issues frequently associated with prolonged use of testosterone replacement therapies, most notably injectable agents, include the fact that gonadotropin levels (specifically luteinizing hormone (LH) and follicle stimulating hormone (FSH) levels) frequently decrease and result in diminished endogenous testosterone production (primarily through the reduction of LH) and reduced sperm production (primarily through the reduction of FSH), both of which have negative implications on reproductive health and overall male hormonal balance.

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 of Natesto administration. Also, hematocrit (responsible for maintaining blood thickness) was not significantly impacted by Natesto over 360 days of treatment. It has been established that other testosterone replacement therapies alter levels of follicle stimulating hormone (FSH) and luteinizing hormone (LH) and increase hematocrit, so we believe Natesto's clinical profile may offer distinct safety advantages for patients over the other currently available therapies.

Patients treated with Natesto for 90 days, restored serum testosterone levels while FSH and LH levels remained within the reference range as depicted in the figure below.

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

Similarly, these same patients maintained normal hematocrit levels over a 360-day extension period in the pivotal trial – as depicted in the figure below.

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)

Natesto Product Features and Patient Benefits

We believe Natesto has a unique opportunity to gain market share in the more than $1.8 billion U.S. market given Natesto'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;
- Natesto has a favorable safety profile as demonstrated by the following:

    - Lower incidence of rising Prostate specific antigen ("PSA") levels than the market leading product AndroGel; Natesto demonstrates a 5.5% rate of rising PSA levels in clinical trials, while AndroGel demonstrated a rising PSA rate of over 11% in clinical trials. This is an important consideration as physicians concerned with understanding and tracking prostate cancer risk frequently monitor PSA levels in men over 50 years of age.
    - Natesto restored serum testosterone to normal levels while Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH) remained well within the reference range over 90 days.
    - 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.

Recent Natesto Market Events

Recent market events involving prospective Natesto competitors may lead to an improved competitive position for Natesto in the U.S. as we continue to build awareness and expand market share in the TRT category. On January 10th, 2018 Lipocine Inc. (NASDAQ: LPCN) announced that the Bone, Reproductive and Urologic Drugs Advisory Committee ("BRUDAC" also known as "AdCom") of the U.S. FDA voted six in favor and thirteen against the benefit/risk profile of Tlando, Lipocine's oral testosterone product candidate for testosterone replacement therapy ("TRT") in adult males with hypogonadism. Additionally, on January 9th, 2018 the FDA held a separate Advisory Committee meeting to review privately-held Clarus Therapeutics' oral testosterone candidate Jatenzo. The committee also voted against approving Clarus' candidate primarily over safety concerns. Thus, it is highly unlikely that either product will be approved by FDA at this time, and the prospect of an FDA approval at any point in the future remains doubtful. In fact, Lipocine issued a press release in May 2018 confirming that Lipocine had received a Complete Response Letter (CRL) from the FDA informing the company that Tlando was not approvable in its current form.

We believe that the recommendations to not approve Tlando and Jatenzo and the subsequent Complete Response Letter on Tlando specifically, could yield important commercial benefits for Natesto and further bolsters Natesto's unique market position as the only topical TRT without a BLACK BOX warning explicitly warning users of these agents against the risk of testosterone transference.

One of the issues cited as a reason for the negative AdCom sentiment, and subsequent CRL, on these oral testosterone therapies is related to the products' cardiovascular risk profiles as presented in their New Drug Applications. Also, and more generally, an increase in hematocrit levels is broadly cited as a safety concern in the TRT category and has been noted to be an issue of potential focus for future TRT product candidates. Importantly (and in direct contrast to many agents in the TRT category), Natesto (over 360 days on treatment demonstrated) no significant increase in hematocrit levels and may, therefore, offer an improved safety profile over the established products in the TRT category.

Similarly, in October 2017, Antares Pharmaceuticals received a CRL from the FDA for its product candidate Xyosted®, an injectable testosterone replacement therapy. In its response, the FDA cited multiple safety concerns related and, we believe, the launch of this product may be substantially delayed – or may not occur at all. Antares has recently resubmitted the application for approval for Xyosted, and the FDA has issued a PDUFA date of September 29, 2018.

These CRLs point to the high burden of proof placed on developers of TRT product candidates and, we believe, further validates the value of Natesto as an-already-FDA-approved product in this $1.8 billion product category. With the prospects of future prospective competitive products in doubt, Natesto's competitive position may be improved and even more sustainable for the foreseeable future.

ZolpiMist for the Short-Term Treatment of Insomnia

On June 11, 2018 the Company signed an exclusive license for ZolpiMist™ (Zolpidem Tartrate Oral Spray) with Magna Pharmaceuticals, Inc. This agreement allows for Aytu's exclusive commercialization of ZolpiMist in the U.S. and the ability to sublicense the product for commercialization in Canada. The ZolpiMist license adds another unique, commercial-stage product to the Company's product portfolio and provides our U.S. commercial team with another novel product to sell to their already-called-on physician targets. More than half of our sales force's Natesto physician targets are primary care physicians (family medicine, internal medicine, general practice), so there is a significant overlap in targets and opportunity to enable them to efficiently sell both Natesto and ZolpiMist to these prevalent, high-prescribing clinicians. The Company expects to formally launch ZolpiMist through its U.S. sales force in late 2018.

ZolpiMist is an FDA-approved prescription product that is indicated for the short-term treatment of insomnia and is the only oral spray formulation of zolpidem tartrate - the most widely prescribed prescription sleep aid in the U.S. ZolpiMist is commercially available and competes in the non-benzodiazepine prescription sleep aid category, a $1.8 billion prescription drug category with over 43 million prescriptions written annually. Thirty million prescriptions of zolpidem tartrate (Ambien®, Ambien® CR, Intermezzo®, Edluar®, ZolpiMist™, and generic forms of immediate-release, controlled release, and orally dissolving tablet formulations) are written each year in the U.S., representing almost 70% of the non-benzodiazepine sleep aid category. Approximately 2.5 million prescriptions are written for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets).

ZolpiMist (5 mg per dose and available in both a 30-dose and 60-dose canister) was approved for marketing by the FDA in December of 2008 and was shown to be bioequivalent to Ambien® 5 mg and 10 mg tablets. ZolpiMist is indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation and is contraindicated in patients with a known hypersensitivity to zolpidem tartrate.

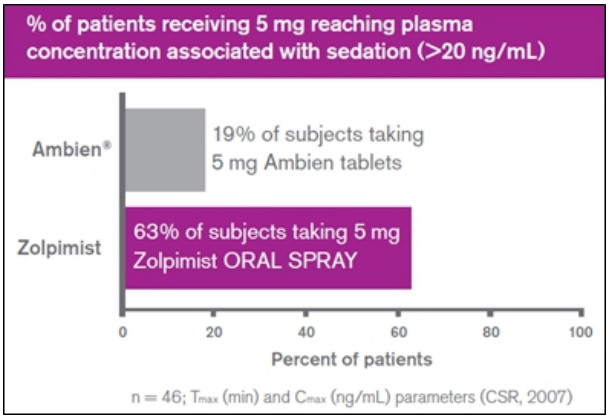
Image of ZolpiMist in its Child-Resistant Container

Due to ZolpiMist's unique oral spray delivery and the resulting rapid absorption through the oral mucosa, ZolpiMist has several clinical advantages over oral tablet formulations, most notably a rapid onset of action that quickly induces sleep. Additionally, and also due to the product's oral spray formulation, ZolpiMist does not require swallowing and may therefore be easier and more convenient to take than tablets for patients who have difficulty swallowing or have an aversion to taking tablets.

Pharmacokinetic data as published in the ZolpiMist Clinical Study Report demonstrate multiple distinctions between ZolpiMist and oral zolpidem tartrate tablets in the study that led to the product's approval. Specifically, more patients achieve high blood levels of zolpidem faster with oral spray delivery than with tablets – and this is expected to derive faster onset of sleep.

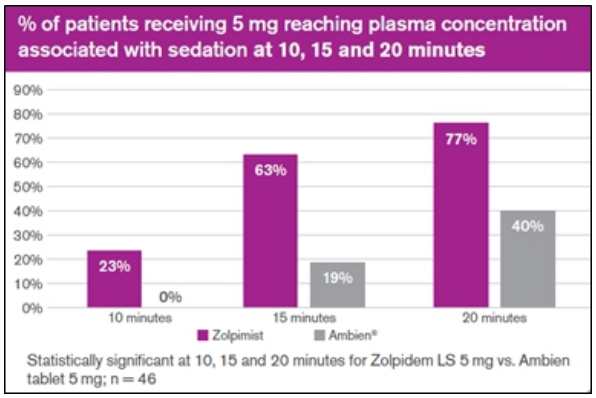
In a study of 46 insomnia patients, a significantly higher proportion of patients receiving 5 mg of zolpidem tartrate achieved plasma levels associated with sedation with the oral spray formulation than with the oral tablet formulation.

The figure below depicts the difference in plasma levels between patients taking ZolpiMist and patients taking Ambien oral tablets.



Additionally, 23% of patients demonstrated sedation-associated blood levels 10 minutes post taking ZolpiMist, while zero zolpidem tartrate tablet patients achieved those levels (20 ng/mL). Similarly, almost twice as many ZolpiMist patients (77%) achieved sedation-associated blood levels than zolpidem tartrate tablet patients (40%) at 20 minutes, a statistically significant difference.

Time to various sedation-associated blood levels are shown in the figure below.



While ZolpiMist offers patients the convenience and speed of onset available through an oral spray, this method of administration may also present a desirable option for patients who have difficulty swallowing. Estimates suggest that 15% of the elderly population is affected by dysphagia, with potentially higher incidence among stroke and dementia patients, as well as patients with neurological diseases, cancers of the head and neck, and esophagus. For these patients, many of whom are challenged with sleep difficulties, ZolpiMist may be an appropriate first option. For patients not affected by dysphagia, they may simply want a faster, more convenient way to take zolpidem tartrate.

The U.S. prescription sleep aid (non-benzodiazepine) category is large, and many primary care physicians prescribe these products routinely. Achieving even a modest 1% share of this 30 million prescription-a-year zolpidem tartrate category could achieve approximately $75 million in net revenues. While the Company has not made revenue projections for ZolpiMist, we do believe this product represents a substantial revenue opportunity for the Company given the product's market potential and the unique product features and patient benefits of ZolpiMist.

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. Since CE marking, MiOXSYS has received Health Canada approval, approval by Australia's TGA, and was most recently approved by Mexico's COFEPRIS.

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 U.S., 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 de novo clearance from the FDA before we can market it for clinical use in the U.S. 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 U.S. 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.

U.S.-Based Proof-of-Concept Clinical Study

Fifty-one (51) male patients were seen at the Cleveland Clinic's andrology laboratory for suspected infertility. In addition to standard semen analyses (WHO 5th Edition, 2010), samples were measured for oxidative stress using the MiOXSYS System. Raw sORP values were normalized 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 given that sORP is a direct measure 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 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 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 additional 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 Hamad Medical Corporation in Doha, Qatar 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 normalized 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 the Hamad urology department clinic confirms the results obtained in the U.S. 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.

Additional clinical and scientific studies have been conducted at leading urology and andrology centers around the world, including seven recently presented studies at the 34th annual meeting of European Society for Reproduction and Human Embryology (ESHRE), which was hosted in Barcelona, Spain July 1-4, 2018. The original abstracts from those presentations are included below.

Investigating the reproducibility and reliability of the ORP measurement as a marker of sperm quality across different fertility centers.

Investigators:

A. Agarwal[1], R. Chandrakumar[1], M. Arafa[2], H. Elbardisi[2], H. Okada[3], K. Suzuki[3], S. Homa[4], A. Killeen[5], B. Balaban[6], A. Ayaz[7] R. Saleh[8], A. Armagan[9], S. Roychoudhury[1], S. Sikka[7]

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7. Tulane University, Urology, New Orleans, U.S.A.
8. Sohag University, Urology, Sohag, Egypt.
9. Bezmialem Vakif University, Urology, Istanbul, Turkey.
10. Assam University, Life Science and Bioinformatics, Silchar, India.

Study question:

Investigate the reproducibility and reliability of the ORP measurement as a marker of sperm quality across different fertility centers.

Summary answer:

ORP provided equal or less variability than the current semen analysis measures across 9 different fertility centers.

What is known already:

Discrete measures of free radicals, antioxidant activity, and oxidative damage suggest an ambiguous relationship between the redox system and male fertility. Static oxidation-reduction potential (sORP) measures the balance between all oxidants and antioxidants providing a comprehensive status of the redox system. In a previous study, ORP and semen analysis data were compared between two andrology laboratories, in which ORP remained consistent in both datasets individually or in combined data.

Study design, size, duration:

This prospective study was carried out jointly by nine participating fertility centers on 1,644 subjects. The study was approved by the institutional ethics committee and subjects were consented prior to participation. Subjects were grouped into those that had all normal semen parameters (concentration, total cell, total motility, progressive motility, and morphology) according to WHO 2010 guidelines and those who failed to meet one or more criteria. ANOVA/t-test measures were used to determine significant differences.

Participants/materials, setting, methods:

Exclusion criteria included azoospermia, presence of sexually transmitted disease or chronic disease, use of prescription, OTC medications or antioxidants. Samples were collected, and semen parameters assessed using the WHO 2010 guidelines. ORP was measured (mV) using the MiOXSYS system and normalized to sperm concentration (mV/10 ^{6} sperm/ml). For group comparisons, only those samples with a concentration > 0.999x 106 sperm/ml were included.

Main results and the role of chance:

The results of ORP reflects the oxidative relationship between the sperm cell and its environment - the expulsion of oxidants, a by-product of cellular metabolism, into the seminal environment and the deactivation of them by extracellular antioxidants. The resulting ORP measurement reflects the average of the final ten (10) seconds (or twenty readings) of the sample. Of the 1,644 samples, 138 were found to have normal semen parameters and 1,506 were found to have abnormal semen parameters. The mean ORP value (mV/10 6 sperm/ml) in the semen of the abnormal group was 5.07mV/10 6 sperm/ml whereas that of the normal group was 0.88 mV/106 sperm/ml (p = 0.001) . The SD for ORP was equal to or better than most measures, with exception to morphology. However, it should be noted that morphology is the parameter with the highest variability typically found between laboratories.

Limitations, reasons for caution:
Study enrollment of an even number of healthy controls with proven fertility was limited in comparison to the male infertility group.

Wider implications of the findings:
ORP remains stable even with measurable differences in sperm parameters, and it therefore can be used as a supplementary test to semen analysis to confirm oxidative stress and poor semen quality.

Investigating if ORP can reliably predict semen samples that meet normal reference range of WHO criteria from those that fail to meet across fertility centers

Investigators:
A. Agarwal[1], H. El bardisi[2], M. Arafa[2], H. Okada[3], K. Suzuki[3], S. Homa[4], A. Kileen[5], B. Balaban[6], A. Ayaz[7], R. Saleh[8], A. Armagan[9], C. Dorsey[10], S. Roychoudhury[11], S. Sikka[7]

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10. Aytu BioScience, Englewood, U.S.A.
11. Assam University, Life Science and Bioinformatics, Silchar, India.

Study question:
Identify if ORP measure could reliably predict semen samples that meet normal reference range of WHO criteria from those that fail to meet across fertility centers.

Summary answer:
Of the 1,644 samples analyzed, the ORP measure provided the greatest predictability when distinguishing abnormal from normal semen quality among patients undergoing infertility evaluation.

What is known already:
Discrete measures of free radicals, antioxidant activity, and oxidative damage suggest an ambiguous relationship between the redox system and male fertility. Oxidation-reduction potential (ORP) measures the balance between all oxidants and antioxidants providing a comprehensive status of the redox system. In previous studies, ORP has been tested in semen samples using the MiOXSYS System as an alternative method for measuring oxidative stress and distinguishing normal controls from male factor infertility patients; thus, ORP levels may be used to clarify the relationship between the redox system and semen parameters associated with male infertility.

Study design, size, duration:
This prospective study was carried out jointly by nine participating fertility centers on 1,644 subjects. The study was approved by the institutional ethics committee and subjects were consented prior to participation. Subjects were grouped into those that had all normal semen parameters (concentration, total concentration, total motility, progressive motility, and morphology) according to WHO 2010 guidelines and those who failed to meet one or more criteria.

Participants/materials, setting, methods:
Exclusion criteria included azoospermia, presence of sexually transmitted disease or chronic diseases, use of prescription, OTC medications or antioxidants. Samples were collected and semen parameters assessed using the WHO 2010 guidelines. ORP was measured (mV) using the MiOXSYS system and normalized to concentration (mV/10^6 sperm/ml). For group comparisons, only those samples with a concentration > 0.999xl 0 ^{6} sperm/ml were included.

Main results and the role of chance:
In the current study, using an ORP test in conjunction with the semen analysis measures resulted in the detection of abnormal semen quality with a 98.1% sensitivity, 40.6% specificity, 94.7% positive predictive value, and 66.6% negative predictive value. ORP provides a unique and statistically significant contribution in classifying semen quality into abnormal and normal status. A logistic regression performed on all measures (six semen analysis parameters and ORP measure) revealed the predictability of identifying abnormal/ normal semen quality within the samples. Measures were categorized according to overall contribution and significance. ORP ranked the highest (beta 2.88, p = 0.01) in terms of predicting abnormal/ normal semen quality, followed by progressive motility (beta 2.29, p= 0.001), and total motility (beta .494, p= 0.005). Utilizing ORP and semen analysis combined, the overall performance characteristics were 98.1 sensitivity, 40.6 specificity, 93.3% positive predictive value, and 66.7% negative predictive value.

Limitations, reasons for caution:
A number of healthy controls with proven fertility was limited in comparison to the male infertility group. While semen parameters are an important part of the assessment of the infertile male, the gold standard is the reproductive outcome. Pregnancy outcomes were not prospectively measured in the infertile group.

Wider implications of the findings:
Abnormal ORP levels will be especially useful in pinpointing the altered functional status of the sperm in patients with idiopathic male infertility and thereby directing those men toward accurate therapeutic management.

Does an electrochemical assay using the MiOXSYS CE-marked analyzer, consistently meet the requirements and specifications to reliably measure static oxidation reduction potential (sORP) in human semen?

Investigators:
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4. Guy's Hospital, The Urology Centre, London, United Kingdom.

Study question:
Does an electrochemical assay using the MiOXSYS CE-marked analyzer, consistently meet the requirements and specifications to reliably measure static oxidation reduction potential (sORP) in human semen?

Summary answer:
The MiOXSYS assay is robust, performing according to expectations and has been standardized and validated to reliably and accurately measure sORP in human semen.

What is known already:
Low levels of reactive oxygen species (ROS) are prerequisite for sperm function. Physiological levels of ROS are maintained by antioxidants (reductants) in the local environment. A disturbance in the balance between oxidants and antioxidants leads to oxidative stress (OS), impairing sperm function and genetic integrity. A novel method for assessing OS in semen involves measuring sORP using the MiOXSYS galvanostat-based technology analyzer. ORP measures levels of oxidants and reductants, providing a more comprehensive measure of OS than measurement of ROS alone. Although the MiOXSYS assay effectively measures sORP in semen, it has yet to be fully validated.

Study design, size, duration:
This study was a technical validation of an assay for measuring sORP using the MiOXSYS CE-marked analyzer. It included 40 replicate measurements of control samples on different days and on two separate analyzers. Intra- and inter-technician variability was determined from 40 replicates. The characteristics of sORP in semen and the effects of independent variables were measured in 6 replicate samples from 19 men. Variables included time from ejaculation, temperature, mechanical agitation and freeze-thaw action.

Participants/materials, setting, methods:
The assay requires applying 30µ1 sample onto a disposable sensor which is inserted into the MiOXSYS analyzer and a current is applied. sORP is displayed in mV after 2-4 min. Values were recorded for different operators, days and analyzers using multipurpose handling medium (Irvine Scientific, CA, USA) as a control. Semen samples were obtained from consenting men attending for routine semen analysis to determine the stability of seminal ORP under different conditions.

Main results and the role of chance:
Measurement of sORP (mV) using the CE-marked MiOXSYS platform (Aytu BioScience, CO, USA) demonstrated repeatability between 40 replicates of the same control sample with no significant difference between measurements (mean sORP (mV) ± SEM= 281.5 ± 4.8; CV= 0.1). Readings remained consistent across multiple operators ($p= 0.67$), separate analyzers ($p= 0.95$) and on different days ($p= 0.09$).

Additionally, there was no significant difference between sORP values for 40 replicates of a single semen sample (mean sORP (mV) ± SEM= 45.1 ± 1.0; CV= 0.1). Although readings remain relatively stable in semen up to 45 min post ejaculation (p=0.06), there are significant variations in seminal sORP values across all samples by 60 min post ejaculation (p < 0.005). sORP in semen remains stable after freezing and thawing as values do not change significantly (p= 0.47). This was demonstrated across biological replicates (n= 6).

There was a significant difference between sORP in semen after mechanical agitation using a bench-top vortex (p=0.005) and between samples incubated at different temperatures (2 -6°C, 20-24° (and 36 + 1 °C; p=0.003).

Limitations, reasons for caution:
The validation of the MiOXSYS platform was carried out in one laboratory only. A multicenter validation would assist in confirming the reproducibility and reliability of the test.

Wider implications of the findings:
This simple to use, cost effective assay could be implemented in conjunction with semen analysis providing a welcomed addition to routine diagnostic testing for male infertility. It may be particularly relevant to men with unexplained infertility, whose partners experience a delay in conception, multiple assisted conception failures or miscarriages.

Can sperm oxidative stress, measured as static oxidation-reduction potential (sORP), predict high levels of sperm DNA damage?

Investigators:
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6. Women's College Hospital, Gynaecology, Toronto, Canada.

Study question:
Can sperm oxidative stress, measured as static oxidation-reduction potential (sORP), predict high levels of sperm DNA damage?

Summary answer:
sORP was positively correlated (p= 0.002) to DNA damage and a sORP cut-off of 2.37 mV/10^6 sperm/ml was predictive of high levels of DNA damage.

What is known already:
High levels of sperm DNA damage have been associated with decreased pregnancy rates and an increased risk of miscarriage. While the causes are multifactorial, sperm oxidative stress has been shown to play a key role in the etiology of DNA damage. The MiOXSYS system uses sORP, a global measure of the balance between oxidants and reductants, to determine oxidative stress.

Study design, size, duration:
This prospective, institutional REB approved cross-sectional study was performed on 52 male, infertile patients presenting to the Andrology laboratory for routine semen analysis after 2-5 days of abstinence at the CReATe Fertility Center between July 2017 and January 2018.

Participants/materials, setting, methods:
Male infertility patients with leukocytospermia or sperm concentration <1 million/ml were excluded. Semen analysis was conducted as per WHO 2010 guidelines. sORP was measured using the MiOXSYS system. DNA damage was evaluated by standard flow cytometric acridine orange-based assay as DNA Fragmentation Index (DFI). sORP was compared between a high DFI (30%) and low DFI (<30%) group and correlated to semen parameters. Receiver Operator Curve (ROC) analysis determined the sORP cut-off predictive of high DFI.

Main results and the role of chance:
The mean paternal age was 39.2±6.1 years (age range: 28 - 54 years). The mean sperm concentration was 43.0±37.2 M/ml, total motility was 55.2±14.5 %, morphology was 6.5±4.2 %, and DFI was 21.7±10.1 %. A significant positive correlation was found between sORP and DFI (r=0.43, p= 0.002). A significant negative correlation was found between sORP and concentration (r=-0.46, p= 0.0006) and between sORP and morphology (r=-0.33, p=0.02). Mean sORP was significantly higher (p=0.03) in the high DFI group (4.29±2.52mV/10^6 sperm/ml) compared to the low DFI group (1.87±2.17 mV/106 sperm/ml). ROC analysis indicated that a sORP cut-off of 2.37 mV/10^6 sperm/ml had a sensitivity of 75.0%, a specificity of 77.2%, a positive predictive value (PPV) of 37.5% and a negative predictive value (NPV) 94.5%. The area under the ROC (AUROC) was 0.84 (95% CI: 0.72 - 0.96, p=0.003) and the diagnostic accuracy was 76.9%.

Limitations, reasons for caution:
No additional confirmatory DNA damage methodologies were assessed. The DNA damage assay used in this study is generally considered the gold standard, however several alternatives are also routinely used. Larger standardized studies are needed to confirm the performance characteristics of sORP in predicting high DFI.

Wider implications of the findings:
Requiring as little as 5 minutes to complete and a drop (30 ul) of semen, the MiOXSYS system provides a rapid, cost-effective measure of global oxidative stress easily integrated into clinical workflows. It can be used to specifically identify patients with oxidative stress induced DNA damage for anti-oxidant therapy.

Does evaluation of static oxidation-reduction potential (sORP) with MiOXSYS System relate with WHO 2010 (World Health Organization) sperm parameters and DNA fragmentation in infertile patients?

Investigators:
F. Scarselli[1], S. Gatti[1], E. Cursio[1], A. Pristera[1], V. Zazzaro[1], M. Minasi[1], A. Ruberti[1], S. Muzzi[1], M. Varricchio[1], A. Caragia[1], P. Greco[1], E. Iovine[1], V. Casciani[1], E. Greco[1]

1. European Hospital, Reproductive Medicine, Rome, Italy.

Study question:
Does evaluation of static oxidation-reduction potential (sORP) with MiOXSYS System relate with WHO 2010 (World Health Organization) sperm parameters and DNA fragmentation in infertile patients?

Summary answer:
There is association between sORP and sperm parameters: sORP levels are higher in patients with lower concentration, motility and morphology and with higher DNA fragmentation.

What is known already:
Spermatozoa have a physiological equilibrium between ROS (Reactive Oxygen Species) and anti - oxidants. This equilibrium assures ordinary functions such as chromatin compaction, lipid membrane modification and sperm-oocyte fusion. When ROS are overproduced this equilibrium is lost, generating oxidative stress (OS), possible cause of lipid peroxidation, apoptosis and DNA damages or fragmentation. Seminal plasma contains anti-oxidant factors (enzymatic and non-enzymatic) to prevent post-ejaculation OS, however many studies demonstrate that in infertile men anti-oxidant levels are low and ROS are high; these concentrations may be influenced by both exogenous and endogenous factors: smoking, alcohol assumption, infection and inflammation of male um-genital tract.

Study design, size, duration:
Semen from 84 infertile men were evaluated, according to WHO 2010, during June and July 2017. On their first visit at Reproductive Medicine Unit, patients underwent semen analysis and sORP evaluation and divided in two groups according to semen morphology. Group A (N=45) included patients with morphology 3 or 4 and group B (N=39) patients with morphology <4. Men with ejaculatory dysfunction, varicocele, sexually transmitted diseases and exposed to radiation or chemotherapeutic agents were excluded.

Participants/materials, setting, methods:
Semen samples were produced after 72 -120 hours of sexual abstinence and analyzed after complete liquefaction, evaluating semen parameters and DNA fragmentation with TUNEL (Terminal deoxynucleotidyl transferase UTP-driven Nick End Labeling) test. MiOXSYS was used to evaluate sORP (expressed in millivolt/sperm concentration 10^6/ml), a 'snapshot' of the current balance of the redox system. A higher sORP level indicates an imbalance in the activity of all available oxidants relative to all available antioxidants in ejaculates.

Main results and the role of chance:
Mean male age was 42.1±6.3 in group A and 38.2±6.5 in group B (p<0.05). Semen volume was 3.2±2.3 ml in group A and 3.0±2.0 in group B (NS). Sperm concentration was 47.2±18.0 mil/ml in group A and 24.7±19.0 mil/ml in group B (p< 0.05). Sperm motility (progressive plus not progressive) was 66.7± 7.4 and 44.3± 20.0 in group A and B respectively (p< 0.05). Morphology was 4.2± 0.5 in group A and 2.1± 0.7 in group B (NS). Round cells concentration was 2.3±2.0 and 2.7±2.0 mil/ml in group A and B respectively (NS). DNA fragmentation measure with TUNEL test resulted to be 7.5±6.4 in group A and 11.0±8.1 in group B (p<0.05).

Does varicocelectomy improve Oxidation Reduction Potential (ORP) as an independent measure of oxidative stress (OS) in infertile men?

Investigators:
H. Elbardisi[1], A. Majzoub[1], S. AlSaid[1], A. Agarwal[2], R. Henkel[3], H. Shehadeh[1], K. Alrumaihi[1], M. Arafa[1]

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3. University of the Western Cape, Medical Bioscience, Bellville, South Africa.

Study question:
Does varicocelectomy improve Oxidation Reduction Potential (ORP) as an independent measure of oxidative stress (OS) in infertile men?

Summary answer:
Elevated oxidative stress is related with poor semen quality in men with varicocele. Varicocele surgery reduces the ORP levels and improves sperm count.

What is known already:
Patients with varicocele tend to have poor sperm quality and are at higher risk of being infertile. Although the pathophysiology of infertility in males with varicocele has been extensively studied, the underlying mechanism remains unclear. Many reports have shown that oxidative stress is one of the underlying mechanisms of poor semen quality in infertile men with varicocele. ORP has been validated as a diagnostic marker of poor semen quality and oxidative stress in men with infertility.

Study design, size, duration:
Prospective, case control study of 43 infertile patients with clinical grade 2-3 varicocele attending a male infertility clinic during January to November 2017.

Participants/materials, setting, methods:
All patients underwent microsurgical subinguinal varicocelectomy. Full medical history and clinical examination was collected. Semen samples were done using WHO Fifth edition criteria and ORP levels were measured by MiOXSYS analyzer before surgery and 3 months post-varicocelectomy. The results were compared by Wilcoxon rank sum test and Spearman's correlation test and a P value < 0.05 was considered significant.

Main results and the role of chance:
All semen parameters (concentration, total motility and normal sperm form) showed an improvement post- surgery but it was not statistically significant. However, the ORP level was significantly reduced after the surgery (10.4 ± 3.3 vs. 4.6 ± 1.1, p value <0.001). All semen parameters (concentration, total motility and normal form) were negatively correlated with ORP pre-operatively. However, only sperm count maintained this significant negative correlation post operatively.

Limitations, reasons for caution:
The small sample size of this study may be a limitation. However, we report on a pilot study describing the effect of varicocelectomy on oxidative stress measures using the ORP system.

Wider implications of the findings:
ORP can be used as a prognostic factor for counselling patients before varicocelectomy.

Is oxidative stress a clinical indicator for testicular function in infertile men?

Investigators:
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5. University of Kuwait, Faculty of Medicine, Kuwait, Kuwait

Study question:
Is oxidative stress a clinical indicator for testicular function in infertile men?

Summary answer:
Oxidative stress measured by oxidation reduction potential (ORP) can be considered a clinical indicator of spermatogenic and not endocrine function of the testis.

What is known already:
Oxidative stress plays a major role in the pathogenesis of male infertility. ORP is a new marker of oxidative stress that has been shown to correlate inversely with important semen parameters in infertile men. ORP levels can be used to discriminate normal fertile men from infertile males. Besides semen parameters, testicular size and FSH are considered as prognostic markers of spermatogenesis.

Study design, size, duration:
Cross sectional, retrospective study on 660 patients attending a male infertility clinic during January to March 2017.

Participants/materials, setting, methods:
Medical records of recruited patients were reviewed. The data extracted included medical history, clinical examination, semen analysis (WHO 5 th edition), ORP (using the MiOXSYS system), hormonal assay including FSH, LH, prolactin, testosterone and estradiol as well as testicular size assessment by scrotal ultrasound. After checking for normal distribution of the data by the Chi-squared test, Spearman rank test was used to detect correlations between different parameters. Statistical significance was defined as $p<0.05$.

Main results and the role of chance:
ORP showed negative correlation with sperm count ($r= -0.793$, $P< 0.0001$), motile sperm count ($r= -0.579$; $P< 0.0001$), progressive motility ($r= -0.431$; $P<0.0001$) and normal sperm morphology ($r= -0.458$; $P< 0.0001$). ORP also correlated with sperm DNA fragmentation ($r= 0.264$, $P< 0.0001$). ORP levels showed significant correlation with the testicular size ($r= -0.386$; $P< 0.0001$), serum FSH ($r= 0.273$; $P<0.0001$) and serum LH concentrations ($r= 0.182$; $P=0.0002$), but not with testosterone, estradiol and prolactin.

Limitations, reasons for caution:
The main limitation is the lack of fertile controls in this study.

Wider implications of the findings:
ORP can be used as a marker of spermatogenesis in infertile men. Further studies should be carried out to demonstrate the effect of treating OS on spermatogenesis. Since varicocele patients show seminal oxidative stress, smaller testes and higher FSH values, ORP could possibly be used as adjunct indicator of varicocele.

RedoxSYS System for Research Use & Background of the Development of MiOXSYS

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 around the world. 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 or clinical 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 U.S., Europe, and Asia to develop direct relationships with researchers and distributors of research products. Through these relationships we have conducted various proof of concept studies and clinical exploratory studies. Most notably through these collaborations utilizing the RedoxSYS System, we identified the application of oxidation-reduction potential in male infertility assessment while measuring oxidation-reduction potential in semen and seminal plasma. As such, the MiOXSYS System was developed specifically for assessing semen and seminal plasma ORP levels in a clinical setting for a rapid, reliable oxidative stress assessment. While we expect additional clinical applications to be developed through our research and distributor relationships, our near-term focus is on continuing 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.

Oxidation-Reduction Potential's Role in Assessing 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 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 a distinct element to determine a patient's oxidation reduction potential, which we call Static ORP. Static ORP is defined as 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. Higher levels of seminal oxidative stress (and sORP levels correspondingly) correlate closely with infertility rates in men.

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.

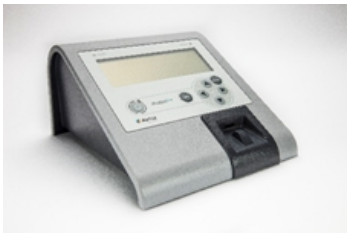
The analyzer contains a 10 MHz external crystal (internal 4X PLL for 40 MHz operation), and a programming/serial header is externally accessible. The device has internal power/heart-beat indicator LED, primary storage of 128Mbit (16Mbyte) SPI Flash (3.3V) (Bulk data storage), and secondary storage of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

The MiOXSYS disposable sensors, 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 Disposable Sensors

Regulatory Pathway

We achieved ISO 13485: 2003 in late 2013 following the successful development of an ISO-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 obtained CE marking for MiOXSYS following technical validation and clinical study completion in male infertility assessment. In March 2016, we obtained Health Canada Class II Medical approvals for MiOXSYS and have subsequently received Australian TGA approval and Mexican COFEPRIS approval in 2018.

In the U.S., we intend to pursue 510k de novo clearance with the FDA for the MiOXSYS System. We have engaged with the FDA and have received confirmation that MiOXSYS is likely appropriate for the 510k de novo pathway, and we are pursuing regulatory clearance accordingly.

U.S. Commercial Strategy

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 allocating our direct sales effort to high priority urology/andrology laboratories, infertility clinics and reference centers across the U.S. We have identified the primary, influential centers in the U.S. 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 sensors. 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, but we have not finalized pricing at this point. We envision selling the MiOXSYS analyzers for approximately $2,500 (pricing not final) but may also pursue an instrument rental agreement model with minimum disposable sensor purchase requirements.

We also intend to leverage our current Natesto commercialization efforts in urology target offices, with a distinct focus on urologists and andrologists who treat and manage male infertility.

ROW Commercial Strategy

Outside the U.S., we have commenced commercialization of the RedoxSYS and MiOXSYS Systems. To efficiently execute our strategy of introducing MiOXSYS to urologists and andrologists around the world, we utilize a network of established distributors in the target markets in Europe and Asia. We have established distribution arrangements with multiple distributors in multiple countries, and through these distributors, we have sold MiOXSYS in over 29 countries around the world. We employ a razor-razorblade revenue model outside the U.S., relying on the initial sale of the MiOXSYS System and repeat purchases of the disposable MiOXSYS sensors by distributors for sale to their direct customers. We also have direct selling relationships with end users and service these accounts directly.

Our Business Development Strategy — Identifying & Acquiring Complementary Assets

A key growth and value driver for our Company is the ongoing identification and acquisition of novel products for commercialization through our commercial infrastructure. We seek to identify unique products serving large areas of unmet needs 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 and subsequently commercialized.

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. However, during fiscal 2019, our primary focus will be on growing our current core assets, advancing the commercialization and U.S. regulatory development of MiOXSYS, 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 one medical device candidate, the MiOXSYS System, for which regulatory approval must be received before we can market this within the U.S. Regulatory approval processes for our current and any future product candidates are discussed below.

Approval Process for Pharmaceutical Products

In the U.S., 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 U.S. 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 Investigational New Drug Application ("IND"), which must become effective before human clinical trials may begin in the U.S., 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.

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 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. They 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 U.S., 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 U.S. 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 de novo 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 de novo 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 de novo 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 de novo clearance process, however, the 510k de novo clearance process has also become increasingly stringent and expensive. The FDA has provided initial guidance to us that the MiOXSYS System is likely appropriate for the 510k de novo clearance process.

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

After a device has received 510k de novo 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 de novo 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 de novo 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 de novo 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 de novo 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 U.S., 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 U.S., 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 U.S., 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.

U.S. 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 U.S. 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 U.S.. 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 for our Products in the U.S.

Natesto and ZolpiMist are covered by many commercial insurance providers and pharmacy benefit management companies and are largely dependent upon reimbursement for continued use in the U.S. market. Natesto and ZolpiMist are 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 and ZolpiMist through their separate Medicare and public assistance programs. Additionally, privately managed Medicare Part D plans may choose to cover Natesto and ZolpiMist prescriptions through their plans' pharmacy benefits. 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 in the U.S. given that infertility testing and treatment is infrequently covered by commercial insurers or public 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.

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 U.S. and generally tend to be significantly lower.

DEA Regulation

Natesto and ZolpiMist, already approved by the FDA, are both a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, because Natesto contains testosterone and ZolpiMist contains zolpidem tartrate. As a result, the U.S. Drug Enforcement Agencies, or DEA, have Natesto listed and regulated as a Schedule III substance and have ZolpiMist listed and regulated as a Schedule IV 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 U.S. 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 U.S. rights 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 nine 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 and RedoxSYS. We have patent protection in the U.S. and several other large markets worldwide for MiOXSYS and the oxidation-reduction potential platform. Specifically, we have numerous patents issued and pending for the RedoxSYS/MiOXSYS systems, the sensors, and their clinical and scientific use in the U.S., Europe, Canada, Israel, Japan, and China.

Our patent portfolio related to RedoxSYS/MiOXSYS is focused on the U.S. and core foreign jurisdictions which include Europe, Canada, Israel, Japan and China. The portfolio is supported in the U.S. and core foreign jurisdictions and consists of 43 issued patents and 23 pending applications.

The portfolio primarily consists of eight families filed in the U.S. and in core foreign jurisdictions. The first family includes seventeen issued patents and one pending application 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 U.S. applications, two issued U.S. patents, two pending applications in core foreign jurisdictions and four issued patents 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 sixteen issued patents and two 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 U.S. application, one issued U.S. patent, two issued patents in core foreign jurisdictions and four 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 U.S. application and seven 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 sixth family includes one pending U.S. application 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 seventh family includes one pending application filed under the Patent Cooperation Treaty with claims directed to methods for embryo selection from the ORP characteristics of a biological sample. The standard 20-year expiration for patents in this family is in 2038. The eighth family includes one pending U.S. provisional application with disclosure directed to methods for determining fertility characteristics from the ORP of a biological sample.

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 U.S. and foreign patent protection for drug and device products we discover, as well as therapeutic and device 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 device 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 U.S. 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 U.S., 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 specialty pharmaceuticals 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 2017 of approximately $1.8 billion. At the current market size of approximately $1.8 billion, a product with 5% market penetration could achieve sales of approximately $90 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®, an injectable pellet typically implanted directly under the skin by a physician, is also FDA-approved. AndroGel is the market-leading TRT and is marketed by AbbVie.

ZolpiMist

ZolpiMist competes in a large prescription category with over 43 million prescriptions written annually and generating $1.8 billion in wholesale sales. The non-benzodiazepine prescription sleep aid market is dominated by zolpidem tartrate (brand name Ambien), which accounts for approximately 30 million prescriptions annually. Various forms of zolpidem tartrate are commercially available, including both immediate release and controlled release tablets as well as orally dissolving tablets. ZolpiMist is the only oral spray formulation of zolpidem tartrate and, if only achieving 1% of the ‘zolpidem market’ this product could generate 300,000 prescriptions annually in the U.S. No zolpidem tartrate products are actively marketed in the U.S., so we believe our sales force will have the ability to effectively influence physician prescribing and grow ZolpiMist prescriptions.

MiOXSYS

With respect to MiOXSYS competitive offerings, there are other oxidative stress diagnostic tests available throughout the world, although none are approved in the U.S. for clinical use, and none are used specifically in semen analysis. ‘General use’ oxidative stress diagnostic systems that are marketed for clinical use outside the U.S. 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 and, again, are not used specifically in semen analysis for infertility testing. These potentially competitive oxidative stress systems’ 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. These tests are used for research use, but they do not measure oxidation-reduction potential and, we believe, are not directly competitive to the MiOXSYS System in the context of research use.

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 as MiOXSYS advances to this stage. To complement our internal clinical research efforts with the MiOXSYS System, we have engaged with numerous academic and private researchers 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, we believe, will enable us to develop new uses for the MiOXSYS and RedoxSYS systems.

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 moderate double digit percentage of net sales for the first year of the agreement, that increased in each of the second and third years and remains constant after that.

MiOXSYS/RedoxSYS

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.

ZolpiMist

On June 11, 2018 we entered into a licensing agreement with Magna Pharmaceuticals, Inc. pursuant to which we assumed a manufacturing agreement with a cGMP compliant contract manufacturer. We expect to continue manufacturing through that third-party and have made an initial purchase of product the we expect to supply us for the foreseeable future.

Employees

As of August 31, 2018, we had 57 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, 2018 and 2017 was $10.2 million and $22.5million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date. 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, ZolpiMist, and MiOXSYS. 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 Natesto and ZolpiMist are each an approved drug that we are marketing, we only acquired Natesto in April 2016 and ZolpiMist in June 2018. In addition, we only 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, ZolpiMist, and MiOXSYS, 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, 2018, our cash, cash equivalents and restricted cash totaling $7.1 million, available to fund our operations offset by an aggregate $2.3 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 gross proceeds of approximately $8.6 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. We also closed on an underwritten public offering of our common stock, warrants, and Series B preferred stock in March 2018 from which we received gross proceeds of approximately $12.9 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 and ZolpiMist 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, ZolpiMist, or MiOXSYS 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 and ZolpiMist 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 and ZolpiMist;
- 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 controls over financial reporting for the year ended June 30, 2018 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 maintain listing on the NASDAQ Capital Market.

Risks Related to Product Development, Regulatory Approval and Commercialization

Natesto, ZolpiMist, and MiOXSYS 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, ZolpiMist, or MiOXSYS; and
- our inability to effectively identify and align with commercial partners outside the U.S., or the inability of those selected partners to gain the required regulatory, reimbursement, and other approvals needed to enable commercial success of MiOXSYS.

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, ZolpiMist, and MiOXSYS. 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 U.S. 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, sold Primsol in March 2017, and abandoned Fiera and ProstaScint in June 2018.

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 U.S. 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 de novo clearance by the FDA prior to its marketing for commercial use in the U.S., and to regulatory approvals beyond CE marking required by certain foreign governmental entities prior to its marketing outside the U.S. 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 de novo clearance, pre-market approval, or foreign regulatory approvals. The 510k de novo 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 de novo clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510k de novo clearance or pre-market approval may never be obtained. We have limited experience in filing FDA applications for 510k de novo 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 U.S. 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 U.S. 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 U.S., or we may simultaneously seek regulatory approvals in the U.S. and other countries. If we or our collaborators seek marketing approval for a product candidate outside the U.S., 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 U.S. 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 ZolpiMist, we compete with companies that design, manufacture and market treatments for insomnia, some of which have a large market share.

For the MiOXSYS System, 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.

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 U.S. 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 U.S., 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 U.S. 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 ZolpiMist 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.

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 ZolpiMist 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 secure collaborations with manufacturing and development partners to enable production to scale of the MiOXSYS System, we may not be successful in selling 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 and ZolpiMist contain, 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 and ZolpiMist, which are both approved by the FDA, are regulated by the DEA as Schedule III controlled substances. 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 and ZolpiMist are, 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 U.S. 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, and ZolpiMist as a Schedule IV 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

We are dependent on our relationships and license agreements, and we rely on the patent rights granted to us pursuant to the license agreements.

A number of our patent rights for are derived from our license agreements with third parties. Pursuant to these license agreements, we have licensed rights to various patents and patent applications within and outside of the United States. We may lose our rights to these patents and patent applications if we breach our obligations under such license agreements, including, without limitation, our financial obligations to the licensors. If we violate or fail to perform any term or covenant of the license agreements, the licensors may terminate the license agreements upon satisfaction of applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of license agreements, whether by us or the licensors will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under these license agreements, we will not be able to commercialize certain products subject to patent or patent application, and our business, results of operations, financial condition and prospects would be materially adversely affected.

The commercial success of our products depends, in large part, on our ability to use patents licensed to us by third parties in order to exclude others from competing with our products. The patent position of emerging pharmaceutical companies like us can be highly uncertain and involve complex legal and technical issues. Until our licensed patents are interpreted by a court, either because we have sought to enforce them against a competitor or because a competitor has preemptively challenged them, we will not know the breadth of protection that they will afford us. Our patents may not contain claims sufficiently broad to prevent others from practicing our technologies or marketing competing products. Third parties may intentionally attempt to design around our patents or design around our patents so as to compete with us without infringing our patents. Moreover, the issuance of a patent is not conclusive as to its validity or enforceability, and so our patents may be invalidated or rendered unenforceable if challenged by others.

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 U.S. 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 U.S. 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 U.S. Supreme Court, other federal courts, the U.S. 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 U.S. 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 U.S. 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 U.S. 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 Natesto in April 2016 and ZolpiMist in June 2018. 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 2018, the great majority of our gross revenue and gross accounts receivable were due to three significant customers, the loss of which could materially and adversely affect our results of operations.

The following customers contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2018 and 2017, respectively. As of June 30, 2018, three customers accounted for 86% of gross revenue. The revenue from these customers as a percentage of gross revenue was as follows:

	Year Ended June 30,	
	2018	2017
Customer A	32%	34%
Customer C	30%	18%
Customer B	24%	22%

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.

We are also subject to credit risk from our accounts receivable related to our product sales. As of June 30, 2018, three customers accounted for 81% of gross accounts receivable. As of June 30, 2017, three customers accounted for 60% of gross accounts receivable.

	Year Ended June 30,	
	2018	2017
Customer C	35%	18%
Customer A	27%	25%
Customer B	19%	17%
Other	12%	0%

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, 2018, we had 52 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 David Green 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, 2018, we had federal net operating loss carryforwards of approximately $59.3 million. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2031 and will completely expire in 2037. 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.

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

In our August 2017 and March 2018 offerings, some entities who invested in our common and preferred stock and warrant financing owned 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

Our failure to meet the continued listing requirements of the NASDAQ Capital Market could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the NASDAQ Capital Market, 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.

On April 9, 2018, we received a letter from NASDAQ indicating that the Company has failed to comply with the minimum bid price requirement of NASDAQ Listing Rule 5550(a)(2). NASDAQ Listing Rule 5550(a)(2) requires that companies listed on the Nasdaq Capital Market maintain a minimum closing bid price of at least $1.00 per share. However, on August 10, 2018, we effected a 1-for-20 reverse stock split, which has brought us back into compliance with NASDAQ Listing Rule 5550(a)(2).

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, 2018, options to purchase 1,798 shares of common stock issued under our 2015 Stock Plan at a weighted average exercise price of $325.97 per share were outstanding. In addition, at June 30, 2018, there were outstanding warrants to purchase an aggregate of 1,882,661 shares of our common stock at a weighted average exercise price of $25.94. 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.

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 effected a reverse stock split at a ratio of 1-for-20 on August 10, 2018, which may not achieve one or more of our objectives.

We have effected four reverse stock splits since June 8, 2015, each of which has impacted the trading liquidity of the shares of our common stock. There can be no assurance that the market price per share of our common stock after a reverse stock split will remain unchanged or increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. The market price of our shares may fluctuate and potentially decline after a reverse stock split. Accordingly, the total market capitalization of our common stock after a reverse stock split may be lower than the total market capitalization before the reverse stock split. Moreover, the market price of our common stock following a reverse stock split may not exceed or remain higher than the market price prior to the reverse stock split.

Additionally, there can be no assurance that a reverse stock split will result in a per-share market price that will attract institutional investors or investment funds or that such share price will satisfy investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve. Further, if a reverse stock split is effected and the market price of our common stock declines, the percentage decline may be greater than would occur in the absence of a reverse stock split.

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

In June 2015, Aytu entered into a 37-month operating lease for office 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 June 2018, the Company entered into a 12-month operating lease, beginning on August 1, 2018, for a new office space in Raleigh. This lease has base rent of $1,100 a month, with total rent over the term of the lease of approximately $13,200. In August 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. In October 2017, the Company signed an amendment to the 37-month operating lease in Englewood, Colorado. The amendment extended the lease for an additional 24 months beginning October 1, 2018. The base rent will remain at $9,000 a month. The Company recognizes rent expense on a straight-line basis over the term of each 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 has been listed on the NASDAQ Capital Market under the symbol "AYTU" since October 20, 2017. Prior to October 20, 2017, our common stock was quoted on the OTCQX and prior to that, on the OTCQB. The following table sets forth the range of high and low bid prices for our common stock on the OTCQX or OTCQB, or high and low sales prices on the NASDAQ Capital Market, as applicable, for the periods shown. The quotations for the OTCQX or OTCQB represent inter-dealer prices without retail markup, markdown or commission, and may not necessarily represent actual transactions. All share prices give effect to our 1-for-20 reverse stock split completed in August 2017, and 2018.

Fiscal Year ended June 30, 2017	High	Low
First Quarter (ended September 30, 2016)	$ 2,000.00	$ 1,204.00
Second Quarter (ended December 31, 2016)	$ 1,556.00	$ 408.00
Third Quarter (ended March 31, 2017)	$ 504.00	$ 296.44
Fourth Quarter (ended June 30, 2017)	$ 364.00	$ 204.00

Fiscal Year ended June 30, 2018	High	Low
First Quarter (ended September 30, 2017)	$ 240.00	$ 66.80
Second Quarter (ended December 31, 2017)	$ 136.40	$ 41.00
Third Quarter (ended March 31, 2018)	$ 85.20	$ 7.60
Fourth Quarter (ended June 30, 2018)	$ 12.80	$ 4.66

On August 31, 2018, the closing price as reported on the NASDAQ of our common stock was $4.31. As of August 31, 2018, there were 497 holders of record of our common stock.

Equity Compensation Plan Information

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 a number 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 one placement agent to purchase an aggregate of 57 shares of our common stock at a weighted average exercise price of $2,031.58 per share and warrants to the other placement agent to purchase an aggregate of 58 shares of our common stock at a weighted average exercise price of $1,920 per share. In connection with our May 2016 public offering, we issued warrants to purchase an aggregate of 279 shares of common stock at an exercise price of $300 to the underwriters of the public offering. In July 2016, we issued warrants to purchase an aggregate of 221 shares of common stock at an exercise price of $1,600 to initial investors. In connection with our November 2016 public offering, we issued warrants to purchase an aggregate of 1,009 shares of common stock with an exercise price of $300.

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, 2018.

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	1,798	$ 325.97	2,961,002
Equity compensation plans not approved by security holders	1,624	$ 594.63	-
Total	3,422	$ 453.47	2,961,002

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, Liquidity and Capital Resources

Aytu is an emerging specialty pharmaceutical company focused on commercializing novel products that address significant medical needs. Aytu is focused on commercializing products that address hypogonadism (low testosterone), insomnia, and male infertility and plans to expand into other therapeutic areas as the company continues to execute on its growth plans.

Prior to the date of this Report, we have financed operations through a combination of private and public debt and equity financings, funds from the sale of our products, and occasionally through divestures of non-strategic assets. Our financing transactions have included private placements of stock and convertible notes, and public offerings of the Company's equity securities. Since the formation of Aytu in June 2015, the Company has raised approximately $49.9 million from the sale of its securities to investors and the exercise of warrants by investors.

Our operations have historically consumed cash and are expected to continue to require cash, but at a declining rate. The Company's revenue has increased 14% and 26% for each of the past two fiscal years and is expected to continue to increase, allowing the Company to rely less on its existing cash balance and proceeds from financing transactions. Despite increased revenue, cash used in operations during fiscal year 2018 was $16 million compared to $13.8 million in 2017, due to the Company completing the build-out of its's commercial infrastructure in 2018. As of the date of this Report, we expect our commercial costs to remain approximately flat or to increase modesty as we continue to focus on revenue growth. Our current asset position of $9.5 million plus the proceeds expected from ongoing product sales will be used to fund operations. We will access the capital markets to fund operations if and when needed, and to the extent it becomes probable that existing cash and other current assets may become exhausted. The timing and amount of capital that may be raised is dependent on market conditions and the terms and conditions upon which investors would require to provide such capital. There is no guarantee that capital will be available on terms that we consider to be in the best interests of the Company and our stockholders, or at all. However, we have been successful is accessing the capital markets in the past and are confident in our ability to access the capital markets again, if needed. Since the Company does not have a cash balance as of June 30, 2018, sufficient to cover potential operating losses for the twelve months following the expected filing date of this Annual Report, ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) requires us to report that there is an indication that substantial doubt about the Company's ability to continue as a going concern exists.

If we are unable to raise adequate capital in the future when it is required, we can adjust our operating plans to reduce the magnitude of the capital need under our existing operating plan. Some of the adjustments that could be made include delays of and reductions to product support programs, reductions in headcount, narrowing the scope of one or more of our commercialization programs, or reductions to our research and development programs. Without sufficient operating capital, we could be required to relinquish rights to product candidates on 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.

We have incurred accumulated net losses since inception, and at June 30, 2018, we had an accumulated deficit of $79.3 million. Our net loss declined to $10.2 million from $22.5 million for fiscal 2018 and 2017, respectively. We used $16.0 million and $13.8 million in cash from operations during fiscal 2018 and 2017.

Results of Operations—June 30, 2018 Compared to June 30, 2017

Results of operations for the year ended June 30, 2018 ("fiscal 2018") and the year ended June 30, 2017 ("fiscal 2017") reflected losses of approximately $10.2 million and $22.5 million, respectively. The decline in losses was driven by increasing revenue, and by non-operating gains resulting from the revaluation of derivative liability related to outstanding warrants and to the reduction of expected milestone payments due to the revaluation of contingent consideration due to GAAP, primarily related to Natesto and the abandonment of the Fiera product offering.

Revenue

Product revenue

We continue to generate material revenues from the commercialization of our products and have recently launched a new product, ZolpiMist, that competes in the $1.8 billion prescription sleep aid market. We recognized approximately $3.7 million and $3.2 million of net revenue from Natesto, ProstaScint, Primsol, MiOXSYS and Fiera sales during fiscal 2018 and 2017, respectively. The addition of ZolpiMist is expected to be additive to the growing base of revenue from Natesto and MiOXSYS. Since we have discontinued the non-strategic assets Primsol, ProstaScint and Fiera, we do not expect to recognize revenue from those products in fiscal year 2019. The majority of our fiscal year 2018 revenue came from Natesto sales. Revenue from Natesto sales increased 155% in fiscal 2018 compared to fiscal 2017.

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 estimated and recorded concurrently with the recognition of gross revenue from product sales and include coupons, discounts, chargebacks, distributor fees, processing fees, 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,	
	2018	2017
Gross product and service revenue	$ 7,861,000	$ 4,694,000
Provisions to reduce gross product sales to net product and service sales	(4,201,000)	(1,472,000)
Net product and service revenue	$ 3,660,000	$ 3,222,000
Percentage to net sales	46.6%	68.6%

Expenses

Cost of Sales

The cost of sales of $2.1 million and $1.4 million recognized for fiscal 2018 and fiscal 2017, respectively, are related to the Natesto, ZolpiMist, ProstaScint, Primsol, Fiera, and the MiOXSYS and RedoxSYS Systems. The increase in cost of sales for fiscal 2018 was due to an increase in product sales and the impairment of the AWH inventory, which represented $0.8 million or 38% of the cost of sales for fiscal 2018. We expect cost of sales to increase in the future due to and in line with growth in revenue from product sales.

Research and Development

Research and development costs consist of clinical trials and sponsored research, 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,	
	2018	2017
Clinical trials and sponsored research	$ 102,000	$ 956,000
Sponsored research - related party	-	388,000
Consultants and other	66,000	4,000
	$ 168,000	$ 1,348,000

Comparison of Years Ended June 30, 2018 and 2017

Research and development expenses decreased $1.2 million, or 87.5%, in fiscal 2018 compared to fiscal 2017. The decrease was due primarily to focusing our resource commitment on our commercial products and our decision to abandon sales and development support of ProstaScint in fiscal 2018, for which we reversed a previously accrued liability in the amount of $398,000 which reduced fiscal year 2018 research and development expenses. We anticipate research and development expense to increase in fiscal 2019 as we anticipate funding a study to further support the clinical application of our MiOXSYS System, and to fund further clinical studies for Natesto to potentially support new claims and to comply with FDA post-marketing study requirements.

Sales, General and Administrative

Sales, general and administrative expenses consist of labor costs, including personnel costs for employees in executive, commercial, business development and operational functions; 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 expenses including rent, governmental and regulatory compliance, insurance, and professional subscriptions; and directors fees. These costs are summarized as follows:

	Year Ended June 30,	
	2018	2017
Labor	$ 8,620,000	$ 7,488,000
Stock-based compensation	597,000	3,227,000
Professional fees	1,437,000	1,133,000
Occupancy, travel and other	6,523,000	5,267,000
Patent costs	395,000	168,000
Director fees	160,000	160,000
Management fee - related party	-	165,000
	$ 17,732,000	$ 17,608,000

Comparison of Years Ended June 30, 2018 and 2017

Sales, general and administrative costs remained approximately level in fiscal 2018 compared to fiscal 2017. The most significant expense was due to labor costs, patent costs, and occupancy, travel and other, which were related to increased labor rates, FDA fees, and increased spend on marketing efforts. This increase was offset by stock-based compensation, compared to fiscal 2017, due to a reduction in the fair value of the stock options and restricted stock that was issued to directors, executives and employees. We expect future selling, general and administrative expenses to remain consistent with historical spending rates.

Impairment of Intangible Assets

The expense related to impairment of intangible assets was $1.9 million for fiscal 2018. The impairment was related to the discontinuation of the Fiera product line due to lower than expected sales performance of the Fiera products and the contract manufacturer no longer supporting the product.

Impairment of intangible assets was $1.3 million for fiscal 2017, which was related to the impairment of the ProstaScint product which was discontinued in fiscal year 2018.

Amortization of Intangible Assets

Amortization expense for the remaining intangible assets was $1.6 million and $1.7 million for fiscal 2018 and fiscal 2017, respectively. This expense is related to corresponding amortization of its finite-lived intangible assets. We expect this expense to remain flat for fiscal 2019.

Net Cash Used in Operating Activities

During fiscal 2018, our operating activities consumed $16.0 million of cash. Our cash use was $5.8 million greater than our net loss, primarily due to non-cash gains such as derivative income and other gains which reduced our fiscal 2018 losses, offset by depreciation, amortization and accretion, and the expense related to the impairment of intangible assets which increased losses in fiscal 2018. Increases in our prepaid expense and decreases in accounts payable and accrued liabilities balance increased cash use in 2018 while an increase in accrued compensation decreased cash use in 2018.

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.

Net Cash Used in Investing Activities

During fiscal 2018, cash of $484,000 was used to acquire fixed and operating assets in addition to a deposit for office space and a royalty payment.

During fiscal 2017, cash was received through the sale of Primsol, the sale of our common stock investment in Acerus and the merger with Nuelle, Inc. Cash was also used to make contractual payments for acquired products, and to purchase fixed assets.

Net Cash from Financing Activities

Net cash of $22.7 million was provided by financing activities during fiscal 2018. The private placement completed in August 2017 contributed gross proceeds of $11.8 million, which was reduced by offering costs of $1.4 million. The March 2018 Offering provided gross proceeds of $12.9 million, which was reduced by offering costs of $1.3 million. Finally, we received aggregate proceeds of $0.7 million from the exercise of warrants by investors.

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.

Recent Developments

Introduction of Natesto Patient Reimbursement Support Services

During the Company's fourth quarter, several factors contributed to accelerate Natesto revenue growth and to position Natesto for further growth. In the third quarter of 2018, the Company piloted an initiative aimed at improving patient access, increasing prescription fill rates, and improving net revenue per prescription. This initiative, called the Natesto Support Program, introduced a third-party resource that assists patients and physician offices with the insurance approval process for Natesto. The program was rolled out across all sales territories in the fourth quarter of 2018. In conjunction with the roll-out of this initiative, the Company eliminated Company funded $0 prescription vouchers.

As a result of management's implementation of the Natesto Support Program and despite the discontinuation of $0 vouchers, the Company realized Natesto net revenue growth of 178% with only a 12% decline in unit volume during the fourth quarter of 2018 compared to the third quarter of 2018. Natesto revenue grew from $292,598 in Q3 to $805,212 in Q4. Historically, the use of $0 vouchers represented the largest deduction from gross revenue in the determination of net revenue, so the elimination of these vouchers while essentially maintaining demand were key elements of the significantly increased revenue. The table below represents the rate of coupon usage, which was the most significant factor in driving revenue growth since the implementation of the Natesto Support Program and elimination of Company funded $0 vouchers in the fourth quarter:

Coupons as a percentage of gross revenue decreased each month over the most recent two quarter period:

- January 2018: 83%
- February 2018: 59%
- March 2018: 62%
- April 2018: 32%
- May 2018: 31%
- June 2018: 23%

The Natesto Support Program has since been enhanced by the addition of other services including, among other items, mail order delivery services. This enhancement, called *Natesto Direct*, was launched in August 2018. Management intends to manage the services under *Natesto Direct* with changes from time-to-time to provide other features that encourage Natesto initial usage and refill rates. As a result, Natesto is well positioned for both volume and revenue growth.

Natesto Spermatogenesis Study

A significant clinical study of Natesto is underway that may substantially improve the product's clinical profile and enable access to a broader subset of hypogonadal patients. In the second half of fiscal 2018 the University of Miami's Department of Urology began an investigator-initiated trial led by Dr. Ranjith Ramasamy, MD, the Director of Reproductive Urology at Miami. The study is entitled *Natesto Effects on Testosterone, Luteinizing Hormone, Follicle Stimulating Hormone and Semen Parameters,* and is designed to test the hypothesis that treatment of hypogonadal men with Natesto maintains normal or near normal semen parameters, while also assessing Natesto's impact on gonadotropin levels and endogenous testosterone production.

If this study proves the hypothesis and demonstrates maintenance of semen parameters, gonadotropins, or endogenous testosterone levels, to our knowledge it would be the first such study to demonstrate any of these effects, which could lead to unique clinical claims in Natesto's product label. The implications of these potential clinical findings are significant as stated by Dr. Ramasamy:

> *"Currently, there are no FDA-approved therapies to treat men with low testosterone who wish to preserve their fertility. About 20% of men with Low T deal with these decisions, and Natesto could be an alternative for simultaneously increasing testosterone while preserving sperm production."*

The study will assess 40 patients with confirmed hypogonadism (testosterone (T) < 350 on two consecutive samples collected more than 1.5 hours apart in the morning, and each man will complete 2 complete sperm cycles (~ 24 weeks; 6 study visits) while taking Natesto three times daily. More than twenty patients have been enrolled to date, and we anticipate that the study's final readout will occur around June 2019. An interim data readout is expected in October or November of 2018.

TRT Market Dynamics

Several recent developments in the U.S. testosterone replacement therapy market may favorably impact Natesto's near and longer-term market position as an FDA-approved treated with an established efficacy and safety profile and being actively marketed by a focused sales infrastructure. First, the market leading product Androgel, has experienced diminished promotion over the last several quarters due to the product's relative age and importance in the AbbVie product portfolio. As such, there is limited field-based promotion and sampling to high prescribing physicians. Also, Eli Lilly formally discontinued Axiron in July 2017 primarily due to patents expiry resulting in further reduction in promotional voice in the U.S. in the TRT category. With the two market-leading products' promotional voice reduced or eliminated, this may present a unique opportunity for the Company and Natesto.

Along with the de-prioritization of the two market leading gels, the TRT pipeline assets experienced significant regulatory setbacks recently. Antares Pharma's injectable candidate Xyosted™ received a Complete Response Letter from the FDA in October 2017 stating that the drug's New Drug Application was not approvable based on safety data presented in the application. Antares has since resubmitted a New Drug Application, but it remains to be seen whether or not the safety concerns have been sufficiently addressed. In May 2018, Lipocine and Clarus Therapeutics' oral testosterone candidates were rejected at the FDA following negative FDA advisory committee sentiment expressed in January of 2018 as to the approvability of both compounds. Both products applications contained data demonstrating significant safety concerns, and both applications received a Complete Response Letter. As such, we understand Lipocine is conducting additional safety studies to potentially overcome the safety concerns, but it should be noted that this was the company's second Complete Response Letter for their candidate, Tlando™. The likelihood of approval in the near term appears in doubt at this time for both oral candidates, and Antares' PDUFA date for the resubmitted application is in late September with no assurance of approval.

Contractual Obligations and Commitments

Information regarding our Contractual Obligations and Commitments is contained in Note 6 to the Financial Statements. We have no off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as "variable interest entities."

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, 2018. 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, 2018, 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

As previously disclosed on our Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2018, on June 11, 2018, Aytu entered into a license agreement with Magna Pharmaceuticals, Inc. On September 5, 2018, Aytu and Magna Pharmaceuticals, Inc. agreed to amend and restate the license agreement effective as of June 11, 2018. The amended and restated license agreement supersedes and replaces the license agreement. Pursuant to the amended and restated license agreement, Magna Pharmaceuticals, Inc. granted to the company an exclusive, sub-licensable, royalty-bearing license in the United States and Canada related to ZolpiMist. The amended and restated license agreement may be terminated by either Aytu or Magna Pharmaceuticals, Inc. on the occurrence of a material breach of the amended and restated license agreement and by Aytu in its discretion upon a sixty (60) day prior written notice and the payment of a termination fee of $50,000. As consideration for the license granted, Aytu made an initial cash payment to Magna Pharmaceuticals, Inc. in the amount of $400,000 on June 11, 2018 and a payment of $300,000 on July 31, 2018. Additionally, the company will pay Magna Pharmaceuticals, Inc. certain royalty fees between 10% and 20% of Net Sales (as defined in the amended and restated license agreement) until 2025.

The foregoing description of the material terms of the amended and restated license agreement is qualified in its entirety by reference to the text of the amended and restated license agreement which is attached hereto as Exhibit 10.31 and is incorporated herein in its entirety by reference.

PART III

Item 10. Directors and Executive Officers, and Corporate Governance

The following table sets forth the names and ages of all of our directors and executive officers as of August 31, 2018. 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	43	Chairman and Chief Executive Officer
Jarrett T. Disbrow	43	Chief Operating Officer
David A. Green	56	Chief Financial Officer, Secretary, and Treasurer
Michael Macaluso	66	Director
Carl C. Dockery	55	Director
John A. Donofrio, Jr.	50	Director
Gary V. Cantrell	63	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 position as Principle of Averaden, LLC. Since July 2015, Mr. Cantrell consulted for pharmaceutical and bio technology companies. Most notably, he served as an exclusive business development consultant with Mayne Pharma (ASX: MYX) for 2.5 years. 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 over 25 years of experience in the pharmaceutical industry. Mr. Donofrio is trusted finance leader with a proven track record of building strategy, financial management, business partnering, leading teams and strong collaboration among all levels of an organization. In March of 2018, Mr. Donofrio was appointed Chief Financial Officer of TrialCard. TrialCard is a technology-enabled pharmaceutical solutions company that provides patient-centric solutions to the pharmaceutical industry improving access, affordability and adherence to medicines. Mr. Donofrio is responsible for overall finance strategy, accounting, tax, treasury management, reporting and internal controls. Prior to joining TrialCard, he served as the Chief Financial Officer and Head of North American Business Development for Merz North America, or Merz. Merz is a specialty healthcare company dedicated to the development and marketing of innovative quality Aesthetics and Neurosciences products for physicians and patients in the U.S. and Canada. 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 diverse 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 E. 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.

David A. Green – Chief Financial Officer, Secretary, and Treasurer

David A. Green has been our Chief Financial Officer since December 18, 2017. Prior to joining Aytu BioScience, Mr. Green was the Chief Accounting Officer from 2016 to 2017 of Intarcia Therapeutics, a biopharmaceutical company engaged in late stage clinical development, where he was involved in IPO readiness and some of the largest private financing transactions in history for a pre-commercial, venture funded, life science company. Mr. Green was a consultant with DAG Associates from 2014 to 2017 working in various senior operating and advisory roles for clients such as Q Therapeutics, Perseon Corporation and Lineagen, Inc. Mr. Green served as Chief Financial Officer of Catheter Connections, a venture financed medical device company that was acquired by Merit Medical [NASDAQ: MMSI] from 2012 to 2014; and CFO of Specialized Health Products International, a publicly traded medical device company that was acquired by C.R. Bard [NYSE: BCR] from 2006 to 2008. Prior to his operating roles, Mr. Green advised a broad range of life science companies on issues of corporate finance and the use of strategic transactions to accelerate growth as a Managing Director of Duff & Phelps and as a member of Ernst & Young's Palo Alto Center for Strategic Transactions®. Mr. Green began his career performing medical research after he received a Bachelor of Science in chemistry from the State University of New York. Mr. Green holds a Masters of Business Administration in finance from the University of Rochester 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 other 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.

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, 2018.

Name	Fees Earned or Paid in Cash	All Other Compensation (1)	Total
Gary V. Cantrell (2)	$ 45,000	$ 101,000	$ 146,000
Carl C. Dockery (2)	$ 45,000	$ 101,000	$ 146,000
John A. Donofrio Jr. (2)	$ 45,000	$ 101,000	$ 146,000
Michael E. Macaluso (2)	$ 25,000	$ 101,000	$ 126,000

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

(2) As of June 30, 2018, the number of restricted shares held by each non-employee director was as follows: 2,663 restricted shares for Mr. Cantrell; 2,663 restricted shares for Mr. Dockery; 2,663 restricted shares for Mr. Donofrio; 2,663 restricted shares for Mr. Macaluso.

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, 2018 and 2017 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 since December 2012*	2018	303,000	-	303,000	-	-	-	-	606,000
	2017	250,000	-	614,000	189,000	-	-	-	1,053,000
Jarrett T. Disbrow *Chief Operating Officer, Secretary and Treasurer*	2018	250,000	-	202,000	-	-	-	-	452,000
	2017	250,000	-	533,000	189,000	-	-	-	972,000
David A. Green (2) *Chief Financial Officer since December 2017*	2018	135,000	-	152,000	-	-	-	-	287,000
	2017	-	-	-	-	-	-	-	-
Gregory A. Gould (3) *Chief Financial Officer*	2018	96,000	-	-	-	-	-	-	96,000
	2017	10,000	-	533,000	79,000	-	-	-	622,000

(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 8 — Equity Instruments.”
(2) Mr. Green was appointed to Chief Financial Officer, Secretary and Treasurer full time effective December 18, 2017.
(3) Mr. Gould was appointed to Chief Financial Officer, Secretary and Treasurer full time effective June 16, 2017 and he resigned in November 2017.

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, 2018:

Name	Grant Date	All Other Stock Awards: Number of Shares of Stock or Units (#)	Base Price of Stock Awards ($/Share)	Grant Date Fair Value of Stock Awards ($)(1)
Named Executive Officers				
Joshua R Disbrow	11/7/2017	7,500	$ 40.40	$ 303,000
Jarrett T Disborw	11/7/2017	5,000	$ 40.40	$ 202,000
David A. Green	1/2/2018	3,750	$ 40.40	$ 151,500

(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 2018

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2018.

	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 Incentive 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	84	42	-	$ 328.00	11/11/2025	7,975	2,074	-	-
Joshua R. Disbrow	50	100	-	$ 328.00	7/7/2026	-	-	-	-
Jarrett T. Disbrow	83	42	-	$ 328.00	11/11/2025	5,413	1,407	-	-
Jarrett T. Disbrow	50	100	-	$ 328.00	7/7/2026	-	-	-	-
David A. Green	-	-	-	$ -		3,750	975	-	-
Gregory A. Gould	53	-	-	$ 328.00	11/15/2019	-	-	-	-
Gregory A. Gould	21	-	-	$ 328.00	11/15/2019	-	-	-	-

(1) Based on $0.26 per share which was the closing price of our common stock on NASDAQ on June 29, 2018, 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 defined 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 defined 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 position 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. On October 26, 2017, Gregory A. Gould resigned as the Chief Financial Officer of Aytu BioScience, Inc. Mr. Gould's resignation became effective on November 15, 2017.

We entered into an employment agreement with David A. Green, effective December 18, 2017, to serve as our Chief Financial Officer. The agreement is subject to termination by us with or without Cause (as defined below) or as a result of Mr. Green's disability, or by Mr. Green with or without Good Reason (as defined below). Mr. Green is entitled to receive $250,000 in annual salary, plus a discretionary performance bonus with a target of 50% 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. Green. Mr. Green 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 and Jarrett Disbrow had a Change in Control occurred as of June 30, 2018, would be the acceleration of the vesting of all options held by them at that date. On June 30, 2018, the closing price of our common stock was below the exercise price for all of the options held by Joshua Disbrow and Jarrett Disbrow and therefore there would have been no economic benefit to them upon the acceleration of vesting of those options.

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

The following table sets forth information with respect to the beneficial ownership of our common stock as of August 31, 2018 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 31, 2018. The percentage ownership information shown in the table is based upon 1,801,411 shares of common stock outstanding as of August 31, 2018.

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 31, 2018. 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 tables below are 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:		
Directors and Named Executive Officers:		
Joshua R. Disbrow [1]	42,360	2.33%
Jarrett T. Disbrow [2]	39,715	2.18%
David A. Green [3]	10,410	*%
Michael Macaluso [4]	2,843	*%
Carl C. Dockery [5]	4,795	*%
John Donofrio [6]	2,701	*%
Gary Cantrell [7]	2,878	*%
All directors and executive officers as a group (seven persons)	105,702	5.74%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 16,573 shares, (ii) 7,975 restricted shares, (iii) 184 vested options to purchase shares of stock, and (iv) 17,628 shares issuable upon the exercise of warrants. Does not include 116 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.

(2) Consists of (i) 16,562 shares, (ii) 5,413 restricted shares, (iii) shares underlying 184 vested options to purchase shares of common stock and (iv) 17,556 shares issuable upon the exercise of warrants. Does not include 116 shares held by an irrevocable trust for estate planning in which Mr. Disbrow is a beneficiary. Mr. Disbrow does not have or share investment control over the shares held by the trust, Mr. Disbrow is not the trustee of the trust (nor is any member of Mr. Disbrow's immediate family) and Mr. Disbrow does not have or share the power to revoke the trust. As such, under Rule 16a-8(b) and related rules, Mr. Disbrow does not have beneficial ownership over the shares purchased and held by the trust.

(3) Consists of restricted shares

(4) Consists of (i) 75 shares, (ii) 2,663 restricted shares, and (iii) vested options to purchase 105 shares of common stock.

(5) Consists of (i) 2,663 restricted shares, (ii) shares underlying vested options to purchase 38 shares of common stock, and (iii) 2,094 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.

(6) Consists of (i) 2,663 restricted shares, and (ii) vested options to purchase 38 shares of common stock.

(7) Consists of (i) 2,663 restricted shares, (ii) 177 shares, and (iii) vested options to purchase 38 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.

Executive Stock Purchases

Two Aytu executive officers, Joshua Disbrow and Jarrett Disbrow, participated in the August 2017 offering. Each officer purchased 4,167 units.

Three Aytu executive officers, Joshua Disbrow, Jarrett Disbrow and David Green, participated in the March 2018 offering. Joshua Disbrow and Jarrett Disbrow each purchased 11,306 units. Mr. Green purchased 3,330 units.

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. Ampio was the Company's largest stockholder during part of this period.

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.

Co-Pay Support

In June 2018, the Company entered into a master services agreement with TrialCard Incorporated ("TCI"), a vendor selected to support the Company sponsored co-pay program. In supporting the program, TCI will make disbursements to qualified patients presenting valid prescriptions for Natesto and ZolpiMist on behalf of Aytu. Disbursements will be based upon business rules determined by Aytu. The Company agreed to pay fees monthly to TCI for account management, data analytics, implementation, and technology and to reimburse TCI for certain direct costs incurred by TCI to support the Company's program. Expenses are expected to be approximately $19,000 per month based on volumes and performance of our program. One of the Aytu directors, Mr. Donofrio, is an executive officer of TCI and has no direct interest in the arrangement.

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 listed on the NASDAQ Capital Market. Therefore, we must comply with the exchange rules regarding director independence. 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 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 2017 and by the Audit Committee for fiscal 2018.

	Year Ended June 30,	
	2018	2017
Audit fees [(1)]	223,000	132,000
Audit-related fees [(2)]	52,000	90,000
Tax fees [(3)]	-	-
Total Fees	275,000	222,000

(1) Audit fees are comprised of annual audit fees and quarterly review fees. In 2018 we also completed a full audit of Nuelle upon the acquisition.
(2) Audit-related fees for both fiscal year 2017 and 2018 were comprised of fees related to registration statements, including for our November 2016 public offering, our August 2017 private offering, S-3 filing and our March 2018 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, 2018 and 2017
- Consolidated Statements of Operations for the years ended June 30, 2018 and 2017
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2018 and 2017
- Consolidated Statements of Cash Flows for the years ended June 30, 2018 and 2017
- 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	Certificate of Amendment of Certificate of Incorporation, effective August 10, 2018	8-K	8/10/18	3.1	
3.7	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	
10.2#	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	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
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				X
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				X
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	10.1	
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	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
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.	10-Q	5/11/17	10.1	
10.25#	Merger Agreement, dated May 3, 2017, between Nuelle, Inc. and Aytu BioScience, Inc.	10-K	8/31/17	10.25	
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	
10.30	Warrant Exercise Agreement dated March 23, 2018	8-K	3/28/18	10.1	
10.31	Amended and Restated Exclusive License Agreement, dated June 11, 2018, between Aytu BioScience, Inc. and Magna Pharmaceuticals, Inc.				X
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, 2018 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.

SIGNATURES

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

AYTU BIOSCIENCE, INC.

Date: September 6, 2018

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities indicated, on September 6, 2018.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chairman and Chief Executive Officer *(Principal Executive Officer)*
/s/ David A. Green David A. Green	Chief Financial Officer *(Principal Financial and Accounting Officer)*
/s/ Michael Macaluso Michael Macaluso	Director
/s/ Carl Dockery Carl Dockery	Director
/s/ John Donofrio Jr. John Donofrio Jr.	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 Shareholders and Board of Directors of
Aytu BioScience, Inc.
Englewood, Colorado

OPINION ON THE FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheets of Aytu BioScience, Inc. (the "Company") as of June 30, 2018 and 2017, and the related consolidated statements of operations, stockholders' (deficit) equity, and cash flows for each year in the two-year period ended June 30, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2018 and 2017, and the results of its operations and its cash flows for each year in the two- year period ended June 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

SUBSTANTIAL DOUBT ABOUT THE COMPANY'S ABILITY TO CONTINUE AS A GOING CONCERN

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

BASIS FOR OPINION

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EKS&H LLLP

Denver, Colorado
September 6, 2018

We have served as the Company's auditor since 2015.

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Balance Sheets

	June 30, 2018	June 30, 2017
Assets		
Current assets		
Cash and cash equivalents	$ 7,012,527	$ 802,328
Restricted cash	100,000	75,214
Accounts receivable, net	578,782	528,039
Inventory, net	1,338,973	1,312,221
Prepaid expenses and other	440,009	310,760
Total current assets	9,470,291	3,028,562
Fixed assets, net	218,684	647,254
Developed technology, net	-	1,337,333
Customer contracts, net	-	77,667
Trade names, net	-	164,037
Licensed assets, net	11,120,086	9,231,072
Goodwill	-	238,426
Patents, net	245,944	271,278
Deposits	5,088	2,888
Total long-term assets	11,589,802	11,969,955
Total assets	$ 21,060,093	$ 14,998,517
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable and other	$ 2,119,672	$ 2,220,400
Accrued liabilities	185,882	782,536
Accrued compensation	540,674	339,704
Current deferred rent	1,450	6,673
Current contingent consideration	547,100	261,155
Total current liabilities	3,394,778	3,610,468
Long-term contingent consideration	4,146,829	7,386,782
Long-term deferred rent	-	1,451
Warrant derivative liability	93,981	-
Total liabilities	7,635,588	10,998,701
Commitments and contingencies (Note 6)		
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 1,794,762 and 41,244, respectively as of June 30, 2018 and 2017	179	4
Additional paid-in capital	92,681,918	73,069,541
Accumulated deficit	(79,257,592)	(69,069,729)
Total stockholders' equity	13,424,505	3,999,816
Total liabilities and stockholders' equity	$ 21,060,093	$ 14,998,517

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

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Statements of Operations

	Year Ended June 30,	
	2018	2017
Product revenue, net	$ 3,660,120	$ 3,221,590
Total product revenue	3,660,120	3,221,590
Operating expenses		
Cost of sales	2,050,544	1,417,355
Research and development	167,595	959,857
Research and development - related party (Note 9)	-	387,960
Sales, general and administrative	17,732,490	17,442,627
Sales, general and administrative - related party (Note 9)	-	165,131
Impairment of intangible assets	1,856,020	1,265,125
Amortization of intangible assets	1,553,705	1,708,771
Total operating expenses	23,360,354	23,346,826
Loss from operations	(19,700,234)	(20,125,236)
Other (expense) income		
Interest (expense)	(749,423)	(2,534,358)
(Loss) on investment	-	(61,519)
Other gain	6,277,873	-
Derivative income	3,983,921	212,809
Total other (expense)	9,512,371	(2,383,068)
Net loss	$ (10,187,863)	$ (22,508,304)
Weighted average number of common shares outstanding	665,605	466,024
Basic and diluted net loss per common share	$ (15.31)	$ (48.30)

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

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

	Preferred Stock		Common Stock		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	Deficit	Equity
Balance - June 30, 2016	-	$ -	9,355	$ 1	$ 56,646,677	$ (46,561,425)	$ 10,085,253
Lincoln Park stock issuance, net of issuance costs $90,924	-	-	966	-	648,933	-	648,933
Stock-based compensation	-	-	-	-	2,502,092	-	2,502,092
Issuance of restricted stock	-	-	2,500	-	724,613	-	724,613
Common stock issued to executives	-	-	357	-	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	-	-	14,338	1	3,671,580	-	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	-	-	7,478	1	1,931,122	-	1,931,123
Warrant amendments	-	-	-	-	64,690	-	64,690
Investment in Subsidiary	-	-	6,250	1	1,837,499	-	1,837,500
Net loss	-	-	-	-	-	(22,508,304)	(22,508,304)
Balance - June 30, 2017	-	-	41,244	4	73,069,541	(69,069,729)	3,999,816
Stock-based compensation	-	-	-	-	348,515	-	348,515
Issuance of restricted stock	-	-	38,350	4	248,415	-	248,419
Earn-out payment to Nuelle shareholders	-	-	3,208	-	250,000	-	250,000
Issuance of preferred and common stock, net of $1,402,831 in cash issuance costs	113	1	159,834	16	6,319,150	-	6,319,167
Issuance of preferred and common stock, net of $1,294,235 in cash issuance costs	161	1	1,076,000	108	9,166,316	-	9,166,425
Warrants issued in connection with registered offering	-	-	-	-	2,439,360	-	2,439,360
Preferred stock converted in common stock	(274)	(2)	394,839	39	(37)	-	-
S-3 registered offering cost	-	-	-	-	(60,450)	-	(60,450)
Warrant exercises	-	-	80,750	8	677,092	-	677,100
Issuance of warrants	-	-	-	-	179,287	-	179,287
Warrant amendments	-	-	-	-	4,633	-	4,633
Warrant exercise of derivative warrants	-	-	-	-	40,096	-	40,096
Adjustment for rounding of shares due to stock split	-	-	537	-	-	-	-
Net loss	-	-	-	-	-	(10,187,863)	(10,187,863)
Balance - June 30, 2018	-	$ -	1,794,762	$ 179	$ 92,681,918	$ (79,257,592)	$ 13,424,505

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (10,187,863)	$ (22,508,304)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	2,591,270	4,364,680
Impairment of intangible assets	1,856,020	1,265,125
Stock-based compensation expense	348,515	2,502,092
Issuance of restricted stock	248,419	724,613
Other gain	(6,277,873)	-
Warrants issuance and amendments	183,920	1,507
Derivative income	(3,983,921)	(212,809)
Amortization of prepaid research and development - related party (Note 9)	-	335,454
Loss on investment	-	61,519
Common stock issued to executives	-	509,996
Issuance of warrants to initial investors	-	596,434
Gain on sale of asset	-	(428,374)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(50,743)	(355,031)
(Increase) decrease in inventory	(26,752)	195,427
(Increase) in prepaid expenses and other	(129,249)	(95,202)
(Decrease) increase in accounts payable and other	(109,707)	493,217
(Decrease) in accrued liabilities	(596,654)	(414,570)
Increase (decrease) in accrued compensation	200,970	(861,226)
(Decrease) in deferred rent	(6,674)	(4,200)
Net cash used in operating activities	(15,940,322)	(13,829,652)
Cash flows used in investing activities:		
Deposit	(2,200)	-
Purchases of fixed assets	(74,707)	(111,608)
Contingent consideration payment	(7,385)	-
Purchase of assets	(400,000)	(6,000,000)
Investment in Acerus	-	1,071,707
Sale of investment in Acerus cost	-	(91,864)
Sales of Primsol assets	-	1,750,000
Purchase of Primsol asset	-	(750,000)
Cash proceed from Nuelle	-	613,309
Cost related to Nuelle acquisition	-	(16,082)
Net cash used in investing activities	(484,292)	(3,534,538)
Cash flows from financing activities:		
Issuance of preferred, common stock and warrants	11,839,995	-
Issuance costs related to preferred, common stock and warrants	(1,402,831)	-
Issuance of preferred, common stock and warrants	12,900,020	-
Issuance costs related to preferred, common stock and warrants	(1,294,235)	-
Warrant exercises	677,100	-
S-3 registered offering cost	(60,450)	-
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)
Registered offering	-	8,602,499
Registered offering costs	-	(997,865)
Over-allotment warrants purchased by placement agents	-	2,852
Net cash provided by financing activities	22,659,599	10,187,542
Net change in cash and cash equivalents	6,234,985	(7,176,648)
Cash and cash equivalents at beginning of period	877,542	8,054,190
Cash and cash equivalents at end of period	$ 7,112,527	$ 877,542
Warrants issued to investors and underwriters (see Note 4)	$ 4,117,997	$ -
Warrant exercise of derivative warrants	$ 40,096	$ -
Contingent consideration included in accounts payable	$ 8,980	$ -
Earn-out payment to Nuelle Shareholders	$ 250,000	$ -
Purchase of asset included in contingent consideration	$ 293,216	$ -
Contingent consideration	$ 2,553,169	$ -
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

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

Note 1 – Business, Basis of Presentation, Business Combinations, Divestitures, License/Supply Agreement and Merger

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 an emerging specialty pharmaceutical company focused on commercializing novel products that address significant medical needs. Aytu is focused on commercializing products that address hypogonadism (low testosterone), insomnia, and male infertility and plans to expand into other therapeutic areas.

Basis of Presentation

The audited consolidated financial statements include the operations of Aytu and its wholly-owned subsidiary, Aytu Women's Health, LLC. All significant inter-company balances and transactions have been eliminated in consolidation.

The accompanying consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"). On August 10, 2018, Aytu effected a 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 completed 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), a late life cycle imaging agent, 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 will pay a revenue share of 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. As of June 30, 2018, the value for the contingent consideration was adjusted to $0 based upon the abandonment of ProstaScint in the quarter ended June 30, 2018, thus resulting in no future revenues around this product.

Pursuant to the asset purchase agreement, we were required to make our first revenue share payment to Jazz Pharmaceuticals during the March 31, 2018 quarter which was approximately $7,400. We will make our final revenue share payment to Jazz Pharmaceuticals in the first quarter of fiscal 2019, which is approximately $9,000.

At June 30, 2017, the ProstaScint asset was determined to be impaired based upon sales projections at that time and because we were planning to discontinue sales of ProstaScint in fiscal 2019, consistent with product expiry dating. The value for the intangible assets were adjusted to $54,000 for developed technology, $7,000 for trade names and $0 for customer contracts. At June 30, 2018, we reevaluated the ProstaScint asset and abandoned sales of ProstaScint in the current fiscal year, and we recognized the remainder of the amortization expense in the quarter ended June 30, 2018. The amortization expense was $61,000 and $159,000 for fiscal 2018 and 2017, respectively.

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.

Amortization expense of $0 and $184,000 was recognized in fiscal 2018 and fiscal 2017, 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.

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 ("Acerus"). We acquired the right effective upon the expiration of the former 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 made an upfront payment of $2.0 million to Acerus 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 $0 and $62,000 during fiscal 2018 and 2017, 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 million;
- $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 2018 and fiscal 2017 was $1.3 million, respectively. The estimated future amortization of Natesto after June 30, 2018 is as follows:

2019	1,319,000
2020	1,319,000
2021	1,319,000
2022	1,319,000
2023	1,319,000
Thereafter	1,317,000
	$ 7,912,000

The contingent consideration was initially valued at $3.2 million using a Monte Carlo simulation, as of June 30, 2016. As of June 30, 2018, the contingent consideration was revalued at $1.8 million using the same Monte Carlo simulation methodology, and based on current interest rates, expected sales potential, and Aytu stock trading variables. The contingent consideration accretion expense for fiscal 2018 and 2017 was $694,000, and $228,000, respectively.

License and Supply Agreement—ZolpiMist

In June 2018, Aytu signed an exclusive license agreement for ZolpiMist™ (Zolpidem Tartrate Oral Spray) from Magna Pharmaceuticals, Inc., ("Magna"). This agreement allows for Aytu's exclusive commercialization of ZolpiMist in the U.S. and Canada.

Aytu made an upfront payment of $400,000 to Magna upon execution of the agreement. In July 2018, we paid an additional $300,000, of which, $297,000 was included in current contingent consideration at June 30, 2018.

The intangible asset was valued at $3.2 million and will be amortized over the life of the license agreement up to seven years. The Company's allocation on consideration transferred for ZolpiMist as of the purchase date of June 11, 2018 was as follows:

	Fair Value
Intangible assets	3,200,000
Total assets acquired	$ 3,200,000

The amortization expense for fiscal 2018 was $39,000. The estimated future amortization of ZolpiMist after June 30, 2018 is as follows:

2019	464,000
2020	464,000
2021	464,000
2022	464,000
2023	464,000
Thereafter	888,000
	$ 3,208,000

We also agreed to make certain royalty payments to Magna which will be calculated as a percentage of our ZolpiMist net sales which will be payable within 45 days of the end of the quarter during which the applicable net sales occur.

- Twenty percent (20%) of Net Sales during the period commencing on the effective date and continuing through May 31, 2020
- Fifteen percent (15%) of Net Sales during the period commencing on the effective date and continuing through May 31, 2022
- Ten percent (10%) of Net Sales during the period commencing on the effective date and continuing through May 31, 2025

The contingent consideration, related to these royalty payments, was valued at $2.6 million using a Monte Carlo simulation, as of June 11, 2018. The contingent consideration accretion expense for fiscal 2018 and 2017 was $23,000, and $0, respectively.

Merger/Subsidiary

In May 2017, Aytu Women's Health, LLC., ("AWH") a wholly-owned subsidiary of Aytu, acquired Nuelle, Inc. ("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 6,250 shares of our common stock and agreed to make future revenue earn-out and milestone payments subject to certain performance criteria.

Nuelle preferred stockholders were 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.

The first $1.0 million of revenue earn-out payments was 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 revenue 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 revenue earn-out or any public disclosure by us of the earn-out being due and payable.

Amortization expense of $110,000 and $22,000 was recognized in fiscal 2018 and 2017, respectively.

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 2018 and 2017 was $64,000, and 12,000 respectively.

During the quarter ended September 30, 2017, we paid the first revenue earn-out payment to Nuelle shareholders of $12,000 issued in Aytu common stock, which represented the revenue earn-out payment for fiscal 2017.

During the quarter ended December 31, 2017, we made a $238,000 prepayment, issued in Aytu common stock, which represented the revenue earn-out payment for the remaining balance due on the first $1.0 million in net revenue.

At March 31, 2018, the AWH assets were determined to be impaired based upon sales performance and the manufacturer no longer supporting the product. The value for all AWH intangible assets were adjusted to zero. The contingent consideration was revalued to zero as well.

	Contingent Consideration
Balance as of June 30, 2017	$ 1,940,000
Increase due to accretion	64,000
Decrease due to contractual payment	(250,000)
Decrease due to remeasurement	(1,754,000)
Balance as of June 30, 2018	$ -

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, and as of June 30, 2018, Aytu has maintained balances in excess of federally insured limits.

Revenue Recognition

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,
- 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. Certain contracts allow for revenue recognition at the time of shipment and others at the time of delivery.

Delivery has occurred - The Company recognizes revenue when delivery of certain products occurs at the customers' designated location.

Device sales are typically recorded when products are shipped to customers. Drug sales are typically 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, 2018, and 2017, we accrued $17,000 and $58,000, respectively, in our estimated returns allowance. Estimates of potential returns and allowances are trued up each quarter for the difference between estimates made in the prior quarter and actual results that become available after the end of each reporting period.

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 estimated net realizable value. Aytu evaluates collectability of accounts receivable on a quarterly basis and records a valuation allowance accordingly. As of June 30, 2018, we had an allowance for doubtful accounts of $0, and as of June 30, 2017, there had been an allowance for doubtful accounts of $44,000.

Concentration of Business Risks

The following counterparties contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2018 and 2017, respectively. The counterparties, sometimes referred to as partners or customers, are large wholesale distributors that resell our products to retailers. As of June 30, 2018, three customers accounted for 84% of gross revenue. The revenue from these counterparties as a percentage of gross revenue was as follows:

	Year Ended June 30,	
	2018	2017
Customer A	32%	34%
Customer C	30%	18%
Customer B	24%	22%

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, 2018.

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, 2018, three customers accounted for 81% of gross accounts receivable. As of June 30, 2017, three customers accounted for 60% of gross accounts receivable.

	Year Ended June 30,	
	2018	2017
Customer C	35%	18%
Customer A	27%	25%
Customer B	19%	17%
Other	12%	0%

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. Inventory for our abandoned products was written down during fiscal 2018. Therefore, we currently have a reserve of $0 for slow moving inventory as of June 30, 2018 and $310,000 at June 30, 2017.

Inventory balances consist of the following:

	June 30,	
	2018	2017
Raw materials	$ 239,000	$ 442,000
Work in process	-	442,000
Finished goods	1,100,000	738,000
Reserve	-	(310,000)
	$ 1,339,000	$ 1,312,000

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	June 30,	
	in years	2018	2017
Manufacturing equipment	2 - 5	$ 213,000	$ 405,000
Leasehold improvements	3	112,000	111,000
Office equipment, furniture and other	2 - 5	344,000	287,000
Lab equipment	3 - 5	90,000	90,000
Less accumulated depreciation and amortization		(540,000)	(246,000)
Fixed assets, net		$ 219,000	$ 647,000

Aytu recorded the following depreciation and amortization expense in the respective periods:

	Year Ended June 30,	
	2018	2017
Depreciation and amortization expense	$ 294,000	$ 134,000

Patents

Costs of establishing patents, consisting of legal and filing fees paid to third parties, are expensed as incurred. 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,	
	2018	2017
Patents	$ 380,000	$ 380,000
Less accumulated amortization	(134,000)	(109,000)
Patents, net	$ 246,000	$ 271,000

Aytu recorded the following amortization expense in the respective periods:

	Year Ended June 30,	
	2018	2017
Amortization expense	$ 25,000	$ 26,000

Future amortization from the year ended June 30, 2018 is as follows:

2019	$ 25,000
2020	25,000
2021	25,000
2022	25,000
2023	25,000
Thereafter	121,000
	$ 246,000

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. There was an impairment of $238,000 related to the Fiera goodwill during the year ended June 30, 2018.

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 for tax years ending 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 740-10. “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. Forfeitures are adjusted for as they occur.

Restricted Stock

The Company is recognizing compensation cost equal to the fair value of the stock at the grant dates prorated over the vesting period of each award.

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 2018 and 2017. Although there were common stock equivalents of 1,923,199 and 18,366 shares outstanding at June 30, 2018 and 2017, respectively, consisting of stock options, unvested restricted stock 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 and Derivative Liability

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 was based on quoted market prices.

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 lattice 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 lattice valuation methodology. Changes in the fair value in subsequent periods were recorded to derivative income or expense.

Adoption of Newly Issued Accounting Pronouncements

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. In the quarter ended March 31, 2018, the Company adopted this pronouncement, the impact of which was immaterial.

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 annual periods beginning after December 15, 2017, including interim periods within those periods. Early adoption is permitted. As of the quarter ended June 30, 2018, the pronouncement does not apply to the Company, 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 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 early adopted this standard in fiscal 2018. There was no impact on its consolidated financial statements.

Recently Issued Accounting Pronouncements, Not Adopted as of June 30, 2018

From March 2016 through December 2016, the Financial Accounting Standards Board (the "FASB") issued ASU 2016-20, ASU 2016-12, ASU 2016-11, ASU 2016-10 and ASU 2016-08. These updates all clarify aspects of the guidance in ASU 2014-09, Revenue from Contracts with Customers (Topic 606), which represents comprehensive reform to revenue recognition principals related to customer contracts. The effective date of these updates for the Company is July 1, 2018. Adoption of this ASU is either full retrospective to each prior period presented or modified retrospective with a cumulative adjustment to retained earnings or accumulated deficit as of the adoption date.

We finalized our assessment of the new standard and will be adopting using the modified retrospective method as we have concluded that the impact of adopting the new standard is not significant as it relates to historical revenues, future revenues, or accounting for incremental costs of obtaining a contract with a customer. Going forward we will need to have disclosures de-segregating revenue to comply with this standard.

We have analyzed the five-steps for each type of contract with our customers and concluded that: (1) The new guidance will not change our existing policy and practice for identifying contracts with customers, nor give rise to changes to our existing policy and practice or create new concern surrounding the collectability of our receivables from customers, (2) none of our contracts with customers contain multiple performance obligations that are not fulfilled at the same time, and (3) the new guidance will not change our existing policy and practice regarding the recording of variable consideration. Our financial reporting process will remain essentially unchanged.

Additionally, Subtopic 340-40 requires the capitalization of all incremental costs that we incur to obtain a contract with a customer that would not have been incurred if the contract had not been obtained, provided we expect to recover those costs. We performed an analysis and noted that there are no material customer acquisition costs that are incremental and that are expected to be recovered at a future time.

The aforementioned modified retrospective method of transition will not result in a cumulative adjustment as of July 1, 2018. Additionally, no other line items in the statement of operations or the balance sheet will reflect any changes due to the adoption of the new standard. Adoption of the standards related to revenue recognition had no material impact to cash from or used in operating, financing, or investing on our consolidated cash flows statements.

In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses" to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. The standard is effective for interim and annual reporting periods beginning after December 15, 2019. Early adoption is permitted for interim and annual reporting periods beginning after December 15, 2018. The Company is currently assessing the impact that ASU 2016-13 will have on its consolidated financial statements but does not anticipate there to be a material impact.

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. In July 2018, the FASB issued ASU 2018-10, "Codification Improvements to Topic 842, Leases." The improvements in this amendment will be effective at the same time as ASU 2016-02. Also, in July 2018, the FASB issued ASU 2018-11, "Leases (Topic 842): Targeted Improvements." The Board decided to provide another transition method, in addition to the existing transition method, by allowing entities to initially apply the new leases standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company is currently evaluating the impact of its adoption of these standards on its consolidated financial statements.

Note 3 – Going Concern

As reflected in the accompanying financial statements, for the year ended June 30, 2018, the Company had a net loss of $10.2 million and net cash used in operations of $16.0 million. At June 30, 2018, Aytu had $7.1 million of cash, cash equivalents and restricted cash, stockholders' equity of $13.5 million and an accumulated deficit of $79.3 million. In addition, the Company is in the early stage of commercialization and has not yet generated profits for the most recent four quarters ended June 30, 2018. We used an average of $4.0 million of cash per quarter for operating activities. These factors raised substantial doubt about the Company's ability to continue as a going concern.

Looking forward, we expect cash used in operating activities to be in the range of historical amounts, and we expect our revenue to increase. We also expect to raise new capital if and when needed. Therefore, it is uncertain as to whether the Company is sufficiently capitalized. Since the Company does not have a cash balance as of June 30, 2018, sufficient to cover potential operating losses for the twelve months following the expected filing date of this Annual Report, ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) requires us to report that there is an indication that substantial doubt about the Company's ability to continue as a going concern exists.

The ability of the Company to continue its operations is dependent on management's plans, which include continuing to build on the historical growth trajectory of Natesto, launching the recently licensed ZolpiMist product, seeking to acquire cash generating assets and if needed, accessing the capital markets through the sale of our securities. Based on our ability to raise capital in the past as well as our continued growth, the Company believes additional financing will be available and will continue to be available to support the current level of operations for at least the next 12 months from the date of this report. There can be no assurance, however, that such financing will be available on terms which are favorable to the Company, or at all. While Company management believes that its plan to fund ongoing operations will be successful, there is uncertainty due to the Company's limited operating history and therefore no assurance that its plan will be successfully realized.

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 – 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 the warrant derivative liability was valued using the lattice valuation methodology. 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 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, 2018 and 2017, by level within the fair value hierarchy:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
June 30, 2018				
LIABILITIES				
Warrant derivative liability	$ -	$ -	$ 94,000	$ 94,000
Contingent consideration	$ -	$ -	$ 4,694,000	$ 4,694,000
June 30, 2017				
LIABILITIES				
Warrant derivative liability	$ -	$ -	$ -	$ -
Contingent consideration	$ -	$ -	$ 7,648,000	$ 7,648,000

The warrant derivative liability was valued using the lattice valuation methodology because that model embodies the relevant assumptions that address the features underlying these instruments. The warrants related to the warrant derivative liability are not actively traded and are, therefore, classified as Level 3 liabilities. 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 issuance and as of June 30, 2018:

	June 30, 2018	At Issuance
Warrants:		
Volatility	173.4%	188.0%
Equivalent term (years)	4.13	5.00
Risk-free interest rate	2.69%	1.83%
Dividend yield	0.00%	0.00%

The following table sets forth a reconciliation of changes in the warrant derivative liability for the period ended June 30, 2018

	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	$ -
Warrant issuances	4,118,000
Warrant exercises	(40,000)
Change in fair value included in earnings	(3,984,000)
Balance as of June 30, 2018	$ 94,000

We classify our contingent consideration liability in connection with the acquisition of ProstaScint, Natesto, ZolpiMist and the merger with Nuelle within Level 3 as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity. We estimate the fair value of our contingent consideration liability based on contractual payment obligations, discount rates, probabilities of payment, and expected future performance. Contingent payment amounts are discounted back to the current period using a discounted cash flow methodology. The contingent consideration related to the AWH assets was prepaid up to the first $1.0 million in net revenue. Since we will not be able to manufacture more product (see Note 1), we will not generate any additional revenue. Therefore, we will not exceed $1.0 million and thus, we have adjusted the remaining contingent consideration balance to zero. This adjustment is reflected in Other Gain on the Consolidated Statement of Operations. We also reduced the contingent consideration for ProstaScint by $57,000 to reflect that product's abandonment. As of June 30, 2018, the value for the contingent consideration was adjusted to $0 based upon the abandonment of ProstaScint in June 2018. Also, as of June 30, 2018, the contingent consideration related to Natesto was revalued at $1.8 million.

The following table sets forth a summary of changes in the contingent consideration for the period ended June 30, 2018:

	Contingent Consideration
Balance as of June 30, 2016	$ 3,869,000
Increase due to purchase of assets	1,927,000
Increase due to accretion	306,000
Increase due to remeasurement	2,256,000
Decrease due to impairment	(710,000)
Balance as of June 30, 2017	$ 7,648,000
Increase due to purchase of assets	2,846,000
Increase due to accretion	801,000
Decrease due to contractual payment	(266,000)
Decrease due to remeasurement	(6,335,000)
Balance as of June 30, 2018	$ 4,694,000

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.

Note 5 – 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.

	6/30/2018	6/30/2018	6/30/2017	6/30/2017
Benefit at statutory rate	(2,807,000)	-27.55%	(7,653,000)	-34.00%
State income taxes, net of federal benefit	(585,000)	-5.74%	(681,000)	-3.03%
Stock based compensation	22,000	0.22%	116,000	0.52%
Offering costs	-	0.00%	203,000	0.90%
Contingent consideration	(465,000)	-4.56%	4,000	0.02%
Change in taxrate	(31,000)	-0.30%	(11,000)	-0.05%
Remeasurement of deferred taxes	6,648,000	65.25%	-	0.00%
Effect of phased-in taxrate	891,000	8.75%	-	0.00%
Change in valuation allowance	(2,745,000)	-26.94%	7,922,000	35.20%
Derivative income	(1,029,000)	-10.10%	-	0.00%
Other	101,000	0.97%	100,000	0.44%
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:

	6/30/2018	6/30/2017
Deferred tax assets (liabilities):		
Deferred rent	-	3,000
Accrued expenses	136,000	127,000
Net operating loss carry forward	14,458,000	15,435,000
Intangibles	651,000	1,559,000
Share-based compensation	1,044,000	1,362,000
Fixed assets	139,000	191,000
Unrealized loss on investment	-	-
Capital loss carry forward	204,000	385,000
Contribution carry forward	29,000	41,000
Warrant liability	53,000	75,000
Inventory	4,000	174,000
Allowance for doubtful accounts	-	17,000
Total deferred income tax assets (liabilities)	16,718,000	19,369,000
Less: Valuation allowance	(16,718,000)	(19,369,000)
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 $59.3 million and $42.3 million as of June 30, 2018 and June 30, 2017, 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 2037. The Company has state net operating losses of approximately $50.3 million and $32.8 million as of June 30, 2018 and June 30, 2017, 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 2037. 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, 2018, and 2017, 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 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 2014 and 2013, respectively. However, given the net operating losses generated since inception, all tax years since inception are subject to examination.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act (the "Tax Reform Act") was signed into law by the President of the United States. The Tax Reform Act significantly revised the U.S. corporate income tax regime by, among other things, lowering the U.S. corporate tax rate from 35% to 21% effective January 1, 2018. GAAP requires that the impact of tax legislation be recognized in the period in which the law was enacted. As a result of the Tax Reform Act, the Company recorded a tax expense of $6.6 million due to a re-measurement of deferred tax assets and liabilities at a blended rate in the three months ended December 31, 2017, which is fully offset by a reduction in valuation allowance. The Company recorded additional tax expense of $0.1 million related to re- measurement of deferred tax assets and liabilities in the three months ended March 31, 2018. The tax expense is a provisional amount and the Company's current best estimate. Any adjustments recorded to the provisional amounts will be included in income from operations as an adjustment to tax expense, net of any related valuation allowance. The provisional amount incorporates assumptions made based upon the Company's current interpretation of the Tax Reform Act and may change as the Company receives additional clarification and implementation guidance.

Note 6 – Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of June 30, 2018:

	Total	2019	2020	2021	2022	2023	Thereafter
Prescription database	$ 774,000	$ 774,000	$ -	$ -	$ -	$ -	$ -
Natesto	2,500,000	-	-	-	-	2,500,000	-
Supply order	167,000	167,000	-	-	-	-	-
Office lease	258,000	122,000	109,000	27,000	-	-	-
	$ 3,699,000	$ 1,063,000	$ 109,000	$ 27,000	$ -	$ 2,500,000	$ -

Prescription Database

In May 2016, Aytu entered into an agreement with a vendor that will provide Aytu with prescription database information. 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.

Natesto

In April 2016, the Company entered into an agreement with Acerus, whereby Aytu is required to make milestone payments to Acerus. The first milestone payment of $2.5 million must be paid even if the milestone is not reached.

Supply Order

In June 2018, Aytu submitted a purchase order for 45,000 units of ZolpiMist, which are expected to arrive in fiscal 2019.

Office Lease

In June 2015, Aytu entered into a 37-month operating lease for office 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 June 2018, the Company entered into a 12-month operating lease, beginning on August 1, 2018, for a new office space in Raleigh. This lease has base rent of $1,100 a month, with total rent over the term of the lease of approximately $13,200. 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. In October 2017, the Company signed an amendment to the 37-month operating lease in Englewood, Colorado. The amendment extended the lease for an additional 24 months beginning October 1, 2018. The base rent will remain at $9,000 a month. The Company recognizes rent expense on a straight-line basis over the term of each 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 was as follows:

	Year Ended June 30,	
	2018	2017
Rent expense	$ 142,000	$ 139,000

Note 7 – Common Stock

Capital Stock

At June 30, 2018 and June 30, 2017, Aytu had 1,794,762 and 41,244 common shares outstanding, respectively, and no preferred shares outstanding. The Company has 100 million shares of common stock authorized with a par value of $0.0001 per share and 50 million shares of preferred stock authorized with a par value of $0.0001 per share, of which 500 were designated Series A Convertible Preferred Stock and 161 were designated as Series B Convertible Preferred Stock. Included in the common stock outstanding are 38,738 shares of restricted stock granted to executives, directors, employees and consultants.

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 335 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 131 shares of common stock. Between September 2016 and June 2017, Lincoln Park purchased an additional 500 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 2,500 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 357 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 14,338 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 $744.00 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 2,151 shares of common stock and/or warrants. The underwriters purchased 714 of this Over-Allotment Option for the warrants and paid $4.00 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 $300.00 per share, (i) outstanding warrants to purchase 4,334 shares of common stock with an exercise price of $2,400.00 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 15,051 shares of common stock with an exercise price of $744.00 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 7,477 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 $2,400.00 per share and $744.00 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 6,250 shares of our common stock.

On August 11, 2017, we entered into a Securities Purchase Agreement with various accredited investors pursuant to which, upon closing on August 15, 2017, we sold 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 price of $60.00 per unit. Class B units consist of one (1) share of our newly created 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 price of $20,000.00 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 stock were convertible into common shares at $60.00 per common share, or an aggregate of 37,500 shares of common stock.

In the offering, we issued an aggregate of 159,834 shares of our common stock, 113 shares of Series A Preferred Stock and warrants to purchase up to an aggregate of 315,755 shares of our common stock, which included 19,749 warrants issued to the placement agents as compensation for the transaction.

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.

In September 2017, Aytu issued 151 shares of common stock in connection with the Nuelle earn-out (see Note 1). In October 2017, we made a $238,000 prepayment in Aytu common stock, which represented the revenue earn-out payment for the remaining balance due on the first $1.0 million in net revenue.

In October 2017, investors holding Aytu Series A Preferred shares exercised their right to convert 18 Aytu Series A Preferred shares into 5,834 shares of Aytu common stock.

In February 2018, investors holding Aytu Series A Preferred shares exercised their right to convert 95 Aytu Series A Preferred shares into 31,667 shares of Aytu common stock.

On March 6, 2018, Aytu completed an underwritten public offering for total gross proceeds of $12 million, before deducting cash offering costs inclusive of underwriting discounts, commissions and other offering expenses totaling $1.2 million.

The securities sold by the Company consist of (i) Class A Units consisting of an aggregate of 976,000 shares of our common stock and warrants to purchase an aggregate of 976,000 shares of common stock, at a public offering price of $9.00 per Class A Unit, and (ii) Class B Units consisting of 161 shares of our Series B Preferred Stock, with a stated value of $20,000 per share, and convertible into an aggregate of 357,356 shares of common stock, and warrants to purchase an aggregate of 357,356 shares of common stock, at a public offering price of $20,000 per Class B Unit. The warrants have an exercise price of $10.80, are exercisable upon issuance and will expire five years from the date of issuance. The Company granted the underwriters a 45-day option to purchase an additional 200,000 shares of common stock and/or warrants to purchase an additional 200,000 shares of common stock. In connection with the closing of this offering, the underwriters partially exercised their over-allotment option and purchased an additional 200,000 warrants. On March 26, 2018, the underwriters exercised their over-allotment option to purchase an additional 100,000 shares of common stock, resulting in gross proceeds of approximately $900,000, before deducting costs of $63,000.

In March 2018, investors holding Aytu Series B Preferred shares exercised their right to convert 161 Aytu Series B Preferred shares into 357,356 shares of Aytu common stock.

In fiscal 2018, warrants issued from the registered offerings to purchase an aggregate of 80,750 shares of common stock were exercised for aggregate gross proceeds to our Company of approximately $677,000.

Note 8 – Equity Instruments

Options

On June 1, 2015, Aytu's stockholders approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which, as amended in July 2017, provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 3.0 million 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. As of June 30, 2018, we have 2,961,055 shares that are available for grant under the 2015 Plan.

Pursuant to the 2015 Stock Plan, 3.0 million 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. There's no issuances during the year ended June 30, 2018, therefore, no assumptions are used for fiscal 2018.

The assumptions used for the year ended June 30, 2017, as none were issued in fiscal 2018, are as follows:

	Year Ended June 30, 2017
Expected volatility	178% - 185%
Risk free interest rate	0.97% - 1.88%
Expected term (years)	5.0 - 6.5
Dividend yield	0%

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2016	829	$ 7,204.00	9.33
Granted	1,197	$ 364.00	
Exercised	-	$ -	
Forfeited	(75)	$ 1,664.00	
Cancelled	(4)	$ 1,292.00	
Outstanding June 30, 2017	1,947	$ 326.20	8.40
Granted	-	$ -	
Exercised	-	$ -	
Forfeited	(129)	$ 328.00	
Cancelled	(20)	$ 328.00	
Outstanding June 30, 2018	1,798	$ 325.97	6.95
Exercisable at June 30, 2018	1,375	$ 325.24	6.69
Available for grant at June 30, 2018	2,961,002		

The following table details the options outstanding at June 30, 2018 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
$ 280.00	76	$ 280.00	8.85	76	$ 280.00
$ 328.00	1,722	$ 328.00	6.86	1,299	$ 328.00
	1,798	$ 325.97	6.95	1,375	$ 325.35

In September 2017, Aytu issued 10,000 shares of restricted stock to employees pursuant to the 2015 Plan, which vest in September 2027. In November 2017, 150 of these restricted shares were cancelled. Also, in November 2017, Aytu issued 24,750 shares of restricted stock to executives, directors and consultants pursuant to the 2015 Plan, which vest in November 2027.

In January 2018, Aytu issued 3,750 shares of restricted stock to an officer pursuant to the 2015 Plan, which vest in January 2028. In March 2018, Aytu issued 650 shares of restricted stock to employees pursuant to the 2015 Plan, which vest in March 2028. During the three months ended March 31, 2018, 650 shares of restricted stock were cancelled.

During fiscal 2018, we modified 2,000 shares of restricted stock for accelerated vesting and recognized an increase in aggregate stock compensation expense of $14,000.

Restricted stock activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Life in Years
Unvested at June 30, 2017	-	$ -	-
Granted	39,150	$ 39.80	
Vested	(1,150)	$ 40.40	
Cancelled	(800)	$ 40.40	
Unvested at June 30, 2018	37,200	$ 39.80	9.4

Aytu previously issued 1,538 shares of restricted stock outside the Aytu BioScience 2015 Stock Option and Inventive Plan, which vest in July 2026. The unrecognized expense related to these shares was $1,593,000 as of June 30, 2018 and will be recognized over the 10-year vesting period. During fiscal 2018, the expense related to these awards was $139,000. During the quarter ended December 31, 2017, we modified 413 shares of restricted stock for accelerated vesting and recognized a reduction in aggregate stock compensation expense of $36,000. During the quarter ended March 31, 2018, we modified 200 shares of restricted stock for accelerated vesting and recognized a reduction in aggregate stock compensation expense of $37,000.

Stock-based compensation expense related to the fair value of stock options and restricted stock was included in the statements of operations as selling, general and administrative expenses as set forth in the table below. Aytu determined the fair value of stock compensation 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 stock option and restricted stock issuances for fiscal 2018 and 2017:

	2018	2017
Sales, general and administrative:		
Stock options	$ 349,000	$ 2,502,000
Restricted stock	248,000	725,000
Total share-based compensation expense	$ 597,000	$ 3,227,000

As of June 30, 2018, there was $161,000 of total unrecognized option-based compensation expense related to non-vested stock options. The Company expects to recognize this expense over a weighted-average period of 6.95 years. As of June 30, 2018, there was $2,945,000 of total unrecognized share-based compensation expense related to the non-vested restricted stock. The Company expects to recognize this expense over a weighted-average period of 8.63 years.

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, 2016	5,538	$ 2,480.40	4.71
Issuance of settlement warrants to initial investors	221	$ 1,600.00	
Warrants issued to investors in connection with the registered offering	15,051	$ 744.00	
Warrants issued to placement agents for the registered offering	1,009	$ 300.00	
Warrants exercised	(7,477)	$ 300.00	
Outstanding June 30, 2017	14,342	$ 1,005.80	4.23
Warrants issued in connection with the August 2017 private offering	296,006	$ 72.00	
Warrants issued to underwriters in connection with the August 2017 private offering	19,749	$ 72.00	
Warrants issued in connection with the March 2018 public offering	1,533,356	$ 10.80	
Warrants issued to investor	100,000	$ 10.80	
Warrants expired	(42)	$ 21,744.00	
Warrants exercised	(80,750)	$ 8.20	
Outstanding June 30, 2018	1,882,661	$ 25.94	4.61

During fiscal 2017, Aytu issued warrants to purchase 221 shares of common stock to initial investors of the Company at an exercise price of $1,600.00 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 1,009 shares of common stock at an exercise price of $744.00 and a term of five years. These warrants are accounted for under equity treatment. In February 2017, we reduced the exercise price of these warrants to $300.00.

Also, in connection with our November 2016 public offering, we issued to investors warrants to purchase an aggregate of 15,051 shares of common stock, which includes the over-allotment warrants, at an exercise price of $744.00 with a term of five years. These warrants are accounted for under equity treatment.

In February 2017, the Company consummated its warrant tender offer to exercise, at a temporarily reduced exercise price of $300.00 per share, (i) outstanding warrants to purchase 4,334 shares of common stock with an exercise price of $2,400.00 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 15,051 shares of common stock with an exercise price of $744.00 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 7,477 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 $2,400.00 per share and $744.00 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 1,288 warrants to purchase shares of common stock, which were originally issued as underwriters' compensation in the May 2016 and October 2016 financings, from $2,400.00 per share and $744.00 per share, respectively, to $300.00 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.

In connection with our August 2017 private offering, we issued warrants to purchase an aggregate of 315,755 shares of common stock at an exercise price of $72.00 and a term of five years to investors and underwriters. The remaining outstanding warrants from that offering are accounted for using derivative liability treatment (see Note 5).

In connection with our March 2018 public offering, we issued to investors and underwriters warrants to purchase an aggregate of 1,533,356 shares of common stock at an exercise price of $10.80 with a term of five years from March 6, 2018. These warrants are accounted for under equity treatment. Of the 1,533,356 warrants issued in the March 2018 public offering, 5,750 were exercised in fiscal 2018.

In March 2018, Aytu BioScience, Inc. entered into a warrant exercise agreement with an investor of the Company's outstanding warrants. Pursuant to the exercise agreement, the Company agreed to reduce the exercise price of the investor's warrant to purchase 75,000 shares of the Company's common stock from $72.00 to one cent less than the closing price on the last trading day prior to the exercise date; provided that the investor exercised the warrant for cash by March 23, 2018, and the Company also agreed to issue the investor a new warrant to purchase 100,000 shares of the Company's common stock at an exercise price of $10.80 per share. In accordance with the exercise agreement, the investor exercised the warrant and the Company received net proceeds of $615,000. The new warrant to purchase 100,000 shares of the Company's common stock are accounted for under equity treatment and have a fair value of $179,000.

In May 2018, the warrants we issued to the placement agent, in connection with our private placement in 2013, expired. The 42 placement agent warrants have a term of five years from the date of issuance and an exercise price of $21,744.00.

The warrants related to the August Financing issued in fiscal 2018 were valued using the lattice option pricing model. These warrants were accounted for as liability warrants (see Note 5). The warrants related to the March Financing in fiscal 2018 were valued using the Black Scholes pricing model and were accounted for as equity warrants. In order to calculate the fair value of the warrants, certain assumptions were made, including the selling price or fair market value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and contractual life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing a weighted average of comparable published betas 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.

Significant assumptions in valuing the warrants issued and modified during the year ended June 30, 2018 were as follows:

	Year Ended June 30,	
	2018	2017
Expected volatility	173.40% - 188.00%	156.64% - 169.22%
Risk free interest rate	1.83% - 2.69%	1.63% - 1.87%
Contractual term (years)	4.13 - 5	3.46 - 4.67
Dividend yield	0%	0%

Note 9 – Related Party Transactions

Executive Stock Purchases

Two Aytu executive officers, Joshua Disbrow and Jarrett Disbrow, participated in the August 2017 offering. Each officer purchased 4,167 units.

Three Aytu executive officers, Joshua Disbrow, Jarrett Disbrow and David Green, participated in the March 2018 offering. Joshua Disbrow and Jarrett Disbrow each purchased 11,306 units. Mr. Green purchased 3,330 units.

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. Ampio was the Company's largest stockholder during part of this period.

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.

Co-Pay Support

In June 2018, the Company entered into a master services agreement with TrialCard Incorporated ("TCI"), a vendor selected to support the Company sponsored co-pay program. In supporting the program, TCI will make disbursements to qualified patients presenting valid prescriptions for Natesto and ZolpiMist on behalf of Aytu. Disbursements will be based upon business rules determined by Aytu. The Company agreed to pay fees monthly to TCI for account management, data analytics, implementation, and technology and to reimburse TCI for certain direct costs incurred by TCI to support the Company's program. Expenses are expected to be approximately $19,000 per month based on volumes and performance of our program. One of the Aytu directors, Mr. Donofrio, is an executive officer of TCI and has no direct interest in the arrangement.

Note 10 – 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,	
	2018	2017
Consolidated revenue:		
Aytu	$ 3,417,000	$ 3,175,000
Aytu Women's Health	243,000	47,000
Consolidated revenue	$ 3,660,000	$ 3,222,000
Consolidated net loss:		
Aytu	$ (7,783,000)	$ (22,349,000)
Aytu Women's Health	(2,405,000)	(159,000)
Consolidated net loss	$ (10,188,000)	$ (22,508,000)
Total assets:		
Aytu	$ 21,053,000	$ 11,779,000
Aytu Women's Health	7,000	3,220,000
Total assets	$ 21,060,000	$ 14,999,000

Note 11 – 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 2018, the Company's match was $119,000.

Note 12 – Subsequent Events

On July 31, we made the second payment towards an asset purchase totaling $300,000.

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 10, 2018. This adjustment is reflected in this Annual Report.

In August, the Aytu sales force began promotions of ZolpiMist to U.S. clinicians.

On September 5, 2018, Aytu and Magna Pharmaceuticals, Inc. agreed to amend and restate the license agreement effective as of June 11, 2018.

LICENSE, DEVELOPMENT

AND COMMERCIALIZATION AGREEMENT

BETWEEN

AMPIO PHARMACEUTICALS, INC.

AND

DAEWOONG PHARMACEUTICALS CO., LTD

LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS LICENSE, DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (this "Agreement") is made and entered into on August 23, 2011 (the "Effective Date") by and between Ampio Pharmaceuticals, Inc., a Delaware corporation having its principal place of business at 5445 DTC Parkway, Suite 925, Greenwood Village, Colorado 80111 ("Ampio"), and Daewoong Pharmaceuticals Co., Ltd, having its principal place of business at 163-3 Samsungdong, Kangnam-gu, Seoul, Republic of Korea ("Daewoong"). Each of Ampio and Daewoong is sometimes referred to herein as a "Party" and collectively, as the "Parties."

WHEREAS, Ampio has developed certain intellectual property relating to the use of Tramadol for the treatment of premature ejaculation;

WHEREAS, Daewoong has substantial expertise in the research, development, distribution, sales and marketing of pharmaceutical products in the Republic of Korea; and

WHEREAS, Ampio desires to grant to Daewoong, and Daewoong desires to obtain from Ampio, the right to develop, market and sell products containing Tramadol for certain indications in the Republic of Korea, all on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises, covenants and conditions contained in this Agreement, the Parties hereto agree as follows:

1 Definitions

1.1 "Affiliate" means any corporation, firm, partnership, limited liability company or other entity that controls, is controlled by or is under common control with a Party to this Agreement. For purposes of this definition, any entity will be regarded as in "control" of another entity if (a) it directly or indirectly owns more than fifty percent (50%) of the voting stock of the other entity or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited, (b) it owns or has a right to own more than fifty percent (50%) of the net assets of an entity without voting securities, or (c) it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity, whether through contract or otherwise.

1.2 "Ampio" means Ampio Pharmaceuticals, Inc.

1.3 "Ampio Know-How" means all Information that is Controlled by Ampio or its Affiliates as of the Effective Date or during the Term and is necessary or useful for the Development, Manufacture or Commercialization of the Product in the Field in accordance with the terms of this Agreement. For clarity, Ampio Know-How excludes Information claimed in any Ampio Patent. For avoidance of doubt, Ampio Know-How shall exclude the Information of any Third Party that becomes an Acquiror of Ampio, except for any Information included within the definition of "Ampio Know-How" that is developed by such Acquiror after the closing of such acquisition in the course of conducting activities on behalf of Ampio under this Agreement.

1.4 “Ampio Licensee” means licensees of Tramadol and/or Products outside the Territory during the Term of this Agreement, under any Ampio Patents (both inside and outside the Territory), Ampio Know-How or Ampio Regulatory Documentation.

1.5 “Ampio Patents” means any Patent that (a) is Controlled by Ampio or its Affiliates as of the Effective Date or at any time during the Term, and

(b) claims the composition of matter, use or Manufacture of a Product in the Field. A list of Ampio Patents in existence as of the Effective Date is attached hereto as Exhibit 1.5, and Ampio shall update such list from time to time to include additional Ampio Patents, including patents issuing from any listed application or claiming priority thereto or otherwise continuing therefrom. For the avoidance of doubt, Ampio Patents shall include Product Patents (as defined in Section 11.1), and shall exclude the Daewoong Patents and the Patents of any Third Party that becomes an Acquiror of Ampio, except for (i) any Patents claiming inventions that are included within the definition of an “Ampio Patent” that are developed by such Acquiror in the course of conducting activities on behalf of Ampio under this Agreement, or (ii) any Patents Controlled by such Acquiror at the closing of the acquisition of Ampio that claim the composition, use or manufacture of the Product as in existence as of the Effective Date.

1.6 “Ampio Technology” means the Ampio Patents and Ampio Know-How.

1.7 “CMC” means chemistry, manufacturing and controls as specified by the FDA.

1.8 “Combination Product” means a Product that includes Tramadol and a PDE5 inhibitor.

1.9 “Commercially Reasonable Efforts” means those efforts consistent with the exercise of prudent scientific and business judgment in an active and ongoing program as applied by a Party to the development and commercialization of its own pharmaceutical products at a similar stage of development and with similar market potential. Commercially Reasonable Efforts requires that a Party, at a minimum, assigns responsibility for such obligations to qualified employees, sets annual goals and objectives for carrying out such obligations, and allocates resources designed to meet such goals and objectives.

1.10 “Commercialization” with a correlative meaning for “Commercialize” and “Commercializing”, means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, promotion, detailing, medical education and medical liaison activities, marketing, pricing, reimbursement, sale, and distribution of the Products, including: (a) strategic marketing, sales force detailing, advertising, medical education and liaison, and market and Product support; (b) any postmarketing clinical studies for use in generating data to be submitted to Regulatory Authorities (and all associated reporting requirements); and (c) all customer support, Product distribution, invoicing and sales activities.

1.11 “Confidential Information” means, with respect to a Party, all reports and other Information of such Party that is disclosed to the other Party under this Agreement, whether in oral, written, graphic, electronic or other form. All Information disclosed by either Party pursuant to the Mutual Confidentiality Agreement between the Parties dated December 8, 2010 (the “Mutual CDA”), shall be deemed to be such Party’s Confidential Information disclosed hereunder.

1.12 “Control” means, with respect to any material, Information, or intellectual property right, that a Party owns or has a license to such material, Information, or intellectual property right and, in each case, has the ability to grant to the other Party access, a license, or a sublicense (as applicable) to the foregoing on the terms and conditions set forth in this Agreement without violating the terms of any then-existing agreement or other arrangement with any Third Party.

1.13 “Develop” or “Development” means all activities relating to preparing and conducting preclinical testing, toxicology testing, human clinical studies, and regulatory activities (e.g., regulatory applications) with respect to the Product, together with the manufacturing of the Product for the purpose of conducting the foregoing activities.

1.14 “Development Costs” means the internal costs and out-of-pocket costs incurred as an expense by or on behalf of a Party or its Affiliates in carrying out the Development of the Product in accordance with the approved Development Plan, including, without limitation, (i) the costs of clinical trials (including costs of procuring the Product(s), placebos and comparator drugs used in such clinical trials), (ii) filing fees and other costs associated with any Regulatory Filings; (iii) costs related to manufacturing development; and (iv) all other costs that are directly attributable and reasonably allocable to the Development activities for the Products. For purposes of this definition: (a) out-of-pocket costs mean the actual expense incurred with respect to a Third Party for specific Development activities relating to the Products; and (b) internal costs means the applicable FTE rate multiplied by the number of FTE hours expended in carrying out the Development activities in accordance with the Development Plan. For clarity, the costs associated with attending or participating in meetings of the JSC are expressly excluded from this definition.

1.15 “Dollar” means a U.S. dollar, and “$” shall be interpreted accordingly.

1.16 “Daewoong” means Daewoong Pharmaceuticals Co., Ltd.

1.17 “Daewoong Know-How” means all Information that (a) is Controlled by Daewoong or its Affiliates as of the Effective Date and applied or used in connection with the Development, Manufacture or Commercialization by Daewoong of the Product, or (b) arises from Daewoong’s activities under this Agreement, but excluding any and all Product Inventions (as defined in Section 11.1). For clarity, Daewoong Know-How excludes Information claimed in any Daewoong Patent. For the avoidance of doubt, Daewoong Know-How shall exclude the Information of any Third Party that becomes an Acquiror of Daewoong, except for any Information included within the definition of “Daewoong Know-How” that is developed by such Acquiror after the closing of such acquisition in the course of conducting activities on behalf of Daewoong under this Agreement.

1.18 “Daewoong Patent” means any Patent that (a) is Controlled by Daewoong or its Affiliates as of the Effective Date and applied or used in connection with the Development, Manufacture or Commercialization by Daewoong of the Product hereunder, or (b) claims any inventions made by Daewoong, other than the Product Inventions (as defined in Section 11.1), in the course of conducting its activities under this Agreement. A list of the Daewoong Patents in existence as of the Effective Date, if any, is as attached hereto as Exhibit 1.18, and Daewoong shall update such list from time to time to include additional Daewoong Patents, including patents issuing from any listed application or claiming priority thereto or otherwise continuing therefrom. For the avoidance of doubt, Daewoong Patents shall exclude the Patents of any Third Party that becomes an Acquiror of Daewoong, except for (i) any Patents claiming inventions that are included within the definition of a “Daewoong Patent” that are developed by such Acquiror in the course of conducting activities on behalf of Daewoong under this Agreement, or (ii) any Patents Controlled by such Acquiror at the closing of the acquisition of Daewoong that claim the composition, use or manufacture of the Product as in existence as of the Effective Date.

1.19 “Daewoong Technology” means the Daewoong Patents and Daewoong Know-How.

1.20 “FDA” means the United States Food and Drug Administration and any successors thereof.

1.21 “Field” means the treatment of premature ejaculation and/or erectile dysfunction.

1.22 “Finish” means to label and package vials or other containers of a Product suitable for distribution to final users.

1.23 “First Commercial Sale” means the first sale to a Third Party of a Product in a given regulatory jurisdiction after Regulatory Approval has been obtained in such jurisdiction.

1.24 “Governmental Authority” means any multi-national, federal, state, local, municipal, provincial or other government authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.25 “Information” means any data, results, technology, business information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

1.26 “Laws” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign, including any regulatory agency policy or informal regulatory agency guidance.

1.27 “Manufacture” with a correlative meaning for “Manufacturing,” means all activities related to the manufacturing of a pharmaceutical product, or any ingredient thereof, including manufacturing Product in finished form for Development, manufacturing finished Product for Commercialization, packaging, in-process and finished Product testing, release of Product or any component or ingredient thereof, quality assurance activities related to manufacturing and release of Product, ongoing stability tests and regulatory activities related to any of the foregoing.

1.28 “Net Sales” means the gross sales price for the Product invoiced by Daewoong or any of its Affiliates or Sublicensees to Third Party customers for sales or other transfers or dispositions for consideration of a Product, less (i) documented discounts (including customary trade, quantity, cash and patient discount programs discounts), retroactive price reductions, charge-back payments and rebates granted to managed health care organizations or to federal, state and local governments, their agencies, and purchasers and reimbursers or to trade customers; (ii) credits for returns, such as unrecoverable damaged goods or rejections and including Product returned in connection with recalls or withdrawals; (iii) transportation charges including insurance; and (iv) any value added taxes or governmental charges, including custom duties, levied on the sale of the Product. Net Sales shall not include any payments among Daewoong, its Affiliates and Sublicensees.

1.29 “Patent” means (a) pending patent applications (and patents issuing therefrom), issued patents, utility models and designs; and (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations- in-part, or divisions of or to any patents, patent applications, utility models or designs, in each case being enforceable within the applicable territory.

1.30 “Product” means any formulation that includes Tramadol that is suitable for use in the Field. Product includes, without limitation, Combination Products.

1.31 “Regulatory Approval” means, with respect to a Product in any country or jurisdiction, all approvals (including, where required, pricing and reimbursement approvals), registrations, licenses or authorizations from the relevant Regulatory Authority in a country or jurisdiction that is specific to Product and necessary to market and sell such Product in such country or jurisdiction.

1.32 “Regulatory Authority” means, in a particular country or regulatory jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval and/or, to the extent required in such country or regulatory jurisdiction, pricing or reimbursement approval of a Product in such country or regulatory jurisdiction.

1.33 “Regulatory Documentation” means all Regulatory Filings, registrations, filings, applications, licenses, authorizations and approvals (including Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authorities), and all clinical studies, data and supporting documents contained therein, in each case relating to Tramadol or the Products, and all data contained in any of the foregoing (including advertising and promotional and marketing documents, adverse event files, PSURs, medical event reports, compliant files and the like).

1.34 “Regulatory Filings” means, with respect to the Products, any submission to a Regulatory Authority of any appropriate regulatory application specific to Products, and shall include, without limitation, any submission to a regulatory advisory board and any supplement or amendment thereto.

1.35 “Retained Territory” means all countries and territories in the world other than the Territory.

1.36 “Territory” means the Republic of Korea.

1.37 “Third Party” means any party other than a Party to this Agreement and such Party’s Affiliates.

1.38 “Tramadol” means 2-[(dimethylamino)methyl]- 1-(3-methoxyphenyl)-cyclohexanol and all pharmaceutically-acceptable forms (e.g., solvates, polymorphs and salts) thereof.

1.39 “Tramadol Only Product” means a Product that includes Tramadol only.

1.40 “Transfer Price” means US$0.97 per tablet, subject to annual adjustment as set forth in the Supply Agreement.

1.41 “Valid Claim” means any claim contained in any Ampio Patent in the Territory which has not been revoked or held unenforceable, unpatentable or invalid by a decision of a court or other governmental agency or competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through abandonment, reissue, disclaimer or otherwise.

1.42 “Zertane” means Ampio’s trademark and/or trade dress for Tramadol.

2 Licenses

2.1 License to Daewoong.

(a) Subject to the terms and conditions of this Agreement, Ampio hereby grants Daewoong an exclusive (even as to Ampio except as provided in this Section 2.1 below), royalty-bearing license, with the right to sublicense directly or through multiple tiers as provided in Section 2.3, under the Ampio Technology, to research, Develop, Finish, use, have used, sell, have sold, offer for sale, have offered for sale, distribute, have distributed, import, have imported, and otherwise Commercialize the Products in the Field in the Territory. For clarity, the foregoing licenses exclude the right to Manufacture or have Manufactured the Product, except for the right to Finish the Product.

(b) Notwithstanding the rights granted to Daewoong in Section 2.1 and without limiting the generality of Section 2.4, Ampio retains the following: (i) the right to conduct or have conducted clinical trials and other studies in the Territory for the generation of data in support of any regulatory submissions to any Regulatory Authority in the Retained Territory; and (ii) the right to Manufacture or have Manufactured Product anywhere in the Territory, in each case together with the right to import and export the Product in such territories for such purposes.

2.2 License to Ampio. Subject to the terms and conditions of this Agreement, Daewoong hereby grants to Ampio (a) a non-exclusive, royalty-free license (with the right to sublicense as provided below) in the Field under the Daewoong Technology to Develop, use, make, and have made the Products in the Territory pursuant to the terms of this Agreement and the Supply Agreement, and (b) a non-exclusive, royalty-free, perpetual, irrevocable license, with the right to grant sublicenses through multiple tiers, under the Daewoong Technology to research, develop, use, have used, sell, have sold, offer for sale, have offered for sale, distribute, have distributed, import, have imported, export, have exported and otherwise commercialize the Products in the Retained Territory.

2.3 Sublicenses.

(a) Daewoong may grant sublicenses to one or more Third Parties (any such Third Parties, together with all their direct and indirect Sublicensees, collectively, "Sublicensees") of the licenses granted to Daewoong hereunder, subject to Ampio's prior written consent with respect to the identity of the potential Sublicensee, such consent shall not be unreasonably withheld. Daewoong shall remain responsible for the performance of its obligations set forth herein by each of its Sublicensees.

(b) Daewoong shall, within thirty (30) days after granting any sublicense under Section 2.1(a) above, notify Ampio of the grant of such sublicense and provide Ampio with a true and complete copy of such sublicense agreement. Each sublicense agreement shall not conflict with the terms and conditions under this Agreement. Daewoong shall, in each agreement under which it grants a sublicense under the license set forth in Section 2.1 (each, a "Sublicense Agreement"), include the following terms and conditions: (i) the Sublicensee is required to carry out such tasks to ensure that Daewoong will comply with its obligations to Ampio hereunder; (ii) the Sublicensee is required to provide the following to Daewoong if such Sublicense Agreement terminates during the term of this Agreement: (A) the assignment and transfer of ownership and possession of all Regulatory Filings and Regulatory Approvals held or possessed by such Sublicensee, and (B) the assignment of all intellectual property Controlled by such Sublicensee that covers or embodies a Product or its respective use, manufacture, sale, or importation and was created by or on behalf of such Sublicensee during the exercise of its rights or fulfillment of its obligations pursuant to such Sublicense Agreement; and (iii) if this Agreement terminates pursuant to Section 13.2 prior to the expiration of the Term, then Ampio may, at its sole discretion: (X) assume Daewoong's rights and obligations under such Sublicense Agreement; or (Y) terminate such Sublicense Agreement. Each Sublicense Agreement shall include the Sublicensee's obligations set forth herein.

2.4 Negative Covenant; No Implied License. Each Party covenants that it will not use or practice any of the other Party's intellectual property rights licensed to it under this Article 2 except for the purposes expressly permitted in the applicable license grant. Except as explicitly set forth in this Agreement, neither Party grants any license, express or implied, under its intellectual property rights to the other Party.

2.5 Diversion.

(a) Daewoong hereby covenants and agrees that it will not, and will ensure that its Affiliates, Sublicensees and subcontractors will not, either directly or indirectly, promote, market, distribute, import, sell or have sold Products, including via the Internet or mail order, to any Third Party, address or Internet Protocol ("IP") address in the Retained Territory. As to such countries in the Retained Territory: (i) Daewoong shall refrain from establishing or maintaining any branch, warehouse or distribution facility for the Product in such countries; (ii) Daewoong shall not engage in any advertising or promotional activities relating to the Products directed primarily to customers or other buyers or users of the Products located in such countries; and (iii) Daewoong shall not solicit orders from any prospective purchaser located in such countries. If Daewoong receives any order from a prospective purchaser located in a country in the Retained Territory, Daewoong shall immediately refer that order to Ampio. Daewoong shall not accept any such orders. Daewoong may not deliver or tender (or cause to be delivered or tendered) any Products outside of the Territory.

(b) If any of Daewoong's Products is diverted for use in the Retained Territory, the following shall apply: (i) if such Product were diverted by an identifiable customer, distributor, employee, consultant or agent of Daewoong then, upon the request of Ampio, Daewoong shall not sell such category of Product to, or allow the sale of such category of Product by, any such customer, distributor, employee, consultant or agent for the remaining Term and shall use commercially reasonable efforts to buy back all such Product from such customer, distributor, employee, consultant or agent within seven (7) business days of receiving such request from Ampio; or (ii) Daewoong shall use commercially reasonable efforts to investigate the location of such diverted Product and buy it back; but, if and to the extent that, Daewoong elects not to, or is unable to, buy back the applicable diverted Product, then Ampio may, in its sole discretion, buy back the applicable diverted Product and Daewoong shall reimburse Ampio for all reasonable costs incurred by Ampio in connection with the buy-back of any such diverted Product.

2.6 Exclusivity. During the Term: (a) neither Daewoong nor its Affiliates will, either by itself or through the grant of licenses or sublicenses, without Ampio's written consent, commercialize any formulation that includes Tramadol in the Field in the Territory or in the Retained Territory except under this Agreement; and (b) Daewoong will not, and will ensure that its Affiliates will not, either by itself or through the grant of licenses or sublicenses: commercialize another product for the treatment of premature ejaculation and/or erectile dysfunction in the Territory.

2.7 Registration of License. Daewoong shall have the right to record or register the licenses granted hereunder, and allow its Sublicensees to record or register the sublicenses granted under the Sublicense Agreement, at any patent office or other relevant authority in the Territory. Ampio shall execute all documents and give all declarations regarding the licenses or sublicenses and reasonably cooperate with Daewoong or its Sublicensees at the costs of Daewoong or its Sublicensees to the extent such documents, declarations and/or cooperation are required for such record or registration of the licenses or sublicenses for the benefit of Daewoong or its Sublicensees.

3 Disclosure of Know-How

3.1 Disclosure of Ampio Know-How and Ampio Regulatory Documentation. Within sixty (60) days after the Effective Date of this Agreement, Ampio shall disclose or make available to Daewoong copies of all of the Ampio Know-How and Ampio Regulatory Documentation, including such Ampio Know-How and Ampio Regulatory Documentation identified on Exhibit 3.1. Thereafter during the term of this Agreement, Ampio shall disclose and make available to Daewoong all future Ampio Know-How and Ampio Regulatory Documentation on a regular basis, provided that all material new Ampio Know-How and Ampio Regulatory Documentation shall be provided without delay.

3.2 Disclosure of Daewoong Know-How and Daewoong Regulatory Documentation . Daewoong shall disclose or make available to Ampio, during the term of this Agreement, any and all Daewoong Know-How and Daewoong Regulatory Documentation on a regular basis, provided that all material Daewoong Know-How and Daewoong Regulatory Documentation shall be provided without delay.

4 Milestone Payments

4.1 Milestone Payments. In consideration of the rights and licenses granted to Daewoong by Ampio hereunder, Daewoong shall pay to Ampio the following milestone amounts:

Event	Payment (U.S. Dollars)
1. Upon signing of this Agreement by both Parties	$ 500,000
2. Within five (5) business days following the approval of Tramadol for sale in the Territory	$ 500,000
3. Within five (5) business days following the approval of the Combination Product for sale in the Territory	$ 700,000
4. Within twenty (20) business days following the end of the first calendar quarter where cumulative Net Sales in the Territory exceed US$10 million	$ 1 million
5. Within twenty (20) business days following the end of the first calendar quarter whether cumulative Net Sales in the Territory exceed US$20 million	$ 1 million
TOTAL PAYMENTS	$ 3,700,000

For clarity, milestone events 4 and 5 may occur during the same calendar year, in which event each of the accompanying milestone payments shall become due. In addition, the milestones will apply to sales of Products by Daewoong, its Affiliates and Sublicensees.

4.2 Non-Refundable. Any payments made by Daewoong in accordance with Section 4.1 shall, once they are paid, not be refundable nor creditable for any reason whatsoever, unless otherwise expressly provided herein.

4.3 Single Payments. The payments specified in Section 4.1 shall be made only one time upon the first occurrence of the event described in Section 4.1, regardless of how many times such event may be achieved with regard to the Products covered by this Agreement.

5 Management; Joint Steering Committee

5.1 Alliance Managers. Within thirty (30) days following the Effective Date, each Party will appoint (and notify the other Party of the identity of) a representative having the appropriate qualifications including a general understanding of pharmaceutical Development and Commercialization issues to act as its alliance manager under this Agreement ("Alliance Manager"). The Alliance Managers will serve as the primary contact points between the Parties for the purpose of providing each Party with information on the progress of the other Party's Development and Commercialization of the Products. The Alliance Managers will also be primarily responsible for facilitating the flow of information and otherwise promoting communication, coordination and collaboration between the Parties, providing single point communication for seeking consensus both internally within each Party's respective organization, including facilitating review of external corporate communications, and raising cross-Party and/or cross-functional disputes in a timely manner. Each Party may replace its Alliance Manager on written notice to the other Party.

5.2 Joint Steering Committee.

(a) Within thirty (30) days after the Effective Date, the Parties will establish a joint steering committee (the "Joint Steering Committee" or "JSC") to plan, administer, evaluate and carry out all aspects of the Development, manufacture, regulatory and Commercialization activities by Daewoong hereunder with respect to the Products.

(b) The JSC will consist of representatives of Ampio and Daewoong. The representatives may be from various functional groups (e.g., clinical development, regulatory, medical affairs, pharmacovigilance, commercial and manufacturing). Daewoong will appoint a chair of the JSC.

(c) The Parties shall schedule the half-yearly JSC meetings and agree to such schedule at least quarterly in advance. Either Party may call additional ad hoc meetings of the JSC as the needs arise with reasonable advance notice to the other Party, and such ad hoc meetings shall be conducted at times that are mutually agreed upon by the Parties. All meetings and other communications of the JSC shall be conducted in English. No later than five (5) business days prior to any regularly scheduled meeting of the JSC, the chairperson of the JSC shall prepare and circulate an agenda for such meeting and, as soon as practicable, all materials, documents and information for the meeting for distribution to both Parties; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JSC may meet in person, by videoconference or by teleconference. The chairperson of the JSC will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, without limitation, material decisions made at such meetings. The JSC chairperson shall send draft meeting minutes to the Daewoong members and the Ampio members of the JSC for review and approval within ten (10) business days after each JSC meeting. Such minutes will be deemed approved unless one or more members of the JSC objects to the accuracy of such minutes within ten (10) business days of receipt. Further, upon Daewoong's request, Ampio will use commercially reasonable efforts to coordinate any meeting among Ampio, Daewoong and any other Ampio Licensees for the exchange of information helpful for the Development of the Products. In addition to the regularly scheduled meetings, Daewoong shall call additional ad hoc meetings of the JSC prior to making any major decisions in the Development of the Products in the Territory. The Parties shall also maintain regular, frequent and informal communications for Ampio to obtain updates from Daewoong and for the Parties to discuss the progress of the Development of the Products in the Territory.

(d) The JSC shall strive to seek consensus in its actions and decision making process. In the event of a disagreement between the Ampio members and Daewoong members of the JSC, either Party may refer the matter to one senior executive of each Party (i.e., the Chief Executive Officer or Managing Director of such Party or an executive of such Party who reports directly to the Chief Executive Officer or Managing Director) for resolution. If such senior executives cannot resolve the matter within ten (10) business days, then such senior executive of Daewoong shall have the final decision making authority on such matter, provided that any final determination made by such senior executive of Daewoong shall be consistent with the terms of this Agreement, further provided that Daewoong shall not make any decision with respect to the following critical issues without the consent of Ampio, such consent not to be unreasonably withheld or delayed: (A) discontinue the Development of any Product; (B) initiate or discontinue any clinical trial; (C) unreasonably delay the process of or cease to seek Regulatory Approval for any Product; (D) unreasonably delay or cancel the commercial launch of any Product; and (E) remove any Product from the market, other than for safety reasons. For clarity, Ampio shall take the lead with respect to all determinations relating to any clinical trials relating to any Product.

5.3 Costs of Governance. The Parties agree that the costs incurred by each Party in connection with its participation at any meetings under this Article 5 shall be borne solely by such Party, except that the costs of necessary translations and translators shall be divided equally between the Parties.

6 Development

6.1 Development Plan.

(a) Within sixty (60) days after the Effective Date (or such longer period of time as recommended by the JSC), the Parties will agree upon a development plan for the Development of the Products in the Territory (the “Development Plan”). The Development Plan includes all clinical studies to be performed for the Products, including those that are required for Regulatory Approval for the Products in the Territory. The Development Plan shall also each specify the plans, timeline and budget for preparing the necessary Regulatory Filings and for obtaining Regulatory Approvals for the Products in the Territory, which will provide for filing for Regulatory Approvals of the Products in the Territory as soon as practicable following the Effective Date. Daewoong shall conduct the Development activities in accordance with the then-current Development Plan (including the timelines set forth therein) and under the direction of the JSC.

(b) From time to time during the Term, Daewoong shall update and amend, as appropriate, the then-current Development Plan and submit such updated or amended Development Plan for the JSC's approval, such approval not to be unreasonably withheld or delayed. Once approved by the JSC, each updated or amended Development Plan shall become effective and supersede the previous Development Plan as of the date of such approval.

6.2 Daewoong Development Activities.

(a) Daewoong shall Develop the Products and seek Regulatory Approval by timely and diligently conducting all Development activities under the Development Plan (the "Daewoong Development Activities").

(b) The status, progress and results of the Development activities in the Territory shall be discussed at meetings of the JSC, and Daewoong shall provide the JSC with a written report on the status and progress of such Development activities on a half-yearly basis at least five

(5) business days prior to each scheduled JSC meeting. In addition, Daewoong shall make available to Ampio such information about such Development activities as may be reasonably requested by Ampio from time to time.

6.3 Compliance.

(a) Daewoong agrees that in performing its obligations under this Agreement: (i) it shall comply with all applicable Laws; and (ii) it will not employ or engage any person who has been debarred by any Regulatory Authority, or, to such Party's knowledge, is the subject of debarment proceedings by a Regulatory Authority. Daewoong shall have the right to engage subcontractors for the performance of its obligations under the Development Plan. Daewoong remains responsible for the performance of such subcontractor(s) and the engagement of such subcontractors shall not relieve Daewoong from its obligations to comply with the terms and conditions of this Agreement.

(b) Daewoong shall maintain complete, current and accurate records of all work conducted by it under the Development Plan, and all data and other Information resulting from such work. Daewoong shall cause the Sublicensees to maintain complete, current and accurate records of all work conducted by such Sublicensees under the Development Plan, and all data and other Information resulting from such work. Such records shall fully and properly reflect all work done and results achieved in the performance of the Development activities in good scientific manner appropriate for regulatory purposes. Ampio shall have the right to review all records maintained by Daewoong or such Sublicensees at reasonable times, upon Ampio's written request.

(c) Daewoong shall document all preclinical studies and clinical trials conducted by or for it in written study reports and shall provide Ampio with a summary of each such report in English promptly after its completion.

6.4 Development Costs. As between the Parties, Daewoong shall bear all Development Costs for the Development: (a) conducted by or for Daewoong and incurred by Daewoong; or (b) conducted by Ampio for Daewoong at the written request of or with the written consent of Daewoong and incurred by Ampio, in each case after the Effective Date in connection with the research, manufacture and Development (including development of manufacturing processes for the Products and other matters relating to the chemistry, manufacture and controls of the Products) of the Products in accordance with the Development Plan or the other provisions of this Agreement, as well as any other research, manufacture and development of the Products by Daewoong.

7 Regulatory Matters

7.1 Daewoong Regulatory Responsibilities.

(a) Subject to the termination of this Agreement, Daewoong shall own all Regulatory Filings and Regulatory Approvals for the Products in the Territory, and shall be solely responsible for preparing any and all Regulatory Filings for the Products in the Territory at its sole expense in accordance with the Daewoong Development Plan, with the direction of the JSC and subject to the terms of this Article 7. Ampio shall assist Daewoong or its Sublicensees as they may reasonably request in connection with the preparation and filing of such Regulatory Filings, at Daewoong's or its Sublicensees' reasonable request and expense.

(b) Daewoong shall keep Ampio informed of regulatory developments specific to Products throughout the Territory, and Ampio shall have the right to contribute to the regulatory plans and strategies for the Products in the Territory.

(c) Daewoong shall, and shall ensure that its Sublicensees will, lead discussions with any Regulatory Authority related to any Development of any Products. Daewoong will, and will cause its Sublicensees to, inform Ampio of any such discussions in advance to the extent practicable, and Daewoong will, and will ensure that its Sublicensees will, reasonably consider any input from Ampio in preparation for such discussions.

(d) Daewoong shall, and shall ensure that its Sublicensees will, be responsible to ensure, at its sole expense, that the Development, manufacture and Commercialization of the Products in the Territory are in compliance with all applicable Laws, including without limitation all rules and regulations promulgated by any of the Regulatory Authorities in the Territory. Specifically and without limiting the foregoing, Daewoong shall, and shall ensure that its Sublicensees will, file all compliance filings, certificates and safety reporting (subject to Section 7.2(a)) in the Territory at its sole expense.

(e) to the extent permitted by the applicable Regulatory Authority and as requested by Ampio, Daewoong shall, and shall ensure that its Sublicensees will, allow representatives of Ampio to participate in any scheduled conference calls and meetings between Daewoong or its Sublicensees and the Regulatory Authority at Ampio's expense. If Ampio elects not to participate in such calls or meetings, Daewoong shall, and shall ensure that its Sublicensees will, provide Ampio with written summaries of such calls and meetings in English as soon as practicable after the conclusion thereof.

(f) with respect to all Regulatory Filings, Daewoong shall, and shall ensure that its Affiliates and Sublicensees will: (i) submit only data and information that are free from fraud or material falsity; (ii) not use bribery or the payment of illegal gratuities in connection with its Regulatory Filings for the Products; and (iii) submit only data and information that are accurate and reliable in all material respects for purposes of supporting Regulatory Approval.

7.2 Adverse Events.

(a) Within one (1) year prior to the planned first Regulatory Approval of the Products in the Territory, the Parties shall discuss in good faith and enter into a pharmacovigilance and adverse event reporting agreement setting forth the worldwide pharmacovigilance procedures for the Parties with respect to the Products, such as safety data sharing, adverse events reporting and prescription events monitoring (the "Pharmacovigilance Agreement"). Such Pharmacovigilance Agreement shall govern the global pharmacovigilance procedures to be agreed upon by Daewoong, Ampio, Ampio Licensees and the commercial partners of each Party.

(b) Prior to the execution of such Pharmacovigilance Agreement, the Parties agree to coordinate the pharmacovigilance procedures in connection with the Development of the Products, and Daewoong shall submit to Ampio all safety information and reporting in a manner that meets the reporting requirements in the Retained Territory. Each Party shall notify the other Party within twenty-four (24) hours of such Party's learning of any Serious Adverse Events (as defined below) that is attributed to or potentially attributable to the use of the Products. Each Party shall also provide the other Party, on an annual basis and more frequently as reasonably requested by the other Party, a summary report of Adverse Events (as defined below), as well as those Serious Adverse Events that are not attributable to the use of the Products. As used herein, unless defined differently by the FDA, "Adverse Events" means any side effect, injury, toxicity or sensitivity reaction, or any unexpected incident, and the severity thereof, whether or not determined to be attributable to any Product, and "Serious Adverse Events" means an Adverse Event which results in death, is immediately life-threatening, results in persistent and significant disability/incapacity or requires in-patient hospitalization or prolongation of existing hospitalization.

(c) After the execution of the Pharmacovigilance Agreement, the Parties shall comply with such Pharmacovigilance Agreement with respect to all aspects of pharmacovigilance activities with respect to the Products, and Section 7.2(b) above shall be of no further effect.

7.3 No Harmful Actions. If either Party believes that the other Party, as the case may be, is taking or intends to take any action with respect to the Product that could reasonably be expected to have a material adverse impact upon the regulatory status of the Product in the Retained Territory or the Territory, such Party shall have the right to bring the matter to the attention of the JSC. Without limiting the foregoing, unless the Parties otherwise agree: (a) Daewoong shall not communicate with any Regulatory Authority having jurisdiction in the Retained Territory, unless so ordered by such Regulatory Authority, in which case Daewoong shall provide immediately to Ampio notice of such order; and (b) Daewoong shall not submit any Regulatory Filings or seek Regulatory Approvals for the Products in the Retained Territory.

7.4 Notification of Threatened Action. Each Party shall immediately notify the other Party of any information it receives regarding any threatened or pending action, inspection or communication by or from any party, including, without limitation, a Regulatory Authority, which may affect the safety or efficacy claims of a Product or the continued marketing of a Product. Upon receipt of such information, the Parties shall consult with each other in an effort to arrive at a mutually acceptable procedure for taking appropriate action.

7.5 Data Exchange and Use. This Section 7.5 shall not apply to any pharmacovigilance data (which is addressed in Section 7.2). Daewoong shall, and shall ensure that its Sublicensees will, provide Ampio with copies of all final submissions and correspondence to and from all Regulatory Authorities relating to the Products in the Field within seven (7) days of submission or receipt, as applicable, and shall, and shall ensure that its Sublicensees will, provide Ampio a summary of each significant submission (such as application for approval for clinical trials, Regulatory Approval and fast track or orphan drug designation, the protocol for clinical trials and any modifications thereof) in English as soon as practicable but in any event within ten (10) business days after such submission. Each Party shall permit the other Party to access, and shall provide the other Party with rights to reference and use in association with the Products in the Field, all of its, its Affiliates', and its or their licensees' and Sublicensees' regulatory, preclinical and clinical data documentation, Regulatory Filings, and Regulatory Approvals with respect to the Products in the Field.

7.6 Remedial Actions. Each Party will, and will ensure that its Affiliates and Sublicensees will, notify the other Party immediately, and promptly confirm such notice in writing, if it obtains information indicating that a Product may be subject to any recall, corrective action or other regulatory action with respect to a Product taken by virtue of applicable Law in the Territory (a "Remedial Action"). The Parties (or Daewoong's Sublicensees and Ampio), as the case may be, will assist each other in gathering and evaluating such information as is necessary to determine the necessity of conducting a Remedial Action. Daewoong shall, and shall ensure that its Affiliates and Sublicensees will, maintain or have maintained adequate records to permit the Parties to trace the manufacture of the Product and the distribution and, to the extent feasible, the use of the Product. In the event Daewoong or its any Sublicensee determines that any Remedial Action with respect to a Product in the Field in the Territory should be commenced or Remedial Action is required by any Regulatory Authority having jurisdiction over the matter, Daewoong will, and will ensure that its Sublicensees will, as the case may be, control and coordinate all efforts necessary to conduct such Remedial Action. In the event Ampio determines that any Remedial Action with respect to a Product outside the Field in the Territory should be commenced or Remedial Action is required by any Regulatory Authority having jurisdiction over the matter, Ampio will control and coordinate all efforts necessary to conduct such Remedial Action. For clarity, as between the Parties, Ampio shall have sole discretion with respect to any matters relating to any Remedial Action in the Retained Territory. The cost and expense of a Remedial Action arising from the development, manufacture or commercialization of the Product in the Field in the Territory shall be borne solely by Daewoong or its Sublicensees.

7.7 Rights of Reference to Regulatory Documentation. Each Party hereby grants to the other Party a right of reference to all Regulatory Documentation filed by such Party for the Products subject to the scope of the licenses granted hereunder, including, for the avoidance of doubt, all such Regulatory Documentation filed by Ampio for Regulatory Approval of the Products in the Retained Territory and all supplemental filings related thereto, and all "Certificate(s) of Pharmaceutical Product" and/or "Certificate(s) of Free Sales" resulting from Regulatory Approval of such Products, solely for the purpose of seeking, obtaining and maintaining Regulatory Approvals for, and the Commercialization of, the Product in the Territory and the Field, consistent with the roles of the Parties set forth in this Agreement. In addition, Daewoong hereby grants to Ampio a right of reference to all Regulatory Documentation filed by Daewoong in the Territory for the purpose of Ampio, its Affiliates or any Ampio Licensees developing and obtaining and/or maintaining Regulatory Approvals anywhere in the world for the Products in the Field in the Retained Territory.

8 Commercialization

8.1 Overview of Commercialization in the Territory. Daewoong, its Affiliates and its Sublicensees will have responsibility for all decisions related to and implementation of Commercialization activities, including but not limited to price, reimbursement and distribution, for the Products in the Territory, at its sole expense. Daewoong will prepare and submit to the JSC a commercialization plan no later than six (6) months prior to the anticipated date of Regulatory Approval for the first Product in the Territory (the "Commercialization Plan"). Such Commercialization Plan shall incorporate the commercialization diligence requirements set forth below. Daewoong will update such Commercialization Plan on a yearly basis and will provide quarterly reports to Ampio describing Daewoong's progress against such Commercialization Plan. Daewoong shall use Commercially Reasonable Efforts to maximize sales of the Products throughout the Territory in accordance with the Commercialization Plan. Furthermore, Ampio and Daewoong agree that the initial commercial price for a Tramadol Only Product shall be US$5.00 per tablet, and if the parties decide the Net Sales needs to be adjusted, the parties shall discuss in good faith with the JSC. For clarification, the commercial price means the cost of medicine that the patient pays the pharmacy for a Tramadol Only Product.

8.2 Trademark. Daewoong shall have the right to brand the Products using Daewoong related trademarks and any other trademarks and trade names it determines appropriate for the Products in consultation with Ampio ("Product Marks"). Daewoong shall own all rights in the Product Marks and register and maintain the Product Marks in the countries and regions it determines reasonably necessary. Notwithstanding any provisions in this Agreement, Daewoong shall be the exclusive sole owner for the Product Marks even after the termination of this Agreement for whatever reasons.

9 Manufacture and Supply; Payment for Products

9.1 General Supply Terms. Ampio shall, itself or through one or more Third Party contract manufacturers, manufacture the Products in finished form in unlabeled containers in accordance with the terms of Section 9, including the performance of all manufacturing process development and scale-up for the Products (and associated regulatory activities), and shall supply to Daewoong, and Daewoong shall purchase from Ampio, all of Daewoong and its Affiliates' and its/their Sublicensees' requirements of the Products for Development and Commercial activities as and to the extent set forth in this Agreement and the Supply Agreement. Daewoong shall be responsible for labelling and packaging all Products supplied by Ampio to Daewoong under this Agreement and the Supply Agreement.

9.2 Supply Agreement. Within sixty (60) days after the Effective, the Parties shall enter into a supply agreement and quality agreement governing the supply of Products to Daewoong for clinical and commercial use, as well as the quality control and quality assurance procedures thereon (collectively the "Supply Agreement") and any other operational agreements and procedures as deemed necessary by the Parties for such supply of the Products. The terms of such Supply Agreement shall be negotiated in good faith by the Parties.

9.3 Payment and Pricing. The Supply Agreement shall provide for payment by Daewoong for Product supplied by Ampio in the manner prescribed below.

(a) Tramadol-Only Product.

(i) Within thirty (30) days after supply by Ampio to Daewoong, its Affiliates or its Sublicensees of any Tramadol-Only Product, Daewoong shall pay to Ampio an amount equal to Transfer Price.

(ii) Within thirty (30) days after the end of each calendar quarter, Daewoong shall pay to Ampio an amount equal to the difference between (x) 25% of the Net Sales of such Tramadol-Only Product minus (y) the Transfer Price.

(b) Combination Product. The transfer price for the Combination Product will be determined at a later date via the Supply Agreement.

9.4 Reports; Records. During the term of this Agreement after First Commercial Sale of the first Product, Daewoong shall furnish or cause to be furnished to Ampio within thirty (30) days after the end of each calendar quarter (each a "Reporting Period") a written report or reports (the "Sales Report") covering the applicable Reporting Period and containing the following information:

(a) the Net Sales of Products in the Territory during the Reporting Period;

(b) the royalties, payable in U.S. Dollars, which shall have accrued hereunder in respect to such Net Sales;

(c) withholding taxes, if any, required by Law to be deducted in respect of such royalties; and

(d) the exchange rates used in determining the amount of U.S. Dollars.

9.5 Exchange Rates; Reports. With respect to sales of Product invoiced in U.S. Dollars, the Net Sales and royalty payable shall be expressed in such currency as it is. With respect to sales of Product invoiced in a currency other than U.S. Dollars, the Net Sales and royalty payable shall be expressed in the domestic currency of the Republic of Korea together with the U.S. Dollars equivalent of the royalty payable, calculated using the average exchange rates posted in *The Financial Times* published on the first and last days of each month within each calendar quarter (each a "Reporting Period"). Sales Reports shall be due thirty (30) days following the close of each respective Reporting Period. Daewoong and its Affiliates and Sublicensees shall keep legible, verifiable and accurate records in sufficient detail to enable the royalties payable hereunder to be determined and substantiated.

9.6 Withholding Tax. Daewoong shall deduct any withholding taxes and other statutory duties from all payments set forth herein and pay them to the proper tax authorities if required by applicable Law. Daewoong shall maintain official receipts related to any withholding taxes and forward copies of such receipts to Ampio. The Parties will exercise their commercially reasonable efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future double taxation agreement between the Republic of Korea and the United States of America. If, according to Laws applied to the Parties, this reduction requires a certificate of tax exemption, and in order to achieve such reduction, each Party shall cooperate with the other Party with applicable legal procedure and shall provide the other Party with the claim for a certificate of tax exemption in respect of royalties paid on the official form containing a certification of residence of the competent tax authority and other appropriate documents.

9.7 Audit Rights. Ampio shall have the right to have an independent public accounting firm of its own selection, except one to whom Daewoong, its Affiliates or Sublicensees may have reasonable objection, and at Ampio's own expense (except if the result of such audit results in an underpayment exceeding five percent (5%) of the payments that were paid to Ampio), examine the relevant books and records of account of Daewoong and any of its Affiliates and Sublicensees during reasonable business hours upon reasonable prior written notice to Daewoong and not more often than once each calendar year, for not more than two (2) previous years, to determine whether appropriate payment have been made to Ampio hereunder. Ampio may exercise such right until the end of one (1) year after the termination or expiration of this Agreement. Daewoong shall promptly pay to Ampio the full amount of any undisputed underpayment. If the amount of the underpayment is greater than five percent (5%) on an annualized basis, Daewoong shall pay interest on that amount that is in excess of five percent (5%) at the rate of LIBOR plus two percent (2%) per year, compounding annually from the date payment was due. Ampio shall promptly pay to Daewoong the full amount of any overpayment. Such public accounting firm shall treat as confidential, and shall not disclose to Ampio, any information other than information which could otherwise be given to Ampio pursuant to any provision of this Agreement, all of which shall be treated as Confidential Information of Daewoong hereunder.

9.8 Recalls and Voluntary Withdrawals. The Parties shall exchange their internal standard operating procedures ("SOPs") for conducting product recalls reasonably in advance of the First Commercial Sale of Product in the Territory, and shall discuss and resolve any conflicts between such SOPs and issues relating thereto promptly after such exchange. If either Party becomes aware of information relating to any released Product that indicates that a unit or batch of Product may not conform to the specifications thereof, or that potential adulteration, misbranding, and/or other issues have arisen that relate to the safety or efficacy of such released Product, it shall promptly so notify the other Party. To the extent Daewoong requires such information to comply with applicable Laws or to determine whether to conduct a recall, Ampio shall promptly disclose to Daewoong any CMC Information related to such nonconformance, adulteration, misbranding or other related issue. Daewoong shall have the right, at its expense (except as provided herein), to control any Product recall, field correction, or withdrawal of any released Product in the applicable jurisdiction in the Territory. Ampio shall have the right, at its expense, to control any Product recall, field correction, or withdrawal of any released Product in the Retained Territory. Ampio shall be responsible for all costs incurred for any recall, field correction, or withdrawal of any released Product for the Territory to the extent such event of recall, field correction, or withdrawal is due to the material breach by Ampio of this Agreement or the Supply Agreement. Daewoong shall be responsible for all other costs incurred for any recall, field correction, or withdrawal of any released Product for the Territory. The procedures and consequences of such recalls shall be defined in the Supply Agreement. The Party having the right to control such recall pursuant to this Section 9.8 may, at its sole discretion, take appropriate courses of action, which shall be consistent with the internal SOPs of such Party; provided, however, that such controlling Party shall promptly notify the other Party of any recall action being considered and where practicable, consider the views of the non-controlling Party prior to taking any recall action. Daewoong shall maintain complete and accurate records of any recall according to its then current SOPs in the Territory for such periods as may be required by applicable Laws, but in no event for less than three (3) years.

9.9 Payment. Any invoice will be issued by Ampio together with the delivery of the Products to Daewoong and shall be paid by Daewoong within thirty (30) days upon receipt by Daewoong of such invoice and acceptance by Daewoong of the applicable Product shipment by wire transfer on a bank account designated by Ampio. All payments to Ampio shall be in US Dollars.

10 Representations, Warranties and Covenants; Disclaimer

10.1 No Representation of Success. Ampio does not warrant that Daewoong can successfully develop, obtain Regulatory Approvals for, or market the Products in the Territory by using and relying upon the Ampio Patents, the Ampio Know-How and the Ampio Regulatory Documentation supplied by Ampio hereunder and further that, except as expressly provided in Section 10.2, the Ampio Patents, the Ampio Know-How and the Ampio Regulatory Documentation has not any defect.

10.2 Ampio Representations, Warranties and Covenants. Ampio covenants, and represents and warrants to Daewoong as of the Effective Date, that:

(a) Ampio is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated.

(b) Ampio has full right and authority to use the Ampio Patents, the Ampio Know-How and the Ampio Regulatory Documentation and to enter into this Agreement and to grant the licenses to Daewoong as herein described.

(c) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Ampio enforceable against Ampio in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity.

(d) The execution, delivery and performance of this Agreement does not and will not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Ampio is a party, or by which it is bound, nor will it violate any Law applicable to Ampio.

(e) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons or entities required to be obtained by Ampio in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(f) Ampio has not granted as of the Effective Date, and will not grant during the term of this Agreement, any licenses to any Affiliate or Third Party under the Ampio Patents, Ampio Know-How or Ampio Regulatory Documentation which would conflict with the licenses granted to Daewoong hereunder.

10.3 Daewoong Representations and Warranties. Daewoong covenants, and represents and warrants to Ampio as of the Effective Date, that:

(a) Daewoong is a corporation duly organized, validly existing and in good standing under the laws of jurisdiction in which it is incorporated and it has full right and authority to enter into this Agreement and to accept the rights and licenses granted as herein described.

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Daewoong enforceable against Daewoong in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other Laws affecting creditors' rights generally from time to time if effect, and to general principles of equity.

(c) The execution, delivery and performance of this Agreement does not and will not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Daewoong is a party, or by which it is bound, nor will it violate any Law applicable to Daewoong.

(d) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons or entities required to be obtained by Daewoong in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(e) Daewoong has not as of the Effective Date knowingly performed any acts that are inconsistent with the terms and purposes of this Agreement.

(f) Daewoong warrants that any sublicense granted hereunder by Daewoong or any Sublicensee shall be subject to the terms and conditions of this Agreement.

(g) Daewoong has undertaken the investigation and has evaluated documents and information as practically it has deemed necessary to enable it to make an informed and intelligent decision with respect to the execution, delivery and performance of this Agreement. Daewoong agrees to enter into this Agreement in the terms and conditions herein on the Effective Date based upon its own inspection, examination and determination with respect thereto as to all matters, and without reliance upon any express or implied representations or warranties of any nature made by or on behalf of or imputed to Ampio or their Affiliates, except as expressly set forth in this Agreement. Without limiting the generality of the foregoing, and except as expressly set forth in this Agreement, Daewoong acknowledges that Ampio is making no representation or warranty with respect to any Ampio Know-How, Ampio Patent or Ampio Regulatory Documentation licensed to Daewoong hereunder.

10.4 Limitation of Warranty. EXCEPT AS EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTY, AND EACH PARTY HEREBY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO ANY OF THE MATERIALS, INFORMATION, SERVICES OR LICENSES PROVIDED PURSUANT TO THIS AGREEMENT.

10.5 Performance by Affiliates. The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates and Third Party contractors provided, however, that each Party shall remain responsible and liable for the performance by its Affiliates and Third Party contractors and shall cause its Affiliates and Third Party contractors to comply with the provisions of this Agreement in connection with such performance.

11 Intellectual Property

11.1 Ownership of Inventions; Assignment. Each Party shall own all right, title, and interest in and to any inventions made solely by such Party's employees, agents, independent contractors and sublicensees in the course of conducting its activities under this Agreement during the Term, together with all intellectual property rights therein, including any rights to applications or other protections for any of the foregoing. The Parties shall jointly own all inventions made jointly by the employees, agents, independent contractors or sublicensees of each Party, in accordance with joint ownership interests of co-inventors under U.S. patent laws (that is, each Party shall have full rights to license, assign and exploit such joint inventions (and any patents arising therefrom) anywhere in the world, without any requirement of gaining the consent of, or accounting to, the other Party), subject to the licenses granted herein and subject to any other intellectual property held by such other Party; provided, however, that Daewoong shall not have the right to practice any jointly owned invention in any activities related to a product that competes with the Product. The Parties shall determine which Party will file, prosecute and maintain the Patents claiming or covering such jointly owned inventions. Inventorship shall be determined in accordance with U.S. patent laws. Notwithstanding the foregoing, Daewoong agrees to assign and hereby assigns and transfers to Ampio all of its right, title and interest in and to any such solely owned or jointly owned inventions that relate to the composition of matter, manufacture or use of the Product ("Product Inventions"), and agrees to take, and to cause its employees, agents, consultants and sublicensees to take, all further acts reasonably required to evidence such assignment and transfer to Ampio, at Ampio's reasonable expense. Daewoong hereby appoints Ampio as its attorney-in-fact to sign such documents as Ampio deems necessary for Ampio to obtain ownership and to apply for, secure, and maintain patent or other proprietary protection of such Product Inventions if Ampio is unable, after reasonable inquiry, to obtain Daewoong's (or its employee's or agent's) signature on such a document. Daewoong hereby waives, on behalf of itself, its parent, subsidiaries, Affiliates and partners as well as all of its employees and independent contractors, any rights of first refusal it, he, or she may have with respect to any contemplated technology transfer, in whole or in part, of the Product Inventions or any related patent, patent application, copyright or copyright application related thereto as well as any right accorded to it, him, or her, by statute or otherwise, to use any Product Invention or any Patent or copyright related thereto. All Patents claiming or covering any Product Invention shall be referred to herein as "Product Patents."

11.2 Disclosure of Inventions. Daewoong shall, and shall cause its Third Party Subcontractors, Affiliates and Sublicensees to, promptly disclose to Ampio any invention disclosures, or other similar documents, submitted to it by its employees, agents, consultants or independent contractors describing inventions that may be Product Inventions, and all Information relating to such inventions to the extent necessary for the preparation, filing and maintenance of any Patent with respect to such invention.

11.3 Prosecution of Patents.

(a) Ampio shall have the sole right to prepare, file, prosecute and maintain the Ampio Patents at Ampio's own costs and expenses. If Ampio determines in its sole discretion to abandon all claims in any Ampio Patent in the Territory, then Ampio shall provide Daewoong with written notice of such determination within a period of time reasonably necessary to allow Daewoong to determine its interest in such Ampio Patent(s). In the event Daewoong provides written notice expressing its interest in obtaining such Ampio Patent(s), Ampio shall assign and transfer to Daewoong the ownership of, and interest in, such Ampio Patent(s) in the Territory, such transfer to be at Daewoong's reasonable expense (but without payment to Ampio). Thereafter, Daewoong shall bear all of the costs of preparation, filing, prosecution and maintenance of such assigned and transferred Patents, which shall not be treated as Ampio Patents and shall be treated as Daewoong Patents, and Daewoong may prosecute such Daewoong Patents at its sole discretion; provided, however, in the event that Daewoong decides to abandon or not maintain any such Patent(s), Daewoong shall promptly provide Ampio with written notice of such decision.

(b) Daewoong shall be solely responsible to file, prosecute and maintain Daewoong Patents. With respect to Daewoong Patents under which Ampio receives a license pursuant to Section 2.2 hereof, Daewoong shall provide Ampio reasonable opportunity to review and comment on such prosecution efforts regarding such Daewoong Patents, including by providing Ampio with a copy of material communications from any patent authority in the Territory regarding such Daewoong Patent(s), and by providing drafts of any material filings or responses to be made to such patent authorities in advance of submitting such filings or responses. Daewoong shall reasonably consider such comments by Ampio in connection with the prosecution of Daewoong Patents.

11.4 Patent Term Extensions in the Territory. The JSC will discuss and recommend for which, if any, of the Patents within the Ampio Patents and Daewoong Patents in the Territory the Parties should seek Patent Term Extensions in the Territory. Ampio, in the case of the Ampio Patents, and Daewoong in the case of the Daewoong Patents, shall have the final decision-making authority with respect to applying for any such Patent Term Extensions in the Territory, and will act with reasonable promptness in light of the development stage of the Product to apply for any such Patent Term Extensions, where it so elects; provided, however, that if only one such Patent can obtain a Patent Term Extension, then the Parties will consult in good faith to determine which such Patent should be the subject of efforts to obtain a Patent Term Extension, and in any event Ampio's decision on such matter will control in the case of a disagreement. The Party that does not apply for an extension hereunder will cooperate fully with the other Party in making such filings or actions, for example and without limitation, by making available all required regulatory data and information and executing any required authorizations to apply for such Patent Term Extension. All expenses incurred in connection with activities of each Party with respect to the Patent(s) for which such Party seeks Patent Term Extensions pursuant to this Section 11.4 shall be entirely borne by such Party.

11.5 Infringement of Patents by Third Parties .

(a) Each Party shall promptly notify the other Party in writing of any existing or threatened infringement in the Territory of the Ampio Patents or Daewoong Patents of which it becomes aware, and shall provide all evidence in such Party's possession demonstrating such infringement.

(b) If a Third Party infringes any Ampio Patent in the Territory by making, using, importing, offering for sale or selling the Product or a competitive product in the Field (a "Product Infringement"), each Party shall share with the other Party all Information available to it regarding such alleged infringement. Ampio shall have the sole and exclusive right, but not the obligation, to bring an appropriate suit or other action against any person or entity engaged in such Product Infringement in the Territory. Daewoong shall provide to Ampio reasonable assistance in such enforcement, at Ampio's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. Ampio shall keep Daewoong regularly informed of the status and progress of such enforcement efforts, shall reasonably consider Daewoong's comments on any such efforts, and shall seek consent of Daewoong in any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court, which shall not be unreasonably withheld or delayed. Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 11.5(b). Daewoong shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but Daewoong shall at all times cooperate fully with Ampio bringing such action.

(c) If Ampio, in its sole discretion, determines not to exercise its right to bring an action against Product Infringement in the Territory, Daewoong shall be entitled to do so. Ampio shall provide to Daewoong reasonable assistance in such enforcement, at Daewoong's request and expense, including joining such action as a party plaintiff if required by applicable Laws to pursue such action. Daewoong shall keep Ampio regularly informed of the status and progress of such enforcement efforts, shall reasonably consider Ampio's comments on any such efforts, and shall seek consent of Ampio in any important aspects of such enforcement, including determination of litigation strategy and filing of important papers to the competent court, which shall not be unreasonably withheld or delayed. Each Party shall bear all of its own internal costs incurred in connection with its activities under this Section 11.5(c). Ampio shall be entitled to separate representation in such matter by counsel of its own choice and at its own expense, but Ampio shall at all times cooperate fully with Daewoong bringing such action.

(d) For any and all infringement of any Daewoong Patent anywhere in the Territory, Daewoong shall have the sole and exclusive right, but not the obligation, to bring, at Daewoong's expense and in its sole control, an appropriate suit or other action against any person or entity engaged in such infringement of the Daewoong Patent.

(e) Daewoong shall not settle any claim, suit or action that it brought under this Section 11.5 involving Ampio Patents without the prior written consent of Ampio, which consent shall not be unreasonably withheld or delayed; provided that Ampio shall have the sole discretion to withhold consent in the event it determines that such settlement would restrict in any material respect the scope of the Ampio Patents or its rights or interests therein.

(f) If either Party recovers monetary damages from any Third Party in a suit or action brought hereunder with respect to Ampio Patents or Daewoong Patents, including in a settlement, such recovery shall be allocated first to the reimbursement of any expenses incurred by the Parties in such litigation (including, for this purpose, a reasonable allocation of expenses of internal counsel), and any remaining amounts shall be split as follows: (i) the portion of such amounts that represents recovery for lost sales in the Territory shall be retained by Daewoong and treated as Net Sales, on which Daewoong shall make a transfer price payment, and (ii) any remaining amounts shall be retained by the Party bring such suit or action.

11.6 Infringement of Third Party Rights in the Territory.

(a) If any Product used or sold by either Party, its Affiliates, licensees or sublicensees becomes the subject of a Third Party's claim or assertion of infringement of a Patent granted by a jurisdiction within the Territory, the Party first having notice of the claim or assertion shall promptly notify the other Party, the Parties shall agree on and enter into an "identity of interest agreement" wherein such Parties agree to their shared, mutual interest in the outcome of such potential dispute, and thereafter, the Parties shall promptly meet to consider the claim or assertion and the appropriate course of action.

(b) Daewoong shall have the first right, but not the obligation, to defend any such Third Party threatened or asserted claim of infringement of a Patent as described in Section 11.6(a) above, at Daewoong's expense. If Daewoong does not commence actions to defend such claim within thirty (30) days after it receives notice thereof (or within thirty (30) days after it should have given notice thereof to Ampio as required by Section 11.6(a)), then to the extent allowed by applicable Laws, Ampio shall have the right, but not the obligation, to control the defense of such claim by counsel of its choice, at Ampio's expense. The non-defending Party shall reasonably cooperate with the Party conducting the defense of the claim or assertion, including, if required to conduct such defense, furnishing a power of attorney.

(c) Each Party shall have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the participating Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party shall provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party shall take into account reasonable requests of the participating Party regarding such enforcement or defense.

(d) Neither Party shall enter into any settlement of any claim described in this Section 11.6 that affects the other Party's rights or interests or the scope of any Ampio Patent and/or Daewoong Patent in any material respect without such other Party's written consent. Each Party shall have the right to decline to defend or to tender defense of any such claim to the other Party upon reasonable notice, including if the other Party fails to agree to a settlement that such Party proposes. If a Party desires to take a license under any applicable Third Party intellectual property rights for the purpose of Developing or Commercializing the Product in the Field, then such Party shall submit the terms of such license to the JSC for review and approval. Any such license agreement will require the applicable Third Party to grant licenses to both Daewoong and Ampio for performing their respective obligations and exercising their respective rights in the Territory under this Agreement, will contain a release of any liabilities accrued prior to the effective date of such license agreement, and will be subject to the mutual agreement of the Parties.

11.7 Patent Marking. Daewoong (or its Affiliate or Sublicensees) shall mark Product marketed and sold by Daewoong (or its Affiliate or Sublicensees) hereunder with appropriate patent numbers or indicia.

11.8 Patent Oppositions and Other Proceedings .

(a) Daewoong shall be prohibited from initiating or requesting any interference or opposition proceeding with respect to, or making, filing or maintaining any claim to challenge the validity, infringement or enforceability of, any Ampio Patent.

(b) If either Party desires to bring an opposition, action for declaratory judgment, nullity action, interference, declaration for non-infringement, reexamination or other attack upon the validity, title or enforceability of a Patent owned or controlled by a Third Party and having one or more claims that covers the Product, or the use, sale, offer for sale or importation of the Product (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, a Third Party's claim or assertion of infringement under Section 11.6, in which case the provisions of Section 11.6 shall govern), such Party shall so notify the other Party and the Parties shall promptly confer to determine whether to bring such action or the manner in which to settle such action. Daewoong shall have the exclusive right, but not the obligation, to bring at its own expense and in its sole control any such action in the Territory. If Daewoong does not bring such an action in the Territory, within ninety (90) days of notification thereof pursuant to this Section 11.8(b) (or earlier, if required by the nature of the proceeding), then Ampio shall have the right, but not the obligation, to bring, at Ampio's sole expense, such action. The Party not bringing an action under this Section 11.8(b) shall be entitled to separate representation in such proceeding by counsel of its own choice and at its own expense, and shall cooperate fully with the Party bringing such action. Any awards or amounts received in bringing any such action shall be retained by the Party initiating such action.

(c) If any Ampio Patent or Daewoong Patent or Patent Term Extension related thereto becomes the subject of any proceeding commenced by a Third Party within the Territory in connection with an opposition, reexamination request, action for declaratory judgment, nullity action, interference or other attack upon the validity, title or enforceability thereof (except insofar as such action is a counterclaim to or defense of, or accompanies a defense of, an action for infringement against a Third Party under Section 11.5, in which case the provisions of Section 11.5 shall govern), then the Party responsible for filing, preparing, prosecuting and maintaining such Patent or Patent Term Extension as set forth in Sections 11.3 or 11.4 hereof shall control such defense at its own cost and expense. The controlling Party shall permit the non-controlling Party to participate in the proceeding to the extent permissible under applicable Laws, and to be represented by its own counsel in such proceeding, at the non-controlling Party's expense. If either Party decides that it does not wish to defend against such action, then the other Party shall have the right to assume defense of such Third-Party action at its own expense. Any awards or amounts received in defending any such Third-Party action shall be allocated between the Parties as provided in Section 11.5(f).

11.9 Compendial Listing and Register of Exclusive License. Upon request of Daewoong, Ampio shall cooperate with Daewoong to (i) file appropriate information with the applicable Regulatory Authority listing any Ampio Patents in the patent listing source in the Territory that is equivalent or similar to the Orange Book in the U.S., if any, and (ii) register Daewoong's license granted hereunder to the applicable Regulatory Authority, a patent and trademark office or other relevant governmental agency or offices in the Territory, if any.

12 Confidentiality/Publications

12.1 Confidentiality. Subject to any other provisions of this Agreement, each Party (the "Receiving Party"), for itself and its Affiliates and their (direct and indirect) licensees and Sublicensees, agrees that it shall, during the term of this Agreement and for a period of five (5) years thereafter or ten (10) years from the Effective Date, whichever is longer, (i) hold in confidence using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value the Confidential Information received before or after the Effective Date from the other Party (the "Disclosing Party"), (ii) not disclose such Confidential Information to any Third Party, except for those disclosures expressly permitted in this Section 12 below, and (iii) not use such Confidential Information for any purpose other than the purposes expressly permitted by this Agreement, without first obtaining the prior written consent of the Disclosing Party, except as follows:

(a) such Confidential Information is a part of the public domain, or is known to the Receiving Party or any of its Affiliates without any obligation to keep it confidential, prior to its disclosure by the Disclosing Party to the Receiving Party hereunder; or

(b) such Confidential Information becomes a part of the public domain after its disclosure by the Disclosing Party to the Receiving Party hereunder without any breach by the Receiving Party of this Agreement; or

(c) such Confidential Information which the Receiving Party can demonstrate that it has been independently developed either prior to its disclosure by the Disclosing Party to the Receiving Party hereunder or without the use of Confidential Information of the Disclosing Party; or

(d) such Confidential Information is disclosed to the Receiving Party by a Third Party who has the right to make such disclosure; or

(e) such Confidential Information is required to be disclosed by Law.

12.2 Authorized Disclosure. The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is for a permitted purpose and is reasonably necessary in the following instances:

(a) filing or prosecuting Patents;

(b) as part of or in support of Regulatory Filings (provided that such Party has the right to use the Confidential Information for such purpose under Section 2.1;

(c) in prosecuting or defending litigation;

(d) in order to comply with applicable non-patent Laws (including the rules and regulations of the Securities and Exchange Commission (the "SEC") or any other national securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance; and

(e) disclosure, solely on a "need to know basis", to Affiliates, potential and existing collaborators (including Sublicensees), permitted acquirers or assignees under Section 21, subcontractors, investment bankers, investors and lenders, and their and each of the Parties' respective directors, employees, contractors and agents, each of whom prior to disclosure must be bound by written obligations of confidentiality and non-use no less restrictive than the obligations set forth in this Section 12 (other than potential and existing investors and lenders of Daewoong, with respect to which Daewoong shall use commercially reasonable efforts to be so bound); provided, however, that the Receiving Party shall remain responsible for any failure by any Third Party who receives Confidential Information pursuant to this Section 12.2(e) to treat such Confidential Information as required under this Section 12.

If and whenever any Confidential Information is disclosed in accordance with this Section 12.2, such disclosure shall not cause any such information to cease to be Confidential Information except to the extent that such disclosure results in a public disclosure of such information (otherwise than by breach of this Agreement). Where reasonably possible and other than with respect to Section 12.2(e), the Receiving Party shall notify the Disclosing Party of the Receiving Party's intent to make such disclosure pursuant to this Section 12.2 sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate in keeping with the terms of this Agreement to protect the confidentiality of the subject Confidential Information.

12.3 Terms of this Agreement. The Parties shall treat the terms of this Agreement as Confidential Information of both Parties.

12.4 Relationship to Confidentiality Agreement. This Agreement supersedes the Mutual CDA, provided that all “Information” disclosed or received by the Parties thereunder shall be deemed “Confidential Information” hereunder and shall be subject to the terms and conditions of this Agreement.

12.5 Publications. If either Party wishes to publish any information, data or results regarding Tramadol or Products in written, oral or other form in any scientific journals or scientific conferences, a manuscript of the proposed publication shall first be sent to the other Party at least thirty (30) days in advance of such publication for review. Unless the reviewing Party informs the other in writing during this thirty (30) day period that the proposed publication must be delayed in order to protect a patentable invention or changed to avoid disclosure of Confidential Information of the Reviewing Party, the other Party shall be free to publish such results without restriction. In the event that a delay of the proposed publication is required, the other Party shall withhold such submission for publication for one additional period, up to sixty (60) days, or such other period as the Parties may mutually agree.

13 Term and Termination

13.1 Term. This Agreement shall become effective on the Effective Date. Unless sooner terminated in accordance with any other provision of this Agreement, the term of this Agreement shall expire on the tenth anniversary of the date of the First Commercial Sale by Daewoong of the first Product in the Territory (the “Initial Term”). Thereafter, this Agreement shall be automatically renewed for successive periods of two (2) years. Either Party shall have the right to terminate this Agreement at the end of the Initial Term or at the end of any two (2) year renewal term by sending to the other Party a written notice of such termination at least ninety (90) days prior to the expiration of such Initial Term or renewal term as the case may be.

13.2 Termination by Either Party. Notwithstanding the stipulation in Section 13.1, either Party may terminate this Agreement upon the occurrence of any of the following itemized events:

(a) Such Party notifies the other Party of the fact of material default or breach of any material provision in this Agreement by the notified Party, and the notified Party fails to take corrective measures to mitigate or cure such default or breach within sixty (60) days from the date of notification; or

(b) The other Party files in any court or agency pursuant to any statute or regulation pertaining to bankruptcy, solvency, or payment of debts, of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, or if such other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if such other Party shall be a party to its dissolution or liquidation, or if such other Party shall make an assignment for the benefit of creditors.

14 Effects of Termination or Expiration

14.1 Survival. Expiration or termination of this Agreement for any reason shall be without prejudice to:

(a) the obligations of confidentiality provided for in Section 12 shall survive;

(b) the Parties' right to receive all payments accrued under this Agreement;

(c) Ampio's right of inspecting books and account of Daewoong and its Affiliates and Sublicensees pursuant to Article 9;

(d) the rights and ownership in any Patents, Know-How and Regulatory Documentation the respective Party has obtained prior to expiration or termination of this Agreement;

(e) Ampio's rights provided for in Section 2.2 shall survive and be co-exclusive, perpetual, irrevocable, royalty-free and fully paid-up; and

(f) any other rights or remedies which either Party may then or thereafter have hereunder or at law or in equity or otherwise.

In addition to the foregoing, the following provisions shall survive expiration or termination of this Agreement for any reason and shall continue in full force and effect: Sections 1, 2.4, 4, 6.4, 7, 10, 11, 12, 14 and 15-27. Unless otherwise provided in this Section 14 and elsewhere herein, the license grants contained in Sections 2.1 (except as otherwise provided in Section 2.3(b)), and all other licenses and other rights and obligations hereunder, shall terminate upon termination of this Agreement.

14.2 Adverse Termination Consequences for Daewoong . Upon termination of this Agreement for any reason, Daewoong, its Affiliates and Terminated Sublicensees shall cease use of the Ampio Patents, Ampio Know-How and the Ampio Regulatory Documentation. In addition, Daewoong shall destroy or return (with confirmation letter to Ampio upon request) to Ampio any and all Ampio Know-How and Ampio Regulatory Documentation in the possession of Daewoong, its Affiliates and Terminated Sublicensees, without delay, with the exception that each of Daewoong and its Affiliates and Terminated Sublicensees may keep one copy for its legal files. Furthermore, upon termination of this Agreement by Ampio under Section 13.2, Daewoong hereby grants to Ampio, effective only upon such termination, a fully paid-up (except as provided below) worldwide non-exclusive license, with the right to sublicense, under the Daewoong Patents, Daewoong Know How and Daewoong Regulatory Documentation, to develop, have developed, make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import and have imported Tramadol and/or Products.

14.3 Inventory Sell-Off. Upon termination of this Agreement for any reason, Daewoong shall notify Ampio of the amount of Tramadol and Products Daewoong and its Affiliates and Sublicensees then have on hand, and, if they so wish, Daewoong and its Affiliates and Sublicensees shall thereupon be permitted to sell that amount of Tramadol and Products.

14.4 Transfer of Regulatory Approvals. Upon termination of this Agreement by Ampio under Section 13.2, Daewoong shall, and shall cause its Affiliates and any Terminated Sublicensees to, upon Ampio's request, transfer to Ampio and/or its Affiliates and/or any Third Party appointed by Ampio (hereinafter referred to as "Transferee") with reasonable assistance, excluding financial assistance, to the extent permissible under the Laws of the Territory, the Regulatory Approvals which Daewoong or its Affiliates or Terminated Sublicensees have with respect to the Products in the Territory, in each case subject to all licenses granted by any of them (whether or not in effect) to any Surviving Sublicensees and further subject to the royalty obligations (if any) set forth in Section 14.2. Such assistance shall include, among others, an authorization by Daewoong or its Affiliates or Terminated Sublicensees given to the Transferee to access to the Regulatory Approvals filed by Daewoong or its Affiliates or Terminated Sublicensees with the Regulatory Authorities with respect to the Products in the Territory (*e.g.*, Regulatory Filings), the provision by Daewoong, if necessary, to the Transferee of the Daewoong Know-How and such other acts which the Transferee may reasonably request Daewoong in order to transfer such Regulatory Approvals with respect to the Products in the Territory, subject in all cases to such licenses held by the Surviving Sublicensees.

15 Announcement

No public announcement concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by any Party to this Agreement, except as may be required by Law or as may be required for recording purposes or as permitted by Section 12.2, without first obtaining the written approval of the other Party and agreement upon the nature and text of such announcement or disclosure. Other than with respect to Section 12.2(e), the Party desiring to make any such public announcement shall inform the other Party of the proposed announcement in reasonably sufficient time prior to public release, and shall provide the other Party with a written copy thereof, in order to allow such other Party to review, comment upon and approve such announcement, which such approval shall not be unreasonably withheld or delayed. It is the intention of the Parties to issue a press release upon signing this Agreement.

16 Governing Law

The formation, validity and performance of this Agreement shall be governed by and interpreted in accordance with the internal substantive laws of the State of Delaware, without giving effect to any choice of law rules in the State of Delaware or elsewhere.

17 Dispute Resolution

17.1 Organization Resolution. The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement ("Dispute"), a Party may notify the other Party in writing of such Dispute. If the Parties are unable to resolve the Dispute within sixty (60) days of receipt of the written notice by the other Party, such Dispute shall be referred to a senior executive of Daewoong and Ampio, who will use their good faith efforts to resolve the Dispute within thirty (30) days after it was referred to them. If the senior executives are unable to resolve the Dispute, the Parties shall refer the Dispute to arbitration as provided for in Section 17.2.

17.2 Jurisdiction by Agreement. Any Dispute that is not resolved as provided in Section 17.1, whether before or after termination of this Agreement, shall be submitted exclusively for resolution to arbitration administrated by the International Chamber of Commerce ("ICC") and be finally settled in accordance with the Rules of International Conciliation and Arbitration of ICC. The arbitration shall be subject to the governing law set forth in Section 16, shall be held in New York, New York, in front of a panel of three (3) arbitrators, shall be conducted in the English language, shall be final and binding determination of the Dispute and not subject to judicial review, and shall not include any award of damages expressly prohibited by Section 17.3, and judgment upon any award rendered by the arbitrators may be entered in any court having jurisdiction over the liable Party. Except for Disputes the resolution of which require the arbitration of material rights of any Third Party, this Section 17.2 shall be the exclusive remedy with respect to any Dispute for either Party or their Affiliates, provided that this Section 17 shall not restrict the Parties' rights to seek preliminary injunctive relief before a court of any jurisdiction.

17.3 Consequential Damages. Neither Party hereto will be liable for special, incidental, indirect, punitive, exemplary or consequential damages arising out of this Agreement or performance of its obligations hereunder or the exercise of its rights hereunder, including lost profits, anticipated profit, lost goodwill, lost revenue, lost contracts, and lost opportunity arising from or relating to any breach of this Agreement, regardless of the causes of action or theories of liability alleged any notice of such damages. Nothing in this Section 17.3 is intended to limit or restrict the indemnification rights or obligations of either Party under Section 20.

18 Notices

18.1 Any notice required to be given under this Agreement shall be given in the English language by sending such notices by postage-prepaid registered airmail or an internationally recognized overnight courier service addressed to the other Party at the address listed below:

For Ampio:

Ampio Pharmaceuticals, Inc.
5445 DTC Parkway, Suite 925
Greenwood Village, Colorado 80111
Attention: Bruce G. Miller and Don Wingerter

With a required copy to:

Goodwin Procter LLP
Exchange Place
53 State Street
Boston, Massachusetts 02109
Attn: Lawrence Wittenberg, Esq.

For Daewoong:

Daewoong Pharmaceuticals Co., Ltd
163-3 Samsungdong, Kangnam-gu
Seoul, Republic of Korea

Attention:

Either Party may notify the other Party of a different address to receive the other Party's notices in accordance with the manner described in this Section 18.

18.2 In the case where any notice is sent by airmail, such notice shall be sent return receipt requested and is deemed to be received by the other Party upon endorsement, by an employee or agent of the other Party of such receipt.

19 Force Majeure

19.1 Neither Party shall be liable for any failure to perform as required by this Agreement if such failure is due to circumstances reasonably beyond the control of such Party, including requisition or interference by any government, state or local authorities, war, riots, civil disturbances, terrorism, strikes or other labour disputes, accidents, failure to secure required governmental approval, civil disorders or acts of aggression, acts of God, energy or other conservation shortages, plague or other such occurrences ("Force Majeure").

19.2 If and when any Party is hindered in its performance of its obligations under this Agreement by reason of Force Majeure, the performance shall be suspended during, but not longer than, the continuance of such circumstances.

19.3 Either Party hereto whose performance of obligations has been hindered by reason of Force Majeure shall, to the extent possible, inform the other Party immediately, and shall use reasonable efforts to overcome the effect of the Force Majeure.

20 Indemnification and Insurance

20.1 Ampio shall defend, indemnify and hold harmless Daewoong and its Affiliates and Sublicensees, and their officers, directors, employees, agents, distributors and suppliers, and their respective successors, assigns, heirs and representatives (collectively, "Daewoong Indemnitees") from and against all liabilities, damages, losses, suits, proceedings, actions, claims, judgments and costs and expenses (including legal fees and expenses) resulting from any Third Party claim made or suit brought (collectively, "Losses") to the extent the same is arising from or related to:

(a) Ampio's material breach of any term of this Agreement (including any express representation or warranty made herein),

(b) the negligence, recklessness or willful misconduct or fraud on the part of Ampio or any of its Affiliates, or Ampio Licensees or any of their respective officers, directors, employees, agents, distributors and suppliers, or any of their respective successors, assigns, heirs or representatives with respect to Tramadol or Products supplied by Ampio or in the performance of Ampio's obligations or exercise of Ampio's rights under this Agreement,

(c) any actual or alleged violation of Law (other than any patent or other intellectual property Laws) in the performance of Ampio's obligations or exercise of Ampio's rights under this Agreement,

(d) any product liability claim related to Tramadol or Products manufactured, used or sold by any of Ampio or its Affiliates or Ampio Licensees or any of their respective successors, assigns, heirs or representatives. prior to the Effective Date or during the term of this Agreement or after termination or expiration of this Agreement, and any product liability claim related to Tramadol or Products arising from manufacturing Tramadol or Products supplied to Daewoong hereunder, including (i) non conformance of Tramadol or Products to Tramadol specifications and (ii) non manufacture of Tramadol or Products according to cGMP, or

(e) any claim of infringement or misappropriation of a Third Party's patent, copyright, trade secret or trademark right, or any other intellectual property right arising from the development, registration, manufacture, marketing, promotion, distribution, importation, offer for sale or sale or other commercialization of Tramadol or Products, or chemical agents for making or using the same, by any of Ampio or its Affiliates or Ampio Licensees or any of their respective successors, assigns, heirs or representatives.

However, Ampio shall not be required to indemnify any Daewoong Indemnitee to the extent that any such claims or suits arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of any Daewoong Indemnitees.

20.2 Daewoong shall defend, indemnify and hold harmless Ampio or any of its Affiliates, or Ampio Licensees or any of their respective officers, directors, employees, agents, distributors and suppliers, or any of their respective successors, assigns, heirs or representatives (collectively, “Ampio Indemnitees”) from and against all Losses to the extent the same is arising from:

(a) Daewoong’s material breach of any term of this Agreement (including any express representation or warranty made herein),

(b) the negligence, recklessness or willful misconduct or fraud on the part of any Daewoong Indemnitee with respect to the Product produced by Daewoong or in the performance of Daewoong’s obligations or exercise of Daewoong’s rights under this Agreement,

(c) any actual or alleged violation of Law (other than any patent or other intellectual property Laws) in the performance of Daewoong’s obligations or exercise of Daewoong’s rights under this Agreement,

(d) any product liability claim related to Tramadol or Product manufactured, used or sold by any Daewoong or its Affiliates or Sublicensees or any of their respective successors, assigns, heirs or representatives during the term of this Agreement or after termination or expiration of this Agreement, unless and to the extent such claim arose out of or resulted from (i) non conformance of Tramadol or Products supplied by Ampio to Tramadol specifications or (ii) non manufacture of Tramadol or Products supplied by Ampio or any of its Affiliates according to cGMP, or

(e) use of any data from any clinical studies conducted by or on behalf of Ampio or Ampio Licensees;

(f) any claim of infringement or misappropriation of a Third Party’s patent, copyright, trade secret or trademark right, or any other intellectual property right arising from the development, registration, manufacture, marketing, promotion, distribution, importation, offer for sale or sale or other commercialization of Tramadol or Product, or chemical agents for making or using the same, by any of Daewoong or its Affiliates or Sublicensees or any of their respective successors, assigns, heirs or representatives.

However, Daewoong shall not be required to indemnify any Ampio Indemnitee to the extent that any such claims or suits arose out of or resulted from the negligence, recklessness or willful misconduct or fraud of any Ampio Indemnitee.

20.3 Indemnification Procedures. A Party which intends to claim indemnification under Section 20.1 or 20.2 (the ”Indemnitee”) will promptly notify the other Party (the “Indemnitor”) in writing of any claim, suit, proceeding or action in respect of which the Indemnitee or any of the other Ampio Indemnitees or Daewoong Indemnitees, as applicable, intend to claim such indemnification within a reasonable period of time after the assertion of such claim; provided, however, that the failure to provide written notice of such claim within a reasonable period of time will not relieve the Indemnitor of any of its obligations hereunder, except to the extent that the Indemnitor is prejudiced by such failure to provide prompt notice. The Indemnitor will have the right to assume the complete control of the defence, compromise or settlement of any such claim (provided that no settlement of any claim will include any admission of wrongdoing on the part of an Indemnitee or the other Ampio Indemnitees or Daewoong Indemnitees, as applicable, or materially and adversely effect the rights of the Indemnitee or the other Ampio Indemnitees or Daewoong Indemnitees, as applicable, in each case without the prior written consent of such Indemnitee, which such consent will not be unreasonably withheld or delayed). The Indemnitor may, at its own expense, employ legal counsel to defend the claim at issue. The Indemnitee may, in its sole discretion and at its own expense, employ legal counsel to represent it and the other Ampio Indemnitees or Daewoong Indemnitees, as applicable (in addition to the legal counsel employed by the Indemnitor) in any such matter, and in such event legal counsel selected by the Indemnitee will be required to confer and cooperate with such counsel of the Indemnitor in such defence, compromise or settlement for the purpose of informing and sharing information with the Indemnitor. The Indemnitee will, at its own expense, make available to Indemnitor those Ampio Indemnitees or Daewoong Indemnitees, as applicable, whose assistance, testimony or presence is necessary, useful or appropriate to assist the Indemnitor in evaluating, defending or settling any such claim; provided, however, that any such access will be conducted in such a manner as not to interfere unreasonably with the operations of the businesses of Indemnitee or the other Ampio Indemnitees or Daewoong Indemnitees, as applicable; and will otherwise fully cooperate with the Indemnitor and its legal counsel in the investigation and defence of such claim.

20.4 Insurance. Both Parties will procure and maintain adequate insurance in order to be able to cover claims under this Agreement. Upon request, each Party shall provide proof of adequate coverage to the other Party.

21 Non-assignability

This Agreement is personal to the Parties hereto and shall not be assignable to any Third Party by either Party without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed; provided, however, that any Party may assign this Agreement in full to an Affiliate of such Party without prior written consent, but with prior written notice, and provided, further, that any Party may assign this Agreement to any entity with which such Party may merge or consolidate (or engage in some other form of corporate combination), or to which it may transfer all or substantially all of its assets to which this Agreement relates. All successors and permitted assignees of a Party shall be subject to, and will be bound by, all the terms and conditions of this Agreement. Any attempted assignment made contrary to the provisions hereof will be void. This Agreement shall inure to the benefit of and be binding on the Parties’ successors, permitted assigns and legal representatives.

22 Language

22.1 This text of this Agreement in the English language shall be the original text, and any text in another language, even if such a text is made by translation of the text in English language or prepared by any of the Parties hereto for the purpose of its own convenience, shall have no meaning for any purpose between the Parties hereto.

22.2 Any information to be provided under this Agreement, including any Know-How, shall be provided in the English language. The words “include”, “includes” and “including” shall be deemed to be followed by the phrase “without limitation”. The words ”herein”, “hereof” and “hereunder”, and words of similar import, shall be construed to refer to this Agreement in its entirety and not to any particular provision hereof.

23 Entire Agreement

This Agreement (together with the Exhibits attached hereto and the Development Plan) shall constitute the entire agreement between the Parties hereto concerning the subject matter hereof and shall supersede any other agreements, whether oral or written, express or implied, with respect to the subject matter hereof.

24 Separability

24.1 In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect.

24.2 If any of the terms or provisions of this Agreement are in conflict with any applicable Law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such Law. The Parties shall make a good faith effort to replace any invalid or unenforceable term or provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized.

25 Independent Contractors; No Partnership

The Parties hereto are independent contractors. In making and performing this Agreement, the Parties are acting, and intend to be treated, as independent entities performing a contract, and nothing contained in this Agreement is to be construed or implied or deemed to create an agency, partnership, joint venture or an employee/employer relationship between Daewoong and Ampio. This Agreement is not, and will not be deemed to be, a partnership agreement or joint venture agreement, expressly or by implication. Employees of each Party remain employees of said Party and will be considered at no time agents of or owing a fiduciary duty to the other Party. Neither Party will have any implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any other contract, agreement or undertaking with any Third Party.

26 Amendment and Waiver

The Parties hereto may amend, modify or alter any of the provisions of this Agreement, but such amendment, modification or alteration will be valid and binding on either Party only if memorized by a written instrument that explicitly refers to this Agreement and is duly executed by both Parties hereto. The failure of any Party to insist on the performance of any obligation hereunder shall not be deemed to be a waiver of such obligation. Waiver of any nonaction of any provision hereof shall not be deemed to be a waiver of any other rights or remedies of such provision or any other provision on such occasion or any succeeding occasion.

27 Counterparts

This Agreement may be executed by the Parties in one or more identical counterparts, all of which together will constitute this Agreement. If this Agreement is executed in counterparts, no signatory hereto will be bound until both Parties have duly executed a counterpart of this Agreement. Facsimile execution and delivery of this Agreement by the Parties shall be legal, valid and binding execution and delivery of this Agreement for all purposes.

[*remainder of this page intentionally left blank*]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate counterparts by their duly authorized representatives, each fully executed copy hereof to be deemed as original, as of the Effective Date.

Ampio Pharmaceuticals, Inc.

By: /s/ DB Wingerter
Name:
Title: CEO

Daewoong Pharmaceuticals Co., Ltd

By: /s/ Jong Wook Lee
Name: Jong Wook Lee
Title: President & CEO

EXHIBIT 1.5

AMPIO PATENTS

To be provided within 15 days after the Effective Date.

EXHIBIT 1.18

DAEWOONG PATENTS

To be provided within 15 days after the Effective Date.

EXHIBIT 3.1

AMPIO KNOW-HOW AND AMPIO REGULATORY DOCUMENTATION

Within sixty (60) days after the Effective Date of this Agreement, Ampio shall disclose or make available to Daewoong copies of all of the Ampio Know-How and Ampio Regulatory Documentation, including the following Ampio Know-How and Ampio Regulatory Documentation:

1. Trial Master File ("TMF") for "A Randomized, Double-blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Doses of Tramadol Hydrochloride Orally Disintegrating Tablets In Male Subjects with Premature Ejaculation" ("Study"), Sponsors Protocol codes: BVF-324.301 and BVF-324.302, as received by Ampio from Kendle International, including:

Protocol Summaries and Synopses
- Protocol Amendments
- ICF/SIS - Study Templates

Q-A Logs
QC Documentation
Case Report Forms and Amendments
eCRF Completion Guidelines
Recruitment Materials
Source Document Templates
Investigator Brochure
Certificates of Analysis
Correspondence
Clinical Study Reports
Audit Certificates
- Regulatory Authority Documents
- Translations, translation certificates & checklists
- Country Documentation
- Central Ethics Committee Documentation
- Final Statistical Analysis Plan
- Investigational Medicinal Product Dossier
- Bioequivalence Study

Alcohol Interference Study

2. SAS datasets with safety and efficacy data for "A Randomized, Double-blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy and Safety of Two Doses of Tramadol Hydrochloride Orally Disintegrating Tablets In Male Subjects with Premature Ejaculation" ("Study"), Sponsors Protocol Codes: BVF-324.301 and BVF-324.302, as received by Ampio from Kendle International.

Exhibit 10.11

VOTING AGREEMENT

THIS VOTING AGREEMENT (this "***Agreement***"), dated as of April 21, 2015, is made between Rosewind Corporation, a Colorado corporation (the "***Company***"), and Ampio Pharmaceuticals, Inc., a Delaware corporation (the " ***Shareholder***").

RECITALS

WHEREAS, the Shareholder is the beneficial owner (as defined in Rule l3d-3 under the Securities Exchange Act of 1934, as amended) of 141,535,750 outstanding shares of common stock, par value $0.001 per share (the "***Common Stock***"), of the Company, which shares entitle the beneficial owner to vote at a meeting of the shareholders of the Company or by written consent;

WHEREAS, each of the Shareholder and the Company will derive significant value from the consummation of the Proposed Transactions (as defined below); and

WHEREAS, in consideration of the foregoing, and for other good and valuable consideration, receipt of which is hereby acknowledged, the Shareholder agrees to vote all of the shares of the Common Stock beneficially owned by the Shareholder at one or more Company shareholder meetings or by written consent in favor of proposals approved by the Board of Directors of the Company (the "Board") and authorizing the Company to (1) re-incorporate into the State of Delaware through a plan of conversion; (2) effectuate a reverse stock split of the Company's common stock, at a ratio of one new share for every approximately 12.174 shares currently outstanding; (3) change the name of the Company from "Rosewind Corporation" to "Aytu Bioscience, Inc."; and (4) approve a new stock option and incentive plan (collectively, the "***Proposed Transactions***").

NOW, THEREFORE, in consideration of the foregoing and the mutual promises, representations, warranties, covenants and agreements contained herein, the parties hereto, intending to be legally bound, hereby agree as follows:

1. **Voting Provisions**

(a) Agreement to Vote Shares of the Company's Stock. The Shareholder hereby agrees during the Term (as defined in Section 3 below) of this Agreement to vote or cause to be voted all shares of Company's Common Stock owned of record and/or beneficially (as defined in Rule 13d-3 of the Exchange Act of 1934, as amended) by the Shareholder (the "***Shares***"), in each case, as of the applicable record date for any annual or special meeting of shareholders or in connection with any solicitation of shareholder action by written consent (each, a "***Shareholders Meeting***"), in favor of each of the Proposed Transactions and to be present for quorum purposes.

(b) No Other Voting Agreement. The Shareholder hereby agrees that the Shareholder shall not enter into any agreement or understanding with any other person the effect of which would be to violate the provisions and agreements contained in this Section 1, provided that the foregoing shall not restrict the Shareholder from selling or otherwise disposing of the Shareholder's Shares.

2. **Other Proxies Revoked**. The Shareholder represents and warrants that any proxies heretofore given in respect of the Shareholder's Shares are not irrevocable, and that all such proxies have been or are hereby revoked.

3. **Term of Agreement**. The term of this Agreement shall commence on the date of this Agreement and shall remain in full force and effect until the approval by the Company's stockholders of the Proposed Transactions (the "***Term***"). For avoidance of doubt, upon the termination of this Agreement, the parties will have no continuing obligations pursuant to this Agreement.

4. **Representations and Warranties of the Shareholder**. The Shareholder hereby represents and warrants to the Company as follows:

(a) Authority, etc. The Shareholder has all necessary power and authority to execute and deliver this Agreement and to consummate the transactions contemplated hereby. The execution and delivery of this Agreement and the consummation of the transactions contemplated hereby by the Shareholder have been duly authorized by all necessary action on the part of the Shareholder and constitutes a legal, valid and binding obligation of the Shareholder, enforceable against the Shareholder in accordance with its terms.

(b) Ownership of Shares. The Shareholder is, as of the date hereof, the beneficial owner of 141,535,750 shares of Common Stock. The Shareholder has sole voting power and sole power to issue instructions with respect to the matters set forth in Section 1 hereof, sole power of disposition, sole power of conversion, sole power to agree to all of the matters set forth in this Agreement, in each case with respect to all of the Shares, with no limitations, qualifications or restrictions on such rights, subject only to applicable securities laws and the terms of this Agreement.

(c) No Conflicts. No filing with, and no permit, authorization, consent or approval of, any governmental entity is necessary for the execution of this Agreement by the Shareholder and the consummation by the Shareholder of the transactions contemplated hereby. None of the execution and delivery of this Agreement by the Shareholder, the consummation by the Shareholder of the transactions contemplated hereby or compliance by the Shareholder with any of the provisions hereof shall (A) conflict with or result in any breach of any applicable documents to which the Shareholder is a party, or (B) violate any order, writ, injunction, decree, judgment, order, statute, rule or regulation applicable to the Shareholder.

(d) No Encumbrances. The Shares and the certificates representing such Shares are now held by the Shareholder, or by a nominee or custodian for the benefit of the Shareholder, free and clear of all liens, claims, security interests, proxies, voting trusts or agreements, understandings or arrangements or any other encumbrances whatsoever, except for any such encumbrances or proxies arising hereunder.

5. **Covenants of The Shareholder**. The Shareholder covenants and agrees that, during the Term, the Shareholder shall not (i) grant any proxies or powers of attorney, deposit any of the Shares into a voting trust or enter into a voting agreement with respect to any of the Shares or (ii) take any action that would make any representation or warranty of the Shareholder contained herein untrue or incorrect or have the effect of preventing, disabling or delaying the Shareholder from performing the Shareholder's obligations under this Agreement.

6. Covenants of the Company.

The Company covenants and agrees that it shall hold a Shareholders Meeting as soon as is reasonably practicable for the purpose of voting upon the Proposed Transactions, unless the Board determines after the date of this Agreement that it is no longer advisable for the Company to do so.

7. (a) **Miscellaneous**

(a) Further Assurances. From time to time, at any other party's written request and without further consideration, each party hereto shall execute and deliver such additional documents and take all such further lawful action as may be necessary or desirable to consummate and make effective, in the most expeditious manner practicable, the transactions contemplated by this Agreement.

(b) Entire Agreement. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all other prior agreements and understandings, both written and oral, between the parties with respect to the subject matter hereof.

(c) Assignment. This Agreement shall not be assigned by operation of law or otherwise without the prior written consent of the other party, provided that the Buyers may assign and transfer, at its sole discretion, its rights and obligations hereunder to any of their affiliates.

(d) Amendments, Waivers, Etc. This Agreement may not be amended, changed, supplemented, waived or otherwise modified or terminated, except upon the execution and delivery of a written agreement executed by all of the relevant parties hereto.

(e) Notices. All notices, requests, claims, demands and other communications hereunder shall be in writing and shall be given (and shall be deemed to have been duly received if so given) by hand delivery, fax, or by mail (registered or certified mail, postage prepaid, return receipt requested) or by any courier service, such as FedEx, providing proof of delivery. All communications hereunder shall be delivered to the respective parties at the following addresses:

If to the Shareholder:

Ampio Pharmaceuticals, Inc.
373 Inverness Parkway, Suite 200
Englewood, Colorado 80112
Attention: Gregory A. Gould
Facsimile: (720) 437-6501

If to the Company:

Rosewind Corporation
373 Inverness Parkway, Suite 200
Englewood, Colorado 80112
Attention: Joshua R. Disbrow
Facsimile: (720) 437-6501

With a copy to:

Goodwin Procter LLP
620 Eighth Avenue
New York, New York 10018
Attention: Andrew H. Goodman, Esq.
Facsimile: (212) 355-3333

or to such other address as the person to whom notice is given may have previously furnished to the others in writing in the manner set forth above.

(f) Severability. Whenever possible, each provision or portion of any provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law but if any provision or portion of any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or portion of any provision in such jurisdiction, and this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provision or portion of any provision had never been contained herein.

(g) Specific Performance. Each of the parties hereto recognizes and acknowledges that a breach by it of any covenants or agreements contained in this Agreement will cause the other party to sustain damages for which it would not have an adequate remedy at law for money damages, and therefore each of the parties hereto agrees that in the event of any such breach the aggrieved party shall be entitled to the remedy of specific performance of such covenants and agreements and injunctive and other equitable relief in addition to any other remedy to which it may be entitled, at law or in equity.

(h) Remedies Cumulative. All rights, powers and remedies provided under this Agreement or otherwise available in respect hereof at law or in equity shall be cumulative and not alternative, and the exercise of any thereof by any party shall not preclude the simultaneous or later exercise of any other such right, power or remedy by such party.

(i) No Waiver. The failure of any party hereto to exercise any right, power or remedy provided under this Agreement or otherwise available in respect hereof at law or in equity, or to insist upon compliance by any other party hereto with its obligations hereunder, and any custom or practice of the parties at variance with the terms hereof shall not constitute a waiver by such party of its right to exercise any such or other right, power or remedy or to demand such compliance.

(j) No Third Party Beneficiaries. This Agreement is not intended to be for the benefit of, and shall not be enforceable by, any person who or which is not a party hereto.

(k) Governing Law. This Agreement, and the legal relations between the parties hereto, shall be governed and construed in accordance with the laws of the State of Delaware.

(l) Waiver of Jury Trial. EACH OF THE PARTIES HEREBY KNOWINGLY, VOLUNTARILY, AND INTENTIONALLY WAIVES ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED HEREON, OR ARISING OUT OF, UNDER, OR IN CONNECTION WITH, THIS AGREEMENT OR ANY OTHER DOCUMENTS ENTERED INTO IN CONNECTION HEREWITH, OR ANY COURSE OF CONDUCT, COURSE OF DEALING, STATEMENTS (WHETHER VERBAL OR WRITTEN), OF ANY PARTY.

(m) Descriptive Headings. The descriptive headings used herein are inserted for convenience of reference only and are not intended to be part of or to affect the meaning or interpretation of this Agreement.

(n) Counterparts. This Agreement may be executed in two or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement. Delivery of an executed counterpart of a signature page to this Agreement by facsimile shall be effective as delivery of a manually executed counterpart of this Agreement.

* * * * *

IN WITNESS WHEREOF, each of the Company and the Shareholder has caused this Voting Agreement to be duly executed as of the day and year first above written.

ROSEWIND CORPORATION

By: _____
Name: Joshua R. Disbrow
Title: President and Chief Executive Officer

AMPIO PHARMACEUTICALS, INC.

By: _____
Name: Gregory A. Gould
Title: Chief Financial Officer

AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT

THIS **EXCLUSIVE LICENSE AGREEMENT** (the "Agreement") is entered into as of June 11, 2018 (the " Effective Date") by and between Aytu BioScience, Inc., a Delaware corporation ("Licensee"), and Magna Pharmaceuticals, Inc. a Kentucky corporation (" Licensor"). Licensor and Licensee may be referred to herein individually as a "Party" or collectively, as the "Parties."

RECITALS

WHEREAS, Licensor owns or controls certain intellectual property, regulatory approvals documentation, data, and other materials with respect to the Product (as defined below); and

WHEREAS, Licensee wishes to license such rights in order to further develop and Commercialize the Products (as defined below).

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

1. DEFINITIONS. The following capitalized terms shall have the subsequent meanings when used in this Agreement.

1.1 "2018 Maintenance Fee" has the meaning assigned to it in the Reimbursement Agreement.

1.2 "Abandoned Patent" has the meaning assigned to it in Section 5.2.

1.3 "Abandoned Trademark" has the meaning assigned to it in Section 5.2.

1.4 "AE" and "SAE" have the meanings assigned to them in Section 4.6.c.

1.5 "Affiliate" means, with respect to either Party, any person, corporation or other business entity which, directly or indirectly through one or more intermediaries, actually controls, is actually controlled by, or is under common control with such Party. As used in this Section 1.1, "control" means to possess, directly or indirectly, the power to affirmatively direct the management and policies of such person, corporation or other business entity, whether through ownership of at least fifty percent (50%) of the voting securities or by contract relating to voting rights or corporate governance.

1.6 "Agreement" has the meaning assigned to it in the Preamble of this document.

1.7 "Applicable Law" means all applicable laws, rules, regulations and guidelines that may apply to the development, marketing, manufacturing or sale of Products or the performance of either Party's obligations, or the exercise of either Party's rights, under this Agreement, including but not limited to all laws, regulations and guidelines governing the import, export, development, marketing, distribution and sale of the Product in the Territory and, to the extent relevant, all GCP, GLP or GMP standards or guidelines promulgated by any Regulatory Authorities or the ICH.

1.8 Intentionally omitted.

1.9 "Business Day" means any day other than Saturday, Sunday, or a day that is a federal legal holiday in the U.S.

1.10 "Buyout Payment" has the meaning assigned to it in Section 3.5.

1.11 "Calendar Day" means each of those seven (7) days in the week.

1.12 "Calendar Quarter" means each of those three (3) calendar month periods of each Calendar Year ending March 31, June 30, September 30 and December 31.

1.13 "Calendar Year" means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the same year, (b) for the Calendar Year in which this Agreement expires or is terminated, the period beginning on January 1 of such Calendar Year and ending on the effective date of such expiration or termination, and (c) for all other years, each successive twelve (12) consecutive month period beginning on January 1 and ending December 31.

1.14 "Claims" has the meaning assigned to it in Section 11.1.

1.15 "Code" has the meaning assigned to it in Section 2.4.

1.16 "Commercialize" or "Commercialization" means all activities that are undertaken after Regulatory Approval of a Product in a particular jurisdiction and that relate to the commercial marketing, sale, and/or distribution of such Product, including but not limited to advertising and/or promotional activities.

1.17 "Commercially Reasonable Efforts" means the carrying out of obligations or tasks in a manner consistent with the efforts that are consistent with the general standards used by comparable companies in the pharmaceutical industry for commercializing similar pharmaceutical products of similar market potential, profit potential or strategic value resulting from its own research efforts or for its own benefit, taking into account technical, regulatory, commercial and intellectual property factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing.

1.18 "Competing Product" means any product or combination(s) of products containing the active pharmaceutical ingredient zolpidem tartrate.

1.19 "Confidential Information" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing under this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business; provided, that, information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how: (a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party, as can be shown by written records; (b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party; (c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information belonging to the disclosing Party.

1.20 "Controlled" means, with respect to any Patent, Know-How, Regulatory Filing or Regulatory Approval, the possession by a Party of the ability to grant a license or sublicense, or make an assignment or transfer thereof, as provided for herein without violating the terms of any arrangement or agreements between such Party and any Third Party.

1.21 "Controlling Party" has the meaning assigned to it in Section 6.5.

1.22 "Cover" "Covered" or "Covering" means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

1.23 "Delivered Inventory" has the meaning assigned to it in Section 4.2.

1.24 "Develop" "Development" or "Developing" means, with respect to a Product, engaging in preclinical, clinical, and other research or development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining the initial Regulatory Approval of a Product in a particular jurisdiction.

1.25 "DMF" means a drug master file, as provided for in the United States Code of Federal Regulations (" CFR") at 21 CFR § 314.420 or similar submission to or file maintained with the FDA or other Governmental Authority or Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

1.26 "Effective Date" has the meaning assigned to it in the Preamble of this document.

1.27 "Executive Officers" has the meaning assigned to it in Section 12.

1.28 "FDA" means the United States Food and Drug Administration, or any successor federal agency thereto.

1.29 "Field" means any use, application, or purpose, including, without limitation, the treatment, palliation, diagnosis, or prevention of any human or animal disease, disorder or condition related to the treatment of insomnia.

1.30 "GCP" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application) of the CFR, as may be amended from time to time, (b) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (c) as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.31 "GLP" means all applicable Good Laboratory Practice standards, including, as applicable, (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in Title 21, Part 58 of the CFR, (b) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex—OECD principles of GLP), and (c) the Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.32 "GMP" means all applicable Good Manufacturing Practices including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, Title 21, Parts 210, 211, 601 and 610 of the CFR, (b) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (c) the principles detailed in the ICH Q7A guidelines, (d) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.33 "Governmental Authority" means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision (including any supra-national agency such as in the European Union).

1.34 "Hatch-Waxman Act" has the meaning assigned to it in Section 6.2.

1.35 "H-W Suit Notice" has the meaning assigned to it in Section 6.2.

1.36 "ICH" means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.37 "IND" means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any Regulatory Authority outside of the United States (including any supra-national agency such as in the European Union) necessary to commence human clinical trials in such jurisdiction, and including all regulations at 21 CFR § 312 *et. seq.*, and equivalent foreign regulations.

1.38 "Infringement" has the meaning assigned to it in Section 6.3.

1.39 "Initiation Notice" has the meaning assigned to it in Section 12.

1.40 "July Payment" has the meaning assigned to it in Section 3.1.b.

1.41 "Know-How" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, inventions, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, records, results and other material, and other drug discovery and development technology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all improvements, whether to the foregoing or otherwise, and other discoveries, developments inventions and other intellectual property (whether or not confidential, proprietary, patented or patentable), provided that Know-How shall not include Patents.

1.42 "Licensee" has the meaning assigned to it in the Preamble of this document.

1.43 "Licensee Indemnitee" has the meaning assigned to it in Section 11.1.

1.44 "Licensee Know-How" means all Know-How coming under the Control of Licensee during the term of this Agreement with respect to its Commercialization of Products in the Territory that is necessary to Develop or Commercialize Products.

1.45 "Licensor" shall have the meaning as set forth in the Preamble of this document.

1.46 "Licensor Approvals" means the Regulatory Approval(s) identified on Schedule 2.2 and all associated Regulatory Approvals and Regulatory Filings in the U.S.

1.47 "Licensor Indemnitees" has the meaning assigned to it in Section 11.2.

1.48 "Licensor Know-How" means all Know-How owned or Controlled by Licensor or its Affiliates as of the Effective Date or during the term of the Agreement relating to the discovery, research, Development, testing, manufacture, or Commercialization of Product.

1.49 "Licensor Patents" means (a) those Patents and Patent applications previously provided to Licensee by Licensor (the " Initial Licensor Patents"); (b) any other Patents owned, controlled, or licensed by Licensor or any Affiliate thereof Covering any of the subject matter described in or Covered by the Initial Licensor Patents; (c) any divisionals, continuations, continuations-in-part, conversion, extensions, term restorations, registrations, re-instatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of the Initial Licensor Patents, and any other Patents owned, controlled, or licensed by Licensor claiming priority to any of the foregoing or any of the Patents referenced in clause (a) or (b) above; and (d) all patents issuing from any of the Patents mentioned in clause (a), (b), or (c) above and any foreign counterparts of any such Patents.

1.50 "Licensor Technology" means the Licensor Know-How and the Licensor Patents.

1.51 "Licensor Trademarks" means the trademarks set forth on Schedule 1.32 attached hereto.

1.52 "Losses" has the meaning assigned to it in Section 11.1.

1.53 "Louisville Product Supply" has the meaning assigned to it in Section 4.2.

1.54 "NDA" means a new drug application (as defined in Title 21 of the CFR, as amended from time to time) submitted to the FDA seeking regulatory approval to market and sell the Product for human therapeutic use in the United States (including a new drug application submitted under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act).

1.55 "Net Sales" means gross amounts invoiced or otherwise received for Licensee's, its Affiliates', and Sublicensees' sales of Products , less the sum of the following, to the extent related to the sale of such Products: (1) discounts in amounts reasonable or customary in the trade, including but not limited to trade, cash, consumer, and quantity discounts, and credits, price adjustments or allowances for damaged Products, returns, defects, recalls or rejections of Products or retroactive price reductions; (2) reasonable rebates, coupons, vouchers, credits, and chargeback payments granted to patients, federal, state/provincial, local and other governments or managed health care organizations, including their agencies, purchasers, and/or reimbursers, under programs available under or required by Applicable Law, or reasonably entered into to sustain and/or increase market share for Products; (3) sales, value added, use, excise, and similar taxes; (4) amounts allowed or credited on returns for defective, damaged, expired, or otherwise unuseable or unsaleable Products; (5) freight, shipping, handling, and insurance charges; (6) import or export duties, tariffs, or similar charges incurred with respect to the import or export of Products into or out of any country; (7) distribution commissions/fees (including fees related to services provided pursuant to distribution service agreements with wholesalers) payable to any Third Party providing distribution services with respect to Products; and (8) amounts repaid or credited or provisions made for uncollectible amounts. Such amounts shall be determined from the books and records of Licensee, its Affiliates, and Sublicensees maintained in accordance with such reasonable accounting principles as may be consistently applied by Licensee, its Affiliates, and Sublicensees.

Products are considered "sold" when billed out or invoiced or, in the event such Products are not billed out or invoiced, when the consideration for sale of the Products is received. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (i) Products used by Licensee, its Affiliates, or Sublicensees for their internal use, (ii) the distribution of reasonable quantities of promotional samples of Products, (iii) Products provided for clinical trials or research, development, or evaluation purposes, or (iv) Products provided by or on behalf of Licensee, an Affiliate or a Sublicensee to Licensee, an Affiliate or a Sublicensee for purposes of resale, provided such resale is subject to or triggers payments due Licensor under Section 3.2 of this Agreement.

1.56 "Party" or "Parties" shall have the meaning as set forth in the Preamble of this document.

1.57 "Patent(s)" means any granted patents and pending patent applications, together with all additions, divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, revalidations, supplementary protection certificates, and renewals of any of the foregoing, and all foreign applications and patents corresponding to or claiming priority from any of the foregoing.

1.58 "Patent Term Extensions" has the meaning assigned to it in Section 5.3.

1.59 "Pricing Approval" means any pricing and reimbursement approvals that must be obtained before placing a Product on the market for sale in a particular jurisdiction.

1.60 "Prior Fees" has the meaning assigned to it in Section 4.3.c.

1.61 "Proceedings" has the meaning assigned to it in Section 9.2.d.

1.62 "Product" means any and all products containing or constituting zolpidem tartrate oral spray (i) that incorporate or are otherwise made, discovered, developed, conceived and/or reduced to practice as a direct result of use of the Licensor Know-How; or (ii) the manufacture, use, sale, offer for sale or importation of which would, absent the license granted to the Licensee hereunder, infringe one or more Valid Claims included in the Licensor Patents.

1.63 "Product Problems" has the meaning assigned to it in Section 4.6.c.

1.64 "Product Supply" has the meaning assigned to it in Section 4.2.

1.65 "Qualified Sublicense" has the meaning assigned to it in Section 9.4.c.

1.66 "Rechon" means Rechon Life Science AB.

1.67 "Rechon Agreement" means that certain Manufacturing Agreement made and entered into on October 14, 2015 between Rechon and Licensor related to the manufacture of the Product.

1.68 Intentionally omitted.

1.69 "Rechon Product Supply" has the meaning assigned to it in Section 4.2.

1.70 "Rechon Purchase Orders" has the meaning assigned to it in Section 3.8.

1.71 "Regulatory Approval" means any and all approvals (including supplements, amendments, and pre- and post-approvals), licenses, registrations, clearances, or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or, in Licensee's reasonable judgment, sale of a Product for human therapeutic use in a particular jurisdiction, including Pricing Approvals. After the Transfer Date, the term "Regulatory Approvals" shall include the Licensor Approvals.

1.72 "Regulatory Authority" means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical or biological products in a particular jurisdiction, including the FDA with respect to the United States, and where applicable any ethics committee or any equivalent review board.

1.73 "Regulatory Documents" has the meaning assigned to it in Section 4.1.

1.74 "Regulatory Filing" means, with respect to the United States, an NDA, IND, any foreign counterparts or equivalents of any of the foregoing, any DMFs, and any other filings or submissions required by or provided to Regulatory Authorities relating to the manufacture, Development or Commercialization of any Product, including any supporting documentation, data, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing.

1.75 "Reimbursement Agreement" has the meaning assigned to it in Section 3.8.

1.76 "Return Date" has the meaning assigned to it in Section 9.4.a.

1.77 "Reporting Requirements" has the meaning assigned to it in Section 4.6.a.

1.78 "Royalty Term" has the meaning assigned to it in Section 3.6.

1.79 "Secondary Party" has the meaning assigned to it in Section 6.5.

1.80 "Sublicense" shall mean a sublicense under the rights granted to Licensee hereunder to Develop, make, have made, use, sell, have sold, offer for sale, promote, market or import any Product.

1.81 "Sublicensee" means a Third Party that has been granted a sublicense to any of the rights granted to Licensee and its Affiliates under this Agreement.

1.82 "Suda Agreement" means that certain Zolpimist License Agreement having an effective date of November 3, 2017 between Suda Ltd. and Licensor.

1.83 "Suda Assignment" has the meaning assigned to it in Section 13.

1.84 "Suda Payment" has the meaning assigned to it in Section 13.

1.85 "Term" has the meaning assigned to it in Section 9.1.

1.86 "Termination Date" has the meaning assigned to it in Section 9.4.b.

1.87 "Territory" means the United States and Canada.

1.88 "Third Party" means any entity other than (a) Licensor, (b) Licensee, or (c) any Affiliate of either Party.

1.89 "Transfer Date" has the meaning assigned to it in Section 4.3.

1.90 "Transition Quantities" has the meaning assigned to it in Section 4.4.a.

1.91 "United States" or "U.S." means the United States of America and its territories and protectorates.

1.92 "Valid Claim" means a claim of an issued and unexpired patent or a supplementary protection certificate, which claim has not been held invalid or unenforceable by a court or other government agency of competent jurisdiction from which no appeal can be or has been taken and has not been held or admitted to be invalid or unenforceable through re-examination or disclaimer, opposition procedure, nullity suit or otherwise, provided that if a particular claim has not issued within five (5) years of its initial filing, it shall not be considered a Valid Claim for purposes of this Agreement unless and until such claim is included in an issued Patent, notwithstanding the foregoing definition.

2. LICENSES; REGULATORY APPROVALS.

2.1 License Grant.

a. Licensor hereby grants to Licensee (i) an exclusive license, with the right to sublicense as set forth in Section 2.3, to the Licensor Technology and until such time as all Licensor Approvals are assigned to Licensee, to the Licensor Approvals to Develop, Commercialize, make, have made, use, sell, have sold, offer for sale, promote, market or import Products in the Field and in the Territory, and (ii) a nonexclusive license, with the right to sublicense as set forth in Section 2.3, to the Licensor Technology and, until such time as all Licensor Approvals are assigned to Licensee, to the Licensor Approvals, including a right of reference with respect to the Licensor Approvals, solely for the purpose of manufacturing the Products outside the Territory for the sole purposes of making, having made, using, selling, or offering for sale the Products in the Territory.

b. To the extent Licensor or any Affiliate has the right to grant such rights to Licensee, Licensor hereby grants to Licensee an exclusive right of reference (with the right to sublicense as set forth in Section 2.3) to any Regulatory Approvals or Regulatory Filings outside the Territory for the purposes of obtaining and maintaining Regulatory Approvals in the Territory or exercising the rights granted under Section 2.1.a.(ii), and Licensor shall use Commercially Reasonable Efforts, at no cost to Licensor, to obtain such rights with respect to any Regulatory Approvals or Regulatory Filings following the Effective Date.

2.2 Licensor Trademarks. Licensor hereby assigns to Licensee all right, title and interest in and to the Licensor Trademarks, together with all goodwill of Licensor associated with, and symbolized by, the Licensor Trademarks, including all applications, registrations, issuances, extensions and renewals of the Licensor Trademarks. The foregoing assignment of the Licensor Trademarks does not include Licensor's rights to the trademark ZOLPIMIST outside of the Territory. At any time and from time to time after the date hereof, Licensor shall, at the request of Licensee, promptly execute and deliver such other instruments of sale, transfer, conveyance, assignment, assumption and confirmation, and take such other action as Licensee may reasonably request to carry out the purpose and intent of the foregoing assignment and to transfer, convey, assign and deliver to Licensee the title in and to the Licensor Trademarks.

2.3 Sublicensing. Licensee shall, through multiple tiers, have the right to sublicense the rights granted to it under Section 2.1 to its Affiliates and Third Parties. No Sublicense shall convey any ownership interest in the rights conveyed to Licensee, nor diminish, reduce or eliminate any of Licensee's obligations or Licensor's rights under this Agreement, and such Sublicense shall not impose any additional obligations on Licensor in excess of those set forth in this Agreement. Each such Sublicense shall be in writing and contain terms and conditions that are (i) not inconsistent with the terms of this Agreement applicable to the Sublicense and (ii) reasonably sufficient to enable Licensee to comply with the terms of this Agreement.

2.4 Bankruptcy. If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code or similar provision in the bankruptcy laws of another jurisdiction (the "Code"), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the United States Bankruptcy Code (or similar provision in the bankruptcy laws of the jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code. The foregoing provisions of this Section 2.3 are without prejudice to any rights a Party may have arising under the Code.

3. FINANCIAL TERMS.

3.1 Initial Compensation.

a. Upon the execution of this Agreement, the Licensee shall pay Licensor a licensee fee in the amount of Four Hundred Thousand Dollars ($400,000).

b. If, on or before June 30, 2018, Licensor has (i) requested the removal of all Product from wholesaler distribution channels in the U.S. (as requested and reasonably determined by Licensee) and (ii) used its Commercially Reasonable Efforts to assist wholesalers and allow Licensee to assist to have such Product removed, then an additional license fee shall become due to Licensor in the amount of Three Hundred Thousand Dollars ($300,000) ("July Payment"), provided, however, that such fee shall not become payable until after July 1, 2018, but shall be paid in full prior to July 31, 2018. The failure of wholesalers to physically remove all Product from their distribution channels shall not relieve Licensee of its obligation to timely pay the July Payment to Licensor so long as Licensor has exercised Commercially Reasonable Efforts to assist wholesalers to remove such Product from the wholesaler distribution channels.

3.2 Royalty Payments. During the periods set forth below in this Section 3.2, Licensee shall pay to Licensor the following royalty payments:

a. twenty percent (20%) of Net Sales during the period commencing on the Effective Date and continuing through May 31, 2020;

b. fifteen percent (15%) of Net Sales during the period commencing on June 1, 2020 and continuing through May 31, 2022; and

c. ten percent (10%) of Net Sales during the period commencing on June 1, 2022 and continuing through May 31, 2025.

3.3 Intentionally Omitted.

3.4 Compulsory Licenses. Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the Applicable Laws of any country in the Territory under the Licensor Patents, the Party receiving notice thereof or otherwise becoming aware thereof shall promptly notify the other Party thereof, including any material information concerning such compulsory license, and the total amount payable under this Section 3 with respect to sales of Products in such country will be adjusted to match any lower amount such Third Party may be allowed to pay with respect to the sales of such Products in such country, with such lower amount subject to further adjustments pursuant to Section 3.3 above.

3.5 Royalty Buyout. Licensee may at any time terminate its obligation to pay royalties pursuant to Section 3.2 by paying Licensor a payment in an amount equal to the different between Four Million Six Hundred Thousand Dollars ($4,600,000) and the amount of royalties paid by Licensee to Licensor under this Agreement at the time such payment is made (the "Buyout Payment").

3.6 Royalty Term. Subject to any earlier termination of this Agreement, amounts due under Section 3.2 shall only be payable until the first to occur of the following (i) the date Licensee pays to Licensor the Buyout Payment, (ii) the date seven (7) years from the Effective Date or (iii) the date the aggregate royalty payments paid by Licensee hereunder equal Four Million Six Hundred Thousand Dollars ($4,600,000) (the period from the Effective Date until such date, the "Royalty Term"). Upon expiration of the Royalty Term, (i) all licenses granted hereunder shall become perpetual, unrestricted, irrevocable, fully-paid and royalty-free, and (ii) Licensor shall assign to Licensee all of its right, title and interest in and to the Licensor Patents. Licensor shall take all actions reasonably requested by Licensee to effectuate and evidence such assignment, including the execution of assignment agreements, in a form reasonably acceptable to Licensor, to be filed with the applicable Governmental Authorities.

3.7 Payments and Payment Reports. Except as otherwise provided in this Section 3, all royalties due under Section 3.2 shall be paid within forty-five (45) Calendar Days of the end of the Calendar Quarter during which the applicable Net Sales occur. Each royalty payment shall be accompanied by a statement stating (as applicable) the aggregate Net Sales and the respective royalty due for such Calendar Quarter.

3.8 Product Supply and Delivered Inventory Payment . In consideration for the Delivered Inventory and Product Supply (each as defined below) delivered to Licensee pursuant to Section 4.2 Licensee shall pay Licensor (i) Fifty Thousand Dollars ($50,000) upon execution of this Agreement and (ii) Fifty Thousand Dollars ($50,000) on or before July 31, 2018. On or before the Effective Date, Licensor shall have submitted to Rechon Purchase Order number 409-634 for the purchase of 5,000 units of Product and Purchase Order number 409-633 for the purchase of 30,000 units of Product ("Rechon Purchase Orders") subject to a Payment and Reimbursement Agreement by and between Licensor and Licensee, as agreed to and acknowledged by Rechon, dated as of May 29, 2018 ("Reimbursement Agreement"), and shall have paid the 2017 Maintenance Fee (as defined in the Reimbursement Agreement) by wire transfer. In addition to the payments for Delivered Inventory and Product Supply, Licensee shall reimburse Licensor Fifty Thousand Dollars ($50,000) pursuant to the Reimbursement Agreement, and shall further reimburse Licensor Twleve Thousand Thirty Two Dollars ($12,032.00) wired by Licensor to Rechon on May 9, 2018 for Schott vials. In accordance with the Reimbursement Agreement, within ten (10) Calendar Days of the Effective Date, (i) Licensor shall pay Rechon an amount equal to Twenty Thousand Eighty Hundred Thirty Three Dollars and 33/100 ($20,833.33), for its portion of the 2018 Maitenance Fee; and (ii) Licensee shall pay Rechon an amount equal to Twenty Nine Thousand One Hundred Sixty Six Dollars and 67/100 ($29,166.67) for its portion of the 2018 Maintenance Fee. The Parties agree that the 2018 Maintenance Fee payment shall be made by wire transfer to a bank account designated by Rechon. Licensee agrees that it shall assume all obligations and liabilities of Licensor under the Rechon Agreement and the Rechon Purchase Orders. Notwithstanding anything to the contrary herein, the failure to obtain Rechon's consent to assignment of the Rechon Agreement or Rechon Purchase Orders shall not impair or otherwise diminish Licensor's rights herein and Rechon's consent to assignment shall not be a condition precedent to any payment due to Licensor. Licensee agrees that it shall accept the Product manufactured by Rechon pursuant to the Rechon Purchase Orders even if it is packaged under Licensor's labeling or labeler codes. All payments to Licensor under this Section 3.8 shall not be considered royalty payments.

3.9 Payment Method. All payments due under this Agreement to Licensor shall be made by bank wire transfer in immediately available funds to an account designated by Licensor in writing. All payments hereunder shall be made in the legal currency of the United States.

3.10 Taxes. In the event any tax or similar amount is paid or required to be withheld by Licensee or any Affiliate thereof for the benefit of Licensor on account of any royalties or other payments payable to Licensor under this Agreement, the corresponding amounts payable to Licensor shall be reduced by the amount of taxes or similar amounts deducted and withheld, and Licensee shall pay the amounts of such taxes or similar amounts to the proper Governmental Authority in a timely manner and promptly transmit to Licensor an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Licensor to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable law to be paid or withheld shall be an expense of, and borne solely by, Licensor. Licensee will provide Licensor with, at Licensor's expense, reasonable assistance to enable Licensor to recover such taxes or amounts otherwise withheld as permitted by law.

3.11 Foreign Exchange. With respect to Net Sales invoiced in a currency other than United States dollars, such Net Sales will be converted into the United States dollar equivalent using the average conversion rate existing in the United States (as reported in *The Wall Street Journal*, New York edition) during the applicable Calendar Quarter. If *The Wall Street Journal* ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

3.12 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, payments under this Agreement arising from activities in that country for which Licensee or an Affiliate thereof does not receive payment in United States' currency, freely useable outside of such country, shall, notwithstanding anything to the contrary, be paid to Licensor in the country in local currency by deposit in a local bank designated by Licensee, unless the Parties otherwise mutually agree in writing.

3.13 Interest. If Licensee fails to make any payment when due to Licensor under this Agreement, then interest shall accrue on the balance due on a daily basis at a rate equal to eight percent (8%) per annum, or at the maximum rate permitted by applicable law, whichever is the lower, until Licensee meets the full financial obligation due.

3.14 Records; Audits. Licensee shall keep or cause to be kept such records as are reasonably required to determine, in a manner, with respect to any financial records, consistent with generally accepted accounting principles in the United States, the amounts due under this Agreement; such records must be kept for a minimum of three (3) years following the Calendar Year to which such records pertain. At the request (and expense) of Licensor, Licensee shall permit Licensor to engage an independent certified public accounting firm reasonably acceptable to Licensee, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary to determine, with respect to any Calendar Year ending not more than three (3) years prior to Licensor's request, the correctness or completeness of any royalty report or payment made under this Agreement. Licensor shall promptly provide a copy of the results of any such audit or examination to Licensee. Licensor shall bear the full cost of the performance of any such audit or examination, unless such audit or examination discloses an underpayment exceeding five percent (5%) of the amount actually due hereunder with respect to any particular Calendar Year, in which case Licensee shall bear the reasonable, documented cost of the performance of such audit or examination. Licensee shall promptly pay to Licensor the amount of any underpayment of royalties revealed by such an examination and review. Any overpayment by Licensee of royalties or any other amount paid to Licensor revealed by an examination and review shall, in Licensee's sole discretion, (i) be fully-creditable against future payments under this Agreement or (ii) refunded to Licensee within thirty (30) Calendar Days of its request.

4. TECHNOLOGY TRANSFER; COMMERCIAL TRANSITION; RELATED MATTERS.

4.1 Technology/Regulatory Transfer. Upon execution of this Agreement, Licensor shall transfer to Licensee, at no additional cost, all Licensor Know-How, which shall include but not be limited to all clinical data, trade secrets, human safety data, and other regulatory data related to the Products in its possession. Licensor shall, at Licensor's cost, take any and all actions reasonably requested by Licensee to effect the purposes of the foregoing as promptly as practicable following the execution of this Agreement. Such actions shall include providing Licensee with:

a. copies of all Regulatory Filings;

b. any communications with Governmental Authorities or Regulatory Authorities, and the minutes of any meetings with Governmental Authorities or Regulatory Authorities, relating to any Product;

c. DMFs and any trial, drug, device, or other master files relating to any Product, including copies of all case report forms;

d. copies of all adverse event reports relating to any Product;

e. the data, files and results of any chemistry, manufacturing, or control-related activities regarding any Product;

f. current market research, training, marketing, sales and medical information materials; and

g. all other information that Licensee may reasonably request that may be useful to Licensee for the manufacturing of Products, obtaining or maintaining Regulatory Approvals or Commercialization of Products (the documents listed in subsections 4.1.a. through 4.1.g. shall be referred to herein as the "Regulatory Documents").

From the Transfer Date to the earlier of the Return Date or Termination Date, Licensee shall, and Licensee shall cause its Affiliates and/or Sublicensees to produce, maintain and retain all Regulatory Documents. In the event of termination under Sections 9.2 or 9.3, Licensee and Licensor shall, subject to the continued rights to any Regulatory Approvals in the Territory by any Sublicensee whose rights by Sublicense survive termination of this Agreement in accordance with Section 9.4.c., within ten (10) Business Days of the termination of this Agreement pursuant to Section 9.2 or 9.3, make such filings with the FDA as are necessary to transfer Regulatory Approvals in the Territory owned by Licensee or any Affiliate thereof back to Licensor, and Licensee shall provide Licensor copies of all Regulatory Documents.

4.2 Product Inventory Transfer. Licensor hereby assigns, transfers, and conveys to Licensee, as of the Effective Date, all of Licensor's right, title, and interest in and to the Product inventory described on Schedule 4.2 ("Delivered Inventory") and unfinished materials and components described on Schedule 4.2 (the "Louisville Product Supply" and "Rechon Product Supply" as identified on Schedule 4.2; collectively, with the Delivered Inventory, "Product Supply"). Within twenty (20) Calendar Days of the Effective Date, Licensor will deliver to Licensee the Delivered Inventory and Louisville Product Supply F.O.B. at Licensor's Louisville warehouse. Licensor will assist Licensee in the transfer and assignment to Licensee of Rechon Product Supply located at Rechon. Licensor will deliver to Licensee all material information in Licensor's possession and control as of the Effective Date regarding the Delivered Inventory. Licensor represents and warrants that, to its knowledge, the Delivered Inventory (including all packaging and labeling) (i) conforms to applicable specifications and any requirements in Regulatory Approvals, (ii) was manufactured, packaged, tested, labeled and released in accordance with Applicable Laws, GMP and Regulatory Approvals and (iii) will not at the time of delivery be adulterated or misbranded or otherwise defective within the meaning of Applicable Laws.

4.3 Transfer of Regulatory Approvals.

a. Provided Licensee is not then in default under the terms of this Agreement, Licensor shall transfer and assign, and hereby assigns, to Licensee all of Licensor's right, title and interest in and to all Licensor Approvals within three (3) Business Days following the earlier of (a) receipt of notice from Suda, or other knowledge of Licensor, that an application for Regulatory Approval (or similar regulatory documentation) has been accepted by the appropriate Chinese regulatory or governmental authorities for the authorization of a clinical trial with Product in the People's Republic of China, or (b) December 31, 2018 (the "Transfer Date"). Licensor and Licensee shall file the Licensor FDA Letter and the Licensee FDA Letter with the FDA within three (3) Business Days after the Transfer Date. Transfer of title to the Regulatory Approvals for the Products in the U.S. will be effective as of the Transfer Date. In addition to the filing of the Licensor FDA Letter and the Licensee FDA Letter, following the Transfer Date, each Party shall, at the reasonable request of the other Party, promptly make any further filings and take any actions reasonably in connection with the transfer of Licensor Approvals to Licensee, including, without limitation, filing with the FDA any other notices, assignments, documents and/or other materials required by Applicable Laws, and change of labeler codes as required under 21 C.F.R. § 201, *et seq*. During the Term, Licensee shall not sell, transfer, assign or otherwise encumber the Regulatory Approvals, the Licensor Know-How, the Licensee Know-How or the Licensor Trademarks, except in accordance with Section 14.2. Any sale, transfer, assignment or other encumbrance in violation of this Section 4.3.a. shall be null and void.

b. The Parties shall provide each other with reasonable assistance in connection with the preparation, review and filings of all Regulatory Filings with the relevant Regulatory Authorities and communications therewith for the purposes of obtaining the Regulatory Approvals in the Territory as provided for in this Section 4.3.

c. Licensee shall assume and have responsibility for any fee or charge associated with the Product assessed by the FDA after the Effective Date including fees and charges authorized pursuant to the Prescription Drug User Fee Act, and any reauthorization thereto, including without limitation, the Food and Drug Administration Safety and Innovation Act, or such other fees which shall include all establishment, user and product or application fee assessed under 21 U.S.C.S. § 379h. Licensor shall retain full responsibility and liability for all fees or charges billed or invoiced to Licensor by the FDA on or prior to the Effective Date ("Prior Fees"). Licensee may, in its sole discretion, pay Prior Fees. In the event Licensee pays any Prior Fees, Licensee shall have the right to setoff such payments against amounts due hereunder until the amount of such setoff equals the amount of such payments. Such setoff amounts shall be deemed payments made to Licensor hereunder.

4.4 Commercialization Transition.

a. Within twenty (20) Calendar Days following the Effective Date, Licensor shall request that all wholesalers remove and use its Commercially Reasonable Efforts to assist wholesalers to remove or have removed from all distribution channels in the U.S. all Products labeled with Licensor's national drug codes (excluding Transition Quantities). "Transition Quantities" means a quantity of Product to be identified in writing by Licensee that will remain in the distribution channels in the U.S.

b. Licensor shall remain responsible for all payments, cost reimbursements, discounts, rebates, refunds, chargeback claims and related fees with respect to any Products labeled with Licensor's national drug codes (excluding Transition Quantities, Delivered Inventory and any Product purchased under the Rechon Purchase Orders). Notwithstanding anything to the contrary herein, in no event shall Licensee be liable in any manner for any audit, dispute, underpayment, act, error or omission with regard to such payments, cost reimbursements, discounts, rebates, refunds, chargeback claims or related fees.

c. Licensee shall not manufacture, use, Develop, promote, sell, distribute, or otherwise Commercialize any Product using the Licensor's national drug code except for Transition Quantities, Delivered Inventory and any Product purchased under the Rechon Purchase Orders.

4.5 Diligence.

a. Licensee shall, during the Term, use Commercially Reasonable Efforts, to Develop and Commercialize the Product in the U.S. From the Effective Date to the Transfer Date, Licensee will provide Licensor's counsel (currently William A. Garvin, Buchanan Ingersoll & Rooney, PC and his colleagues, but in the even Licensor changes counsel, the appropriate counsel for Licensor at that time) a reasonable opportunity to review and comment on any of Licensee's marketing or promotional material related to Products for the sole purpose of ensuring compliance with the requirements of the FDA Office of Prescription Drug Promotion, and all other Applicable Laws.

b. Licensee shall, during the Term, use Commercially Reasonable Efforts to Develop and Commercialize the Product in Canada. Notwithstanding anything to the contrary herein, in the event Licensee materially breaches this Section 4.5.b., and such breach is not cured within ninety (90) Calendar Days' of Licensee's receipt from Licensor of notice of such breach, Licensor shall, as its sole and exclusive remedy for such breach, have the right to amend the definition of Territory to remove Canada.

c. The Parties agree that the efforts of Licensee's Affiliates, Sublicensees, and contractors or consultants of Licensee, its Affiliates, or Sublicensees shall constitute the efforts of Licensee for purposes of satisfying Licensee's obligations under this Section 4.5.

4.6 Licensor and Licensee Regulatory Requirements. From the Effective Date until the Transfer Date:

a. Licensor shall (x) timely comply in all material respects with all reporting requirements with the FDA, including but not limited to those required under 21 C.F.R. §§ 310, 314, *et seq.* ("Reporting Requirements") and (y) take all other steps and measures necessary to ensure that the Licensor Approvals remain in full force and effect;

b. Licensor shall (i) promptly inform Licensee of all material communications with any Governmental Authorities in the U.S. concerning any Product, (ii) provide Licensee copies of proposed material submissions to any Governmental Authorities in the U.S. concerning the Licensed Product reasonably in advance of their submission to Governmental Authority, and (iii) not submit any information or materials to any Governmental Authority in the U.S. without Licensee's prior written approval. Licensor will not respond substantively to any material communication with a particular Governmental Authority in the U.S. or otherwise make any submissions to a Governmental Authority in the U.S. concerning, in either case, a Product, without Licensee's prior written consent. Licensor shall enable an employee or other designee of Licensee to attend, if and as requested by Licensee, lead all formal in person, telephonic, video, or other electronic meetings with any Governmental Authority in the U.S. regarding any Product; and

c. Licensee shall use Commercially Reasonable Efforts to promptly provide all information coming into its possession that is necessary to enable Licensor to comply with its obligations under clause a(x) above. In addition, Licensee shall (i) promptly inform Licensor of all material communications Licensee may have with any Governmental Authorities in the U.S. concerning any Product, (ii) provide Licensor copies of any material submissions being proposed by Licensee to be made to any Governmental Authorities in the U.S. concerning the Licensed Product reasonably in advance of their submission to Governmental Authority, and (iii) not submit any information or materials to any Governmental Authority in the U.S. without Licensor's prior written approval. Licensee will not respond substantively to any material communication with a particular Governmental Authority in the U.S. or otherwise make any submissions to a Governmental Authority in the U.S. concerning, in either case, a Product, without Licensee's prior written consent.

From the Transfer Date to the earlier of the Return Date or Termination Date, Licensee shall timely comply in all material respects with all Reporting Requirements and take all other steps and measures necessary to ensure that the Licensor Approvals remain in full force and effect. In addition thereto, Licensee shall provide Licensor copies of annual reports to any Governmental Authorities in the U.S. concerning the Licensed Product promptly after their submission to Governmental Authority. Each Party shall, to the extent it becomes aware of any of the following, notify the other Party in writing, and on such timing is necessary to enable compliance with Applicable Laws in the territory, of any reported adverse event with respect to any Product ("AE"), serious adverse event with respect to any Product ("SAE"), Product problems and Product use errors ("Product Problems") and shall, during such period as a Party is a holder of title to any Regulatory Approvals in the Territory, otherwise ensure timely reporting of any AE, SAE or Product Problems with the FDA in material compliance with applicable Reporting Requirements.

5. PATENT AND TRADEMARK PROSECUTION AND MAINTENANCE.

5.1 Prosecution and Maintenance by Licensee . Except as provided in Section 5.2 below, Licensee shall assume and have primary responsibility for the filing, prosecution, and maintenance of the Licensor Patents and Licensor Trademarks and, subject to Section 5.2, Licensee will be responsible for all reasonable costs and expenses it incurs with respect its filing, prosecution, and maintenance of the Licensor Patents and Licensor Trademarks. Licensee will, to the extent reasonably practicable, provide Licensor a reasonable opportunity to review and comment on any material patent filings or correspondence with patent authorities pertaining to the Licensor Patents and Licensor Trademarks, provided that all decisions with respect to the filing, prosecution, and maintenance of the Licensor Patents and Licensor Trademarks under this Section 5.1 shall be made by Licensee in its sole reasonable discretion. Licensee shall not abandon prosecution or maintenance of any Licensor Patent or Licensor Trademark without first notifying Licensor in a reasonably timely manner of Licensee's intention and reason therefor, and providing Licensor with reasonable opportunity to assume responsibility for prosecution and maintenance of such Licensor Patent or Licensor Trademarks as set forth in Section 5.2.

5.2 Abandonment by Licensee; Prosecution and maintenance by Licensor. If Licensee provides Licensor with written notification that it will no longer support or pursue the filing, prosecution, or maintenance of a specified Licensor Patent (an "Abandoned Patent") or Licensor Trademarks (an "Abandoned Trademark") in a particular country, then (a) Licensee's responsibility for such filing, prosecution, or maintenance of the Abandoned Patent or Abandoned Trademark in such country, and the fees and costs related thereto, will terminate on the earlier of (x) the date sixty (60) Calendar Days after Licensor's receipt of such written notice from Licensee or (y) Licensor's assumption of the filing, prosecution and maintenance of such Abandoned Patent or Abandoned Trademark in such country, and (b) the specified Abandoned Patent or Abandoned Trademark shall no longer be deemed a Licensor Patent or Licensor Trademark hereunder and in the case of an Abandoned Trademark, the respective Licensor Trademark shall be assigned by Licensee to Licensor. For clarity, following the earlier of clause (x) or (y) in the preceding sentence with respect to a particular Licensor Patent or Licensor Trademark in a particular country, Licensor shall not have any obligation to Licensee under this Agreement with respect to such Licensor Patent or Licensor Trademark in such country. Notwithstanding anything contained in Sections 5.1 or 5.2 to the contrary, Licensee shall not abandon prosecution or maintenance of any Licensor Patent or Licensor Trademark if such abandoment will result in a breach of the Suda Agreement. Licensee acknolwedges and agrees that compliacne with the terms of the Suda Agreement are its sole responsibility, and Licensor shall have no obligations to Licensee or Suda under the terms of the Suda Agreement.

5.3 Patent Term Extensions. Licensee shall promptly notify Licensor of the issuance of each Regulatory Approval and, where reasonably and legally possible and reasonably useful or materially valuable in the Commercialization of Products, use Commercially Reasonable Efforts to apply (or cause its Affiliates or Sublicensee(s) to apply) for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws (collectively, "Patent Term Extensions") in the relevant country(ies) of the Territory. Licensor shall, if and as requested by Licensee, (a) use Commercially Reasonable Efforts to, assist Licensee, its Affiliates, and Sublicensees in obtaining all available Patent Term Extensions and (b) take all actions necessary to obtain all Patent Term Extensions. The Parties shall cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable.

5.4 Intentionally Omitted

6. Patent Infringement.

6.1 Notice. If either Party becomes aware of any actual, potential, or alleged infringement of any of the rights to Licensor Patents or Licensor Trademarks granted to Licensee under this Agreement with respect to Products, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement.

6.2 Hatch-Waxman Act Litigation. Notwithstanding anything herein to the contrary, should a Party receive (a) a certification for a Product pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended (the "Hatch-Waxman Act"), including any notice under 21 U.S.C. § 355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) or a similar notice with respect to, in either case, any Product, or (b) any reasonable equivalent in a country in the Territory other than the U.S., then such Party shall immediately (and in any event no later than within five (5) Business Days after such receipt) provide the other Party with a copy of such certification or notice. The Party with the right to bring suit under the Hatch-Waxman Act or reasonable equivalent in any country outside the United States, as applicable, on account of such certification or notice shall have fifteen (15) Calendar Days from the date on which it receives a copy of the application for which Regulatory Approval is sought, but in no event later than thirty-five (35) Calendar Days from the date of receipt of the certification or notice, to provide written notice to the other Party ("H-W Suit Notice") stating whether it will bring suit, at its expense, within a forty-five (45) Calendar Day period from the date of such certification or notice, including any patent infringement suit (or other applicable time limit for bringing such suit). Should the period referred to in the prior sentence for delivering an H-W Suit Notice expire without the applicable Party providing such H-W Suit Notice, then the other Party shall be free immediately to bring suit in the name of the Party that did not give the H-W Suit Notice. Notwithstanding the foregoing, (I) no Party shall take any action in the course of exercising its rights under this Section 6.2 that (x) admits fault or wrongdoing, or incurs liability, on the part of the other Party or (y) materially limits the scope, validity, or enforceability of any of the Licensor Patents in the Territory without, in either case, the prior written consent of the other Party and (II) if Licensor is the party bringing the suit hereunder, Licensor shall not take any action in the course of exercising its rights under this Section 6.2 that would reasonably be expected to materially adversely affect the ability of Licensee to manufacture, Develop or Commercialize Products without Licensee's prior written consent.

6.3 Infringement. To comply with the Suda Agreement, with respect to any actual, potential, or alleged infringement of the rights to Licensor Patents or Licensor Trademarks (an "Infringement"), Licensee shall initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect to such Infringement. In any such litigation brought by Licensee, Licensee shall have the right to use and sue in Licensor's name and join Licensor as a party to such litigation, and Licensor shall cooperate reasonably, as requested by Licensee and at Licensee's expense (which expense shall be reasonable). If, within one hundred thirty five (135) Calendar Days of the notice in Section 6.1, Licensee shall, (a) have been unsuccessful in persuading the actual, potential, or alleged infringer to desist, (b) shall not have brought and shall not be diligently prosecuting an infringement action with respect to such Infringement, or (c) has not entered into settlement discussions with respect to such Infringement, or if Licensee notifies Licensor that it has decided not to undertake any of the foregoing against any such alleged, potential, or actual infringer, then Licensor shall have the right, but not the obligation, to bring suit to enforce such Licensor Patents or Licensor Trademarks against such actual, alleged, or potential infringer at its own expense, unless Licensee has provided Licensor with a strategic rationale for not taking action to terminate such Infringement. In any such litigation brought by Licensor, Licensor shall have the right to use and sue in Licensee's name and join Licensee as a party to such litigation, and Licensee shall cooperate reasonably, as requested by Licensor and at Licensor's expense (which expense shall be reasonable). The Parties' rights and obligations under this Section 6.3 shall be subject to, and shall not be construed to limit or adversely affect, the Parties' rights and obligations under Section 6.2. Notwithstanding the foregoing, Licensee shall not take any action that would result in a breach of the Suda Agreement. For the avoidance of doubt, Licensor shall have no obligations under this Section 6. 2 to bring suit to enforce such Licensor Patents or Licensor Trademarks even if failure to do so would cause Licensee to be in breach of the Suda Agreement.

6.4 Infringement of Third Party Rights. In the event that a claim of infringement of a Third Party's Patents is made or brought against either Party with respect to the manufacture, use, sale, or importation of the Product, the Party receiving such claim shall promptly inform the other Party in writing, and the Parties shall consult with each other in order to develop a strategy for addressing the alleged infringement. Each Party shall reasonably cooperate with the other in any investigations undertaken to determine any potential infringement. As between the Parties, Licensee (and/or its Affiliates and Sublicensees) shall have the first and primary right, but not the obligation, at its own expense to defend, control the defense of, and/or settle any such claim against Licensee, its Affiliates, or Sublicensees, using counsel of its own choice.

6.5 Litigation Control. The Party pursuing or controlling any action or defense under Section 6.2, 6.3 or 6.4 (the " Controlling Party") shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action or defense, provided, however, that (a) the Controlling Party shall consult with the other Party (the "Secondary Party") prior to entering into any settlement or voluntary disposition thereof, (b) any settlement, consent judgment or other voluntary disposition of such actions which (1) subjects the Secondary Party to any non-indemnified liability or obligation or (2) admits fault or wrongdoing on the part of Secondary Party must, in each case, be approved in advance and in writing by the Secondary Party, (c) any settlement, consent judgment or other voluntary disposition of such actions which materially limits the scope, validity, or enforceability of, or otherwise may adversely affect, any Licensor Patents or Licensor Trademarks or shall not be entered into, consented to, approved, or agreed upon without the other Party's prior written approval, and (d) any settlement, consent judgment or other voluntary disposition of such actions that would reasonably be expected to materially adversely affect the Licensor Patents or Licensor Trademarks or ability of Licensee to manufacture, Develop or Commercialize Products shall not be entered into, consented to, approved, or agreed upon without Licensee's prior written consent. With respect to clause (b) or (c) above in this Section 6.5, the Secondary Party shall provide the Controlling Party notice of its approval or denial of such approval within fifteen (15) Business Days of any request for such approval by the Controlling Party, provided that (X) in the event Secondary Party wishes to deny such approval, such notice shall include a written description summarizing the Secondary Party's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition and (Y) Secondary Party shall be deemed to have approved such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such fifteen (15) Business Day period. Any recovery or damages received by the Controlling Party with respect to the infringement of the rights to Licensor Patents or Licensor Trademarks granted under this Agreement, or in settlement of any matter subject to Section 6.2 or 6.3, shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action or settlement, and the remainder shall be retained by the Controlling Party. Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any proceeding governed by this Section 6.5. Notwithstanding anything contained in Sections 6.2, 6.3 or this 6.5 to the contrary, Licensee acknolwedges and agrees that compliance with the terms of the Suda Agreement are its sole responsibility, and Licensor shall have no obligations to Licensee or Suda under the terms of the Suda Agreement.

6.6 Reimbursement. Each Party shall invoice the other Party for any reasonable, documented costs incurred that are to be borne by the other Party pursuant to this Section 6. Each Party shall pay the other Party such amounts within thirty (30) Calendar Days of its receipt of any such invoice, except to the extent such amounts are the subject of a good faith dispute, in which the amounts subject to such dispute shall be due within thirty (30) Calendar Days of the resolution of such dispute.

7. CONFIDENTIALITY.

7.1 Confidentiality Obligations. The Parties agree that, for the Term and for five (5) years thereafter, each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information of the other Party.

7.2 Authorized Disclosure. Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

a. made in response to a valid order of a court of competent jurisdiction; provided, however, that in each case such disclosing Party will, to the extent reasonably practicable, (i) first have given written notice to the other Party and given such other Party a reasonable opportunity to take appropriate action and (ii) cooperate with such other Party as necessary to obtain an appropriate protective order or other protective remedy or treatment; provided, further, that in each case, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by counsel to the Party that is obligated to disclose Confidential Information pursuant to such order;

b. otherwise required to be disclosed by Applicable Law or the requirements of any stock exchange to which a Party is subject; provided, however, that the Party that is so required will provide such other Party with written notice of such disclosure reasonably in advance thereof to the extent reasonably practicable and reasonable measures will be taken to assure confidential treatment of such information, including such measures as may be reasonably requested by the disclosing Party with respect to such Confidential Information;

c. made by such Party, in connection with the performance of this Agreement to such Party's Affiliates, licensees or sublicensees, directors, officers, employees, consultants, representatives or agents, or to other Third Parties, in each case on a need to know basis and solely to use such information for business purposes relevant to and permitted by this Agreement, and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations no less than substantially as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations; or

d. made by such Party to existing or potential acquirers, existing or potential collaborators, investment bankers, accountants, attorneys, existing or potential investors, merger candidates, partners, venture capital firms or other financial institutions or investors for use of such information for business purposes relevant to this Agreement or for due diligence in connection with the financing, licensing or acquisition of such Party (or such Party's acquisition of, or merger with, a Third Party), and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations (or in the case of attorneys or accountants, an equivalent professional duty of confidentiality) at least as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations.

7.3 Publicity. Press releases or other similar public communication by either Party not required by Applicable Law or the requirements of any stock exchange to which a Party is subject and disclosing the existence or terms of this Agreement, will require the advance written approval of the other Party, which approval will not be unreasonably withheld, conditioned or delayed. The foregoing notwithstanding, communications required by Applicable Law or the requirements of any stock exchange to which a Party is subject, and disclosures of information for which consent has previously been obtained, will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof, provided that, with respect to any such communications required by Applicable Law or the requirements of any stock exchange to which a Party is subject, the Party required to make such disclosure shall, to the extent reasonable practicable and such disclosure does not include information for which consent has previously been obtained, provide the other Party a reasonable opportunity to review and comment on such communications.

8. Non-Competition. Licensor shall (and shall ensure that its Affiliates do):

a. not manufacture, use, develop, promote, sell, distribute, import, export, or otherwise Commercialize any Competing Product in the Territory;

b. not acquire from any Third Party the right to manufacture, use, develop, promote, sell, distribute, import, export, or otherwise Commercialize any Competing Product in the Territory;

c. not enter into any agreement pursuant to which any Third Party may manufacture, use, develop, promote, sell, distribute, or otherwise Commercialize any Competing Product in the Territory; and

d. not otherwise enable any Third Party, directly or indirectly, to manufacture, develop, promote, sell, distribute, or otherwise Commercialize any Competing Product in the Territory.

Notwithstanding the foregoing, in the event that the Regulatory Approvals, Licensor Trademarks and Licensor Know-How are transferred to Licensor pursuant to Section 9.4, then the provisions of this Section 8 shall terminate as of the Return Date.

9. TERM AND TERMINATION.

9.1 Term. This Agreement shall become effective on the Effective Date and shall continue until the earlier of (a) the expiration of the Royalty Term or (b) the effective date of termination pursuant to Section 9.2 or 9.3 (the period from the Effective Date until such expiration or termination, the "Term").

9.2 Termination for Material Breach. If either Party materially breaches this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if (a) such material breach is not cured within forty five (45) Calendar Days of a default in making any undisputed payment when due under Section 3, or ninety (90) Calendar Days following notice by the non-breaching Party to the breaching Party specifying the material breach (or, if such default is capable of being cured but cannot be cured within such 90-day period, the breaching Party has commenced and diligently continued actions to cure such default provided always that, in such instance, such cure must have occurred within one hundred eighty (180) Calendar Days after notice thereof was provided to the breaching Party by the non-breaching Party to remedy such default) and (b) the non-breaching Party provides notice confirming such termination within thirty (30) Calendar Days following the expiration of such forty-five (45), ninety (90) or one hundred eighty (180) Calendar Day period, as applicable, without cure of such material breach. The foregoing notwithstanding, if such material breach is cured or remedied or shown to be non-existent or not material within the aforesaid forty-five (45), ninety (90) or one hundred eighty (180) Calendar Day period, the non-breaching Party's notice(s) hereunder shall be automatically withdrawn and of no effect.

9.3 Termination for Convenience by Licensee. This Agreement may be terminated by Licensee, in its sole discretion, upon (i) sixty (60) Calendar Days prior written notice and (ii) Licensee paying Licensor a termination fee in the amount of Fifty Thousand Dollars ($50,000).

9.4 Effects of Termination.

a. In the event of the termination of this agreement pursuant to Section 9.2 or Section 9.3, all licenses granted to Licensee hereunder shall terminate, and, subject to the continued rights by any Sublicensee whose rights by Sublicense survive termination of this Agreement in accordance with Section 9.4.c., (i) Licensee shall transfer title to all Regulatory Approvals, Licensor Trademarks and Licensor Know-How owned by Licensee, its Affiliates, or any Sublicensee in the Territory to Licensor, free and clear of all liens, claims, and encumbrances, and (ii) Licensee shall grant Licensor a perpetual, nonexclusive, royalty-free license to all Licensee Know-How to make, use, or sell the Products in the Territory following such termination. Licensee shall, within ten (10) Business Days of the termination of this Agreement pursuant to Section 9.2 or Section 9.3, file such documents with the FDA as is reasonably required to effect the transfer of such Regulatory Approvals to Licensor. The filing date of such documentation shall be referred to herein as the "Return Date".

b. Notwithstanding anything to the contrary, in the event of termination of this Agreement pursuant to Section 9.2 or Section 9.3, Licensee and its Affiliates shall (i) request within twenty (20) Calendar Days of the effective date of such termination ("Termination Date") that all wholesalers remove from all distribution channels in the Territory all Product labeled with Licensee's national drug code (for Product within the U.S.) and (ii) use its best efforts to assist wholesalers to have such Product removed, provided that the foregoing shall not apply with respect to any Sublicensee or its Commercialization of Products to the extent such Sublicensee's rights by Sublicense survive termination of this Agreement in accordance with Section 9.4.c. During the one hundred twenty (120) Calendar Days following the Termination Date, Licensee shall have the privilege, subject to the payment of royalties as required under Section 3.2, of (i) completing the manufacture of any Products in the process of manufacture as of the Termination Date, (ii) selling such Products and all finished Products in their possession or under their control as of the Termination Date for a period of one hundred twenty (120) Calendar Days following the Termination Date upon commercially reasonable conditions, and (iii) completing performance of all contracts entered into with Affiliates and Third Parties prior to the Termination Date (1) for the marketing, sale, or manufacture of Products or (2) requiring the use of Products for a period of one hundred twenty (120) Calendar Days following the Termination Date, provided that the foregoing shall not apply with respect to, nor be construed to limit, any Sublicensee's Commercialization of Products to the extent such Sublicensee's rights by Sublicense survive termination of this Agreement in accordance with Section 9.4.c. Licensee shall remain responsible for all payments, cost reimbursements, discounts, rebates, refunds, chargeback claims and related fees with respect to any Products labeled with Licensee's national drug codes and, in no event shall Licensor be liable in any manner for any audit, dispute, underpayment, act, error or omission with regard to such payments, cost reimbursements, discounts, rebates, refunds, chargeback claims or related fees.

c. Notwithstanding any provision herein to the contrary, in the event (i) this Agreement is terminated, (ii) a Sublicense is in effect at the time of termination and (iii) such Sublicense which complies with Section 2.3 and the royalty terms of such Sublicense are not less favorable to Licensor than the royalty terms in this Agreement ("Qualified Sublicense"), such Qualified Sublicense will, to the extent provided for therein, survive such termination and be automatically assigned to Licensor upon such termination in order to provide for the applicable Sublicensee's continued enjoyment of its rights under such Qualified Sublicense.

9.5 Remedies. Any rights or remedies set forth in this Section 9 are not exclusive, and shall not limit any other legal or equitable remedies that are available to the Parties.

9.6 Survival. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration, and any termination or expiration of this Agreement shall not relieve either Party of any obligation that has accrued prior to the effective date of such termination or expiration (including, without limitation payment obligations that have accrued prior to termination), which obligations shall remain in full force and effect. The following provisions shall survive any expiration or termination of this Agreement: Sections 3.1, 3.6, 3.13, 4.1, 4.3, 7, 8 (except as otherwise provided therein), 9.4, 9.5, 9.6, 11, 12, and 14 together with any Sections referenced in such surviving provisions or necessary to give them effect.

10. REPRESENTATIONS AND WARRANTIES.

10.1 Representations and Warranties of Licensor. Licensor represents and warrants to Licensee as follows:

a. Licensor is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.

b. Licensor has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligation of Licensor, enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

c. The execution, delivery and performance by Licensor of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement to which Licensor or any Affiliate thereof is a party.

d. There is no action, suit, litigation, claim, administrative action or proceeding by a Governmental Authority or other person or investigation by a Governmental Authority ("Proceedings") pending or, to Licensor's and its Affiliates' knowledge, currently threatened in writing against or affecting Licensor or any Affiliate thereof that questions the validity of this Agreement or the right of Licensor to enter into this Agreement or consummate the transactions contemplated hereby and, to Licensor's and its Affiliates' knowledge, there is no basis for the foregoing.

e. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority, or any Third Party, on the part of Licensor or any Affiliate thereof is required in connection with the execution, delivery and performance of this Agreement except with respect to those applications, registrations, declarations or other documents submitted to such Governmental Authority pursuant to Section 4.

f. Licensor has disclosed in writing to Licensee all Patents owned or Controlled by Licensor or its Affiliates as of the Effective Date that Cover any Products in the Field, or which relate to Developing, manufacturing or Commercializing Products.

g. To the knowledge of Licensor and its Affiliates, no research or Development of the Licensor Technology, manufacture of Products, or research leading to the inventions Covered by the Licensor Patents was supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.

h. To the knowledge of Licensor and its Affiliates, Licensor Technology, Licensor Trademarks and Regulatory Approvals are wholly-owned by Licensor, free and clear of all mortgages, pledges, charges, liens, equities, security interests, or other encumbrances or similar agreements or any other obligation.

i. To the knowledge of Licensor and its Affiliates, no Third Party or Affiliate of Licensor has any rights or ownership interest in any Licensor Technology, Regulatory Approvals or Licensor Trademarks, and neither Licensor nor any Affiliate thereof obtained rights to any of the Licensor Technology, Regulatory Approvals or Licensor Trademarks by license or any similar contract or agreement with any Third Party or Affiliate of Licensor.

j. Neither Licensor nor any Affiliate thereof is aware of any Third Party intellectual property rights (including any Patent(s)) that were (prior to the Effective Date) or would be (following the Effective Date) infringed, misappropriated, or otherwise violated by the use, manufacture, sale, import, export, Development, or Commercialization of any Products.

k. To the knowledge of Licensor and its Affiliates, Licensor and its Affiliates have taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to Products and Licensor Technology.

l. Neither Licensor nor any Affiliate thereof is aware of any Third Party activities which would constitute misappropriation or infringement of any Licensor Technology or Licensor Trademarks.

m. To the knowledge of Licensor and its Affiliates, all information provided to Licensee, its Affiliates, and their employees, officers, directors, agents, and other representatives by or on behalf of Licensor or any Affiliate thereof with respect to Products, Regulatory Approvals and the Licensor Technology has been accurate, and there is no material information known to, or in the possession or control of, Licensor or any Affiliate thereof related to any Product, Regulatory Approval or the Licensor Technology that has not been provided to Licensee prior to the Effective Date.

n. To the knowledge of Licensor and its Affiliates, all Development of Product was performed in accordance with GLP, GCP, and all Applicable Laws, all human clinical studies of Products were performed in accordance with the protocols established therefor, and all Product or placebo administered to patients or subjects in any such studies was manufactured, handled, shipped, and stored in accordance with GMP, Applicable Laws, and the specifications.

o. Licensor has not received any written notice or, to Licensor's knowledge, other notice that any Governmental Authority has initiated, or threatened to initiate, any action to recall, suspend or otherwise restrict the manufacture, sale, or distribution of any of the Products. There are no pending or, to the knowledge of Licensor, threatened proceedings or requests for information, voluntary or involuntary market withdrawals, field corrective actions (including recalls), safety alerts, or other regulatory enforcement actions related to any of the Products.

p. Licensor has compiled and maintained all Regulatory Approvals in compliance with Applicable Laws. All Regulatory Approvals are in full force and effect. There are no Proceedings pending or, to the knowledge of Licensor, threatened seeking the revocation or suspension of any Regulatory Approval. All maintenance and other fees related to Regulatory Approvals have been paid, or are not chargeable against Licensor as of the Effective Date. Licensor has not received: (i) any FDA Form 483's concerning the Products or (ii) warning letters from the FDA concerning the Products (excluding a warning letter from the OPDP related solely to marketing materials for the Product, which Licensor warrants has been resolved). There are no Proceedings by the FDA or any other Governmental Authority pending or, to the knowledge of Licensor, threatened against Licensor relating to safety or efficacy of the Products. There are no outstanding consent decrees with respect to any of the Products.

10.2 Representations and Warranties of Licensee. Licensee represents and warrants to Licensor as follows as of the Effective Date:

a. Licensee is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.

b. Licensee has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligations of Licensee, enforceable in accordance with their terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

c. The execution, delivery and performance by Licensee of this Agreement and the consummation of the transactions contemplated thereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement material to Licensee, its business or its assets.

d. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Licensee is required in connection with the execution, delivery and performance of this Agreement.

e. There is no action, suit, proceeding or investigation pending or, to Licensee's knowledge, currently threatened against or affecting Licensee or that questions the validity of this Agreement, or the right of Licensee to enter into this Agreement or consummate the transactions contemplated hereby and, to Licensee's knowledge, there is no reasonable basis for the foregoing.

10.3 Warranties excluded. Except as otherwise expressly set forth in this Agreement, the Licensor makes no representations or warranties of any kind, express or implied, concerning the Product, Licensor Technology and Licensor Trademarks, and other materials licensed hereunder, including, without limitation, warranties of merchantability, fitness for a particular purpose, and the absence of latent or other defects, whether or not discoverable.

10.4 Compliance with Applicable Laws. The Parties represent and warrant to each other that they will comply with, and will ensure that their Affiliates (and in the case of Licensee, its Sublicensees) will comply with, all Applicable Laws, including without limitation those local, state, federal and international laws, regulations, and treaties, related to the Development, manufacture, sale, importation, and exportation of the Product during the Term of this Agreement. Licensee will require its Affiliates exercising rights hereunder and any Sublicensee to comply with all such Applicable Laws, and Licensee bears full responsibility for any acts in violation of Applicable Law by its Affiliates or Sublicensees.

11. INDEMNITIES; LIMITS ON LIABILITY.

11.1 Indemnification by Licensor. Subject to Sections 11.3, Licensor hereby agrees to defend, indemnify and hold harmless Licensee, its Affiliates, Sublicensees, any contractors of any of the foregoing, and each of their directors, officers, employees, agents, and other representatives (each a "Licensee Indemnitee") from and against all suits, claims, proceedings or causes of action brought by Third Parties (" Claims"), and all associated damages, liabilities, expenses and/or loss, including reasonable legal expenses and reasonable attorneys' fees ("Losses"), to the extent arising out of a Licensor Indemnitee's (i) negligence or willful misconduct, (ii) breach of this Agreement, (iii) failure to comply with any Applicable Law, (iv) all payments, cost reimbursements, discounts, rebates, refunds, chargeback claims and related fees with respect to any Products labeled with Licensor's national drug codes (excluding Transition Quantities, Delivered Inventory and any Product purchased under Rechon Purchase Orders, if any), provided, however, that Licensor shall not be liable pursuant to this Section 11.1(iv) if any Product is labeled with Licensor's national drug code in violation of Section 4.4.c., or (v) manufacture, use, Development, Commercialization, import, or export of any Product(s) prior to the Effective Date (excluding Product manufactured by Rechon pursuant to the Purchase Orders, Transition Quantities and Delivered Inventory), except to the extent such Losses result from the negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any Licensee Indemnitee.

11.2 Indemnification by Licensee. Subject to Section 11.3, Licensee hereby agrees to indemnify, defend and hold Licensor, its Affiliates, and Licensor's and its Affiliates' officers, directors, employees, contractors, agents, and other representatives (collectively, "Licensor Indemnitees") harmless from and against any Losses resulting from Claims brought against any Licensor Indemnitee(s) resulting from Licensee Indemnitee's or Sublicensees' (i) negligence or willful misconduct, (ii) breach of this Agreement, (iii) failure to comply with Applicable Laws, (iv) breach of the Suda Agreement caused by Licensee's action or inaction, (v) all payments, cost reimbursements, discounts, rebates, refunds, chargeback claims and related fees with respect to any Products labeled with Licensee's national drug codes (including Delivered Inventory, Transition Quantities, and any Product purchased under Rechon Purchase Orders, if any), (vi) all payments, cost reimbursements, discounts, rebates, refunds, chargeback claims and related fees with respect to Delivered Inventory, Transition Quantities, and any Product purchased under Rechon Purchase Orders, or (vii) manufacture, use, Development, Commercialization, import, or export of any Product(s) after the Effective Date (including Product manufactured by Rechon pursuant to the Rechon Purchase Orders, Transition Quantities and Delivered Inventory), except to the extent such Losses result from the negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any Licensor Indemnitee.

11.3 Indemnification Procedures. Each Party's agreement to indemnify, defend, and hold harmless under Section 11.1 or 11.2, as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified matter as soon as reasonably possible, and in any event no later than within thirty (30) Calendar Days after the indemnified Party has actual knowledge of such claim, demand or action, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such claim, demand or action, (c) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such claim, demand or action, and (d) not compromising, settling, or entering into any voluntary disposition of any such claim, demand or action without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; provided, however, that, if the party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action in any manner that admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which may adversely affect any portion of the Licensor Technology in any material respect, or Licensee's ability to exploit Licensor Technology in any material respect, without the other Party's prior written consent.

11.4 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 11.1 AND 11.2 ABOVE OR EITHER PARTY'S LIABILITY FOR A BREACH OF SECTION 7.

11.5 Insurance. Each Party shall carry and maintain insurance of the types and in amounts which are reasonable and customary in the U.S. pharmaceutical industry for companies of comparable size and activities. Such insurance will insure against all liability, including but not limited to, bodily injury or property damage arising out of the manufacture, sale, distribution, marketing, Development or Commercialization of Products. Such insurance shall include (i) commercial general liability insurance and (ii) product liability insurance in the amount of Ten Million Dollars ($10,000,000). Such coverage shall be maintained by each Party for not less than three (3) Calendar Years following expiration or termination of this Agreement or if such coverage is of the "claims made" type, for five (5) Calendar Years following expiration or termination of this Agreement. Upon written request from a Party, the other Party shall promptly provide written evidence (e.g., certificates) of such insurance that is reasonably satisfactory to the requesting Party.

12. Dispute Resolution. In the event that a dispute arises between the Parties in the course of this Agreement, the dispute will be referred to the attention of the Chief Executive Officer of Licensor and the Chief Executive Officer of Licensee or their designees (the "Executive Officers"). The Executive Officers will meet as soon as reasonably possible thereafter and in good faith attempt to resolve such dispute. If, within thirty (30) Calendar Days after referral of such dispute to the Executive Officers by either Party, the Executive Officers are unable to resolve such dispute, either Party will have the right to have the dispute resolved by binding arbitration, initiated by either Party on fifteen (15) Business Days' notice to the other Party following the expiration of the thirty (30) Calendar Day period referenced above (the "Initiation Notice"), under the Rules of the American Arbitration Association then pertaining except where those rules conflict with this provision, in which case this provision controls, applying the laws of Kentucky, without regards to its conflicts of law provisions, before three (3) independent, neutral arbitrators experienced in the pharmaceutical industry and licensing transactions in such industry. The place of arbitration shall be Jefferson County, Kentucky. Licensor and Licensee shall each be entitled to select one (1) such arbitrator, with the two (2) such arbitrators so selected selecting the third (3rd) such arbitrator. In the event either Party fails to select its arbitrator within fifteen (15) Business Days of the Initiation Notice, the arbitrator selected by the other Party within such fifteen (15) Business Day period shall be entitled to select such arbitrator. The arbitration shall be conducted in English. The decision of the arbitrators will be final and binding on the Parties, and any decision of the arbitrators may be enforced in any court of competent jurisdiction. Each Party shall bear its own expenses and an equal share of the reasonable, documented expenses of the arbitration panel and any fees required by ICC to submit such matter to arbitration, unless the panel determines that any such fees or expenses are to be paid by the non-prevailing Party. Notwithstanding the foregoing, either Party may seek injunctive, equitable, or similar relief from a court of competent jurisdiction without the requirement of arbitration.

13. Suda Agreement. Subject to Suda's approval, Licensee agrees that it shall assume all obligations and liabilities of Licensor under the Suda Agreement from and after the Effective Date, with a full release of Licensor within three (3) Business Days of the Effective Date pursuant to the terms of an assignment and assumption agreement to be executed by the Parties, in a form mutually agreed to by the Parties, in their reasonable discretion ("Suda Assignment"). Effective as of the date of the Suda Assignment, Licensee shall have the right to receive all compensation owed to Licensor under the Suda Agreement (the "Suda Payments"). Licensee agrees to pay Licensor Seventy Five Thousand Dollars ($75,000) out of the first One Hundred Thousand Dollars ($100,000) in Suda Payments that Licensee receives from Suda. Licensee acknowledges and agrees that in the event of any conflict between Licensee's obligations under this Agreement and Licensee's obligations under the Suda Agreement, Licensee's obligations under the Suda Agreement shall govern.

14. Miscellaneous.

14.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party, nor be deemed to have defaulted under or breached this Agreement, for failure or delay in fulfilling or performing any term of this Agreement, to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, including fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God or any acts, omissions or delays in acting by any governmental authority or the other Party, provided that, notwithstanding the foregoing, the payment of amounts due under this Agreement may not be delayed due to a force majeure affecting the Party required to make such payment.

14.2 Assignment. Neither Party may assign this Agreement, or any of its rights or obligations hereunder without the other Party's prior written consent, which consent shall not be unreasonably withheld, provided that, notwithstanding the foregoing, each Party shall be entitled, without the other Party's prior written consent, to assign or transfer this Agreement: (a) in connection with the transfer or sale of all or substantially all of such Party's assets or business (or that portion thereof related to the subject matter of this Agreement) or (b) in the event of such Party's merger, consolidation, reorganization, change of control or similar transaction. Any permitted assignee of either Party shall, as a condition to such assignment, assume all obligations of its assignor arising under this Agreement following such assignment. Any purported assignment by a Party of this Agreement, or any of such Party's rights or obligations hereunder, in violation of this Section 14.2 shall be void.

14.3 Severability. If one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions are, in their economic effect, sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In the event that such provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or more provisions of the Agreement shall not affect the validity of this Agreement as a whole.

14.4 Notices. Any notice, consent or report required or permitted to be given or made under this Agreement by one Party to the other Party shall be in English and in writing, delivered personally or by U.S. first class mail or express courier providing evidence of receipt, postage prepaid (where applicable), at the following address for a Party (or such other address for a Party as may be specified by like notice):

To Licensee:
Aytu BioScience, Inc.
Attn: Chief Executive Officer
373 Inverness Parkway, Suite 206
Englewood, CO 80112

To Licensor:
Magna Pharmaceuticals, Inc.
Attn: Chief Executive Officer
10801 Electron Drive
Louisville, KY 40299

All such notices, consents or reports shall be effective upon receipt.

14.5 Applicable Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Kentucky, without regard to the conflicts of law principles that would provide for application of the law of a jurisdiction other than the State of Delaware.

14.6 Entire Agreement. This Agreement (including the Suda Assignment, the Schedules or exhibits attached hereto) contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior express or implied agreements, understandings and representations, either oral or written, which may have related to the subject matter hereof in any way.

14.7 Interpretation. The captions to the several Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be followed by the phrase "without limitation", "including but not limited to", or like expression; (b) the singular shall include the plural and *vice versa*; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable.

14.8 Independent Contractors. It is expressly agreed that Licensee and Licensor shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency or other fiduciary relationship. Neither Licensee nor Licensor shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.

14.9 Waiver; Amendment. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to enforce the same. This Agreement may be amended, and any term of this Agreement may be modified, only by a written instrument executed by a duly authorized representative of each Party.

14.10 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

14.11 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

14.12 No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.

14.13 Further Assurances. Each of the Parties hereto agrees, upon the request of the other Party hereto, from time to time to execute and deliver to such other Party all such instruments and documents of further assurance or otherwise as shall be reasonable under the circumstances, and to do any and all such acts and things as may reasonably be required to carry out the obligations of such requested Party hereunder and to consummate the transactions provided for herein.

[SIGNATURE PAGE TO FOLLOW.]

In Witness Whereof, the Parties have executed this Agreement by their proper officers as of the date and year first above written.

AYTU BIOSCIENCE, INC.	**MAGNA PHARMACEUTICALS, INC.**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____

[SIGNATURE PAGE TO AMENDED AND RESTATED EXCLUSIVE LICENSE AGREEMENT]

SCHEDULE 1.32

LICENSOR TRADEMARKS

Mark	Serial #	Filing Date	USPTO Owner of Record
BETTER SLEEP. BETTER LIFE	86/915,013	2/22/16	MAGNA PHARMACEUTICALS, INC.
SLEEP REINVENTED. LIFE RETURNED.	86/895,571	2/3/16	MAGNA PHARMACEUTICALS, INC.

SCHEDULE 2.2

LICENSOR APPROVALS

New Drug Application No. 22-196 granted to NovaDel by the FDA on December 19, 2008 for zolpidem tartrate oral spray.

SCHEDULE 4.2

Delivered Inventory:

10,000 Zolpimist 30 dose units

Rechon Product Supply:

76,440 Aptar pumps

56,050 CR containers

Louisville Product Supply:

16,100 CR containers

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), Form S-3 (File No. 333-221735) and Form S-1 (File Nos. 333-207421, 333-205414, 333-209874, 333-210144, 333-212100, 333-213738, 333-213489, 333-220351, 333-222994, and 333-223385) of our report dated September 6, 2018, relating to the consolidated financial statements that appear in this Annual Report on Form 10-K.

Our report dated September 6, 2018 contains an explanatory paragraph that states that the Company's recurring losses from operations and accumulated deficit raise substantial doubt about the Company's ability to continue as a going concern, as discussed in Note 3 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ EKS&H LLLP

September 6, 2018
Denver, Colorado

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, 2018 of Aytu BioScience, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 6, 2018

/s/ Joshua R. Disbrow

Joshua R. Disbrow
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David A. Green, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended June 30, 2018 of Aytu BioScience, Inc.;

(2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

(3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects, the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

(4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in the report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: September 6, 2018

/s/ David A. Green

David A. Green
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

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, 2018, 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 David A. Green, Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: September 6, 2018

/s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer
(Principal Executive Officer)

/s/ David A. Green
David A. Green
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)