SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2019

☐ **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	☒	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 comply ing 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 ☒

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	AYTU	Nasdaq Capital Market

The aggregate market value of common stock held by non-affiliates of the Registrant as of December 31, 2018 was $6.9 million based on the closing price of $0.79 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, 2019, there were 17,688,071 shares of common stock issued and outstanding.

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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.

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.

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

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.

Reverse Stock Split

Our common stock began trading on the Nasdaq Capital Market on October 20, 2017. On August 13, 2018, we effected a reverse stock split of the outstanding shares of our common stock by a ratio of one-for-twenty (the "Reverse Stock Split"). Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth herein have, where applicable, been adjusted retroactively to reflect the Reverse Stock Split.

PART I

Item 1. Business

Company Overview

We are a specialty pharmaceutical company focused on identifying, acquiring, and commercializing novel products that address significant patient needs. We have multiple FDA-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 currently are focused on commercialization of four products, (i) Natesto®, a testosterone replacement therapy, or TRT, (ii) Tuzistra ® XR, a codeine based antitussive, (iii) ZolpiMist™, a short-term insomnia treatment and (iv), MiOXSYS ®, a novel in vitro diagnostic system for male infertility assessment. 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.

Corporate History

We were initially 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 Products and Markets

All of our products are sold and distributed through multiple channels, including direct sales to wholesalers or on a sell-through basis using third-party logistics enterprises.

Natesto® (testosterone) nasal gel

On July 1, 2016 we acquired the exclusive U.S. rights to Natesto (testosterone) nasal gel, from Acerus Pharmaceuticals Corporation, or Acerus. Natesto is a patented, FDA-approved testosterone replacement therapy (TRT) for hypogonadism (low testosterone) in men. Natesto offers multiple advantages over currently available TRTs and competes in a $1.8 billion market accounting for over 6.8 million prescriptions annually. It is the only TRT delivered via a nasal gel. 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. Recent clinical trials demonstrate that Natesto achieves hypogonadism symptom improvement, while maintaining function of the Hypothalamic-Pituitary-Gonadal (HPG) axis; and maintenance of reproductive parameters in patients.

We are positioning Natesto as the ideal treatment solution for hypogonadal men with active, busy lifestyles as Natesto is discreet, portable, and easy to use, while delivering efficacy and a safety profile unique to the TRT product category. 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. 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.

On July 29, 2019, we agreed to amend and restate the License and Supply Agreement with Acerus. The effectiveness of the amended Agreement is conditioned upon Acerus obtaining new financing within six months of signing of the amended Agreement. Aytu will continue to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus will receive performance-based commissions on prescriptions generated by urology and endocrinology specialties. Acerus will assume regulatory and clinical responsibilities and associated expenses and will serve a primary role in the development of key opinion leaders in urology and endocrinology. Aytu will focus on commercial channel management, sales to wholesalers and other purchasing customers, and will direct sales efforts in all other physician specialties.

Tuzistra® XR

On November 2, 2018, we obtained an exclusive license of FDA-approved Tuzistra® XR from Tris Pharma, or Tris. Tuzistra XR is the only FDA-approved 12-hour codeine-based antitussive. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension.

The cough and cold prescription market is in excess of $3 billion in sales and more than 30 – 35 million prescriptions. This market is dominated by short-acting treatments requiring 4 – 6 daily doses. Tuzistra utilizes a novel, patented extended release technology enabling 12-hour duration of antitussive effect, offering a significant dosing advantage over current codeine-based treatments.

In addition to Tuzistra XR, we also obtained a license for a complementary antitussive product pending FDA approval.

ZolpiMist™ (zolpidem tartrate oral spray)

On June 11, 2018, we acquired an exclusive license for ZolpiMist from Magna Pharmaceuticals, Inc., or Magna, which we formally launched through our U.S. sales force in early 2019. This agreement allows for our 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 our 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 the sales force to efficiently sell multiple products to these prevalent, high-prescribing clinicians.

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 annually for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets).

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. 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®. 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 reproductive medicine and men's health specialists to improve semen analysis and infertility assessments without having to refer patients to outside clinical laboratories.

MiOXSYS is currently marketed outside the U.S. as we advance MiOXSYS towards FDA clearance as an aid in the assessment of male infertility in the U.S. 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 prevalent and underserved, and oxidative stress is widely implicated in its pathophysiology. The global male infertility market is expected to grow to over $4.7 billion by 2025 with a compound annual growth rate, or CAGR, of nearly 4.6% 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, there is 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 male infertility. We expect to advance MiOXSYS into clinical trials in the U.S. in order to enable 510(k) de novo clearance in the coming twelve to eighteen months.

Our Strategy

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. Our strategy to create value for shareholders in the near-term is by implementing a focused, four-pronged strategy:

- ***Focus on sales growth of existing U.S. product portfolio.*** Our primary focus is on growing sales of Natesto in the U.S. and continuing to ramp-up the market launch of both Tuzistra XR and ZolpiMist through our sales force and strategic partners.
- ***Expand MiOXSYS*** Expand the MiOXSYS business outside the U.S. through continued market development, cultivation of key opinion leaders in large markets, and the advancement of clinical studies that further validate MiOXSYS's clinical utility in male infertility.
- ***Advance MiOXSYS toward FDA Clearance.*** MiOXSYS is already CE Marked, Health Canada, Australian TGA and Mexico COFEPRIS approved. We are focused on completing ongoing clinical trials in order to obtain FDA clearance for sale and distribution in the U.S. 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.
- ***Identify and license or acquire complimentary assets.*** 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 mergers, asset purchases, licensing, co-development, or collaborative commercial arrangements (including co-promotions and co-marketing arrangements).

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 if such efforts are necessary to achieve our strategic goals. Currently, we are developing one medical device candidate for approval by the FDA, the MiOXSYS System, for which regulatory approval must be received before we can market this within the U.S.

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 FDCA, 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.

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.

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.

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.

Drug Quality and Security Act

In 2013, the United States Congress passed the Drug Quality and Security Act ("DQSA"), amending the Federal Food, Drug and Cosmetic Act to grant the FDA more authority to regulate and monitor the manufacturing of compounding drugs. Title I of the DQSA increased regulation of compounding drugs. Title II of the DQSA *Drug Supply Chain Security,* established requirements to facilitate improved tracking of prescription drug products through the supply chain with increased product identification requirements. Currently, we are required to provide product identification information, or serialization, at the manufacturing batch, or lot level. However, going forward the law requires such tracking to done farther down the distribution chain including, (i) wholesalers authentification and verification in November 2019, (ii) pharmacy authentification and verification in the Fall of 2020, and at the unit level throughout the entire supply chain near the end of 2023.

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.

Reimbursement for our Products in the U.S.

Natesto, Tuzistra XR and ZolpiMist (our "US Approved Products") are covered by many commercial insurance providers and pharmacy benefit management companies and are dependent upon reimbursement for continued use in the U.S. market. Additionally, privately managed Medicare Part D and other government plans may choose to cover our U.S. Approved Products prescribed 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 prices generally tend to be lower than in the U.S.

DEA Regulation

Natesto, Tuzistra XR and ZolpiMist, already approved by the FDA, are each a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, because Natesto contains testosterone, ZolpiMist contains zolpidem tartrate, and Tuzistra XR contains codeine. As a result, the U.S. Drug Enforcement Agencies, or DEA, have Natesto and Tuzistra XR listed and regulated as Schedule III substances, while ZolpiMist is 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 and/or imported into 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

Natesto

Aytu has an exclusive license from Acerus Pharmaceuticals Corporation ("Acerus") 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.

On July 29, 2019, we agreed to amend and restate the License and Supply Agreement with Acerus. The effectiveness of the amended Agreement is conditioned upon Acerus obtaining new financing within six months of signing of the amended Agreement. Aytu will continue to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus will receive performance-based commissions on prescriptions generated by urology and endocrinology specialties. Acerus will assume regulatory and clinical responsibilities and associated expenses and will serve a primary role in the development of key opinion leaders in urology and endocrinology. Aytu will focus on commercial channel management, sales to wholesalers and other purchasing customers, and will direct sales efforts in all other physician specialties.

Tuzistra XR

Aytu has an exclusive license to commercialize Tuzistra XR in the US and, through this relationship, Aytu is listed as the Tuzistra XR New Drug Application holder and holder of two Orange Book listed patents protecting Tuzistra XR. Both patents cover the extended release technology supporting Tuzistra XR's long duration of antitussive effect, and the patents extend to March of 2029.

MiOXSYS

We have an extensive range of intellectual property for MiOXSYS. 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 MiOXSYS system, the sensors, and their clinical and scientific use in the U.S., Europe, Canada, Israel, Japan, and China.

Our patent portfolio related to MiOXSYS and the underlying oxidation-reduction potential (ORP) technology 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 44 issued patents and 18 pending applications.

The portfolio primarily consists of eight families filed in the U.S. and in core foreign jurisdictions. The first family includes thirteen issued patents 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, three issued U.S. patents, one pending application 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 nineteen issued patents 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 two issued U.S. patents, 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, one issued U.S. patent 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 application filed under the Patent Cooperation Treaty with claims directed to methods of treating infertility in varicocele patients.

We have also exclusively licensed the issued and pending patents protecting Natesto. There are four FDA Orange Book-listed patents surrounding methods of use of a nasally-administered testosterone gel and formulations thereof. The standard 20-year expiration for patents across these four patents is 2024.

There are two FDA Orange Book-listed patents protecting Tuzistra XR. Through our exclusively commercialization agreement with TRIS Pharma, we are the FDA-recognized New Drug Application holder and thus the designated holder of these patents. The first patent describes a coated ion-exchange resin complex delivering an extended release formulation and methods therein. The standard 20-year exclusivity for this patent is in 2029. The second patent covers an aqueous liquid suspension containing a drug-ion exchange resin complex and methods therein. The standard 20-year exclusivity for this patent is in 2027.

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.

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.

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.

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

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.

Tuzistra XR

Tuzistra XR competes in the approximately $3.0 billion antitussive category and has a distinct advantage over the existing codeine-based antitussives. Tuzistra XR is the only liquid codeine antitussive with a 12-hour duration of effective, which provides more dosing convenience than the current 4-6 hour codeine cough syrups.

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

The research and development required for FDA approval of Natesto, ZolpiMist, and Tuzistra XR has been conducted by either previous owners of the products or the companies from which we licensed or acquired these products. To the extent we seek to further develop our products and/or improve clinical claims. we rely upon outside collaborators to conduct research as we focus primarily on commercialization.

Currently, there is an ongoing investigator-initiated study for Natesto. We are financially supporting the study being conducted at the University of Miami, through which the investigators seek to demonstrate that Natesto improves hypogonadism while preserving fertility. The study has been designed and is led by Dr. Ranjith Ramasamy, MD, Director of Reproductive Urology at the University of Miami's Department of Urology. The study is expected to be completed in 2019. If found to preserve fertility, Natesto would be the first TRT to demonstrate this and, we expect, these results would further support the clinical differentiation of Natesto in the TRT category.

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.

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.

Tuzistra XR

On November 5, 2018 we entered into a licensing, manufacturing and supply agreement with TRIS, pursuant to which TRIS has the exclusive rights to manufacture, label, package and supply us Tuzistra XR on an exclusive basis in the U.S. We expect to continue to source Tuzistra XR under this arrangement for the term of the agreement with TRIS.

ZolpiMist

On June 11, 2018 we entered into a licensing agreement with Magna, 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 and subsequent purchase of product that we expect to supply us for the foreseeable future.

MiOXSYS

We secured supply and quality agreements with manufacturers for both the MiOXSYS instrument as well as MiOXSYS sensor strips. Both manufacturers hold long-standing ISO 13485:2003 certifications and are established medical device manufacturers. Both manufacturers have high volume manufacturing capacity such that production volumes can be easily scaled. Both manufacturers have been audited by our quality engineers and are fully compliant.

Employees

As of August 31, 2019, we had 53 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, 2019 and 2018 was $27.1 million and $10.2 million, 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, Tuzistra XR, 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, Tuzistra XR and ZolpiMist are each an approved drug that we are marketing, we only acquired Natesto in April 2016, ZolpiMist in June 2018, and Tuzistra XR in November 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, Tuzistra XR, 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, 2019, our cash, cash equivalents and restricted cash totaling $11.3 million, available to fund our operations offset by an aggregate $3.4 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, Tuzistra XR, 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, Tuzistra XR, 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, Tuzistra XR 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, Tuzistra XR 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, 2019 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, Tuzistra XR, 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. 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, Tuzistra XR, 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, Tuzistra XR, 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 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 delays, 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, Tuzistra XR 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. We have an agreement for supplies of Tuzistra XR with Tris, from whom we license Tuzistra XR. 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.

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, Tuzistra XR, 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, Tuzistra XR and ZolpiMist, which are 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, Tuzistra XR 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.

There is a risk we may unable to sell and distribute certain of our products if we cannot comply with the serialization requirements of the Drug Quality and Security Act within the necessary time frames.

Title II of the Drug Quality and Security Act of 2013 provided increased FDA oversight over the ability to track and monitor the sale and distribution of prescription drugs. Over time, the level within the supply chain for which prescription drugs are to be tracked gets farther and farther down the chain. Currently, we are required to provide product identification information, or serialization, at the manufacturing batch, or lot level. However, going forward the law requires such tracking to done farther down the distribution chain including, (i) wholsaler authentification and verification in November 2019, (ii) pharmacy authentification and verification in the Fall of 2020, and at the unit level throughout the entire supply chain near the end of 2023. There is no guarantee that we will be able to satisfy each ever-stringent product identification requirements. Failing to do so could result in a delay or inability to sell our products within the United States of America.

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 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.

We may renegotiate any of our existing license agreements or other material contracts on terms that might not be received by the market as favorable.

From time to time we may renegotiate the terms of our existing licensing agreements. There can be no guarantee that the terms of the renegotiated license agreement or other material contract will be viewed favorably by the market as evidenced by our stock price although the renegotiated terms might be advantageous to our business.

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

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

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

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

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

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

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

The patent positions of pharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the 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

Armistice Capital, LLC and Armistice Capital Master Fund Ltd. (collectively, "Armistice") own a significant percentage of our stock and Steven Boyd, the managing member of Armistice Capital, LLC and director of Armistice Master Fund is a member of our board of directors. As a result, Armistice could be able to exert significant control over us.

Since 2017, Armistice has invested approximately $14.6 million in our company through the purchase of our common stock, preferred stock and warrants in a series of our financings. Many of the securities Armistice holds limits their ability to beneficially own in excess of 4.99% or 9.99% of our common stock. However, the Series E Preferred Stock Armistice holds permits Armistice to convert the Series E Preferred Stock into shares of common stock so long as their ownership percentage in us does not exceed 40%. On April 15, 2019, Steven Boyd was appointed to our board of directors. The significant ownership interest Armistice has, the significant investment that they have made in our company, and Steven Boyd's position on our board of directors could give Armistice 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 40% 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.

We intend to acquire, through mergers, 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 mergers, 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, ZolpiMist in June 2018, and Tuzistra XR in November 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 2019, 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.

In fiscal 2019, four customers contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2019 and 2018, respectively. As of June 30, 2019, four customers accounted for 87% of gross revenue. 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, 2019, four customers accounted for 88% of gross accounts receivable. As of June 30, 2018, four customers accounted for 93% of gross accounts receivable.

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, 2019, we had 61 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, 2019, we had federal net operating loss carryforwards of approximately $73.8 million. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2025 and will, except for certain indefinite-lived net operating loss carryforwards, will completely expire in 2038. 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 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 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.

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, 2019, options to purchase 1,607 shares of common stock issued under our 2015 Stock Plan at a weighted average exercise price of $325.73 per share were outstanding. In addition, at June 30, 2019, there were outstanding warrants to purchase an aggregate of 16,459,663 shares of our common stock at a weighted average exercise price of $4.16. 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 August 2015, we 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. In April 2019, the Company extended the lease for an additional 36 months beginning October 1, 2020.

In June 2015, we 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.

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. The following table sets forth the range of high and low sales prices on the NASDAQ Capital Market, as applicable, for the periods shown.

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

Fiscal Year ended June 30, 2019	**High**	**Low**
First Quarter (ended September 30, 2018)	$ 7.80	$ 2.40
Second Quarter (ended December 31, 2018)	$ 3.23	$ 0.68
Third Quarter (ended March 31, 2019)	$ 2.53	$ 0.78
Fourth Quarter (ended June 30, 2019)	$ 2.61	$ 1.50

On August 30, 2019, the closing price as reported on the NASDAQ of our common stock was $1.39. As of August 31, 2019, there were 489 holders of record of our common stock.

Equity Compensation Plan Information

In June 2015, our shareholders approved the adoption of a stock and option award plan (the "2015 Plan"). At the Special meeting of stockholders on July 26, 2017, the Aytu Stockholders voted to increase the plan to 3.0 million shares. The 2015 Plan permits grants of equity awards to employees, directors and consultants. The following table displays equity compensation plan information as of June 30, 2019 relating to securities reserved for future issuance upon exercise.

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 Remainin Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)**
Equity compensation plans approved by security holders	1,607	$ 325.73	652,179
Equity compensation plans not approved by security holders	1,624	$ 594.63	-
Total	3,231	$ 460.89	652,179

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 thew 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

We are a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs such as hypogonadism (low testosterone), cough and upper respiratory symptoms, insomnia, and male infertility and plans to expand opportunistically into other therapeutic areas as we continue to execute on our growth plans.

Prior to the date of this Annual 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, we have raised approximately $70.3 million from the sale of our 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. Revenues have increased 100% and 14% for each of the years ended June 30, 2019 and 2018, respectively, and is expected to continue to increase, allowing us to rely less on our existing cash balance and proceeds from financing transactions. Despite increased revenue, cash used in operations during fiscal year 2019 was $13.8 million compared to $16.0 million in 2018, due to our completing the build-out of our commercial infrastructure in 2019. As of the date of this Annual Report, we expect our commercial costs to remain approximately flat or to increase modestly as we continue to focus on revenue growth.

Our current asset position of $34.8 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 favorable to us 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 we do not have sufficient cash and cash equivalents on-hand as of June 30, 2019, to cover potential net cash outflows for the twelve months following the filing date of this Annual Report, ASU 2014-15, Presentation of Financial Statements—Going Concern (Subtopic 205-40) requires us to report that there exists an indication of substantial doubt about our ability to continue as a going concern.

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, 2019, we had an accumulated deficit of $106.4 million. Our net loss increased to $27.1 million from $10.2 million for years ended June 30, 2019 and 2018, respectively. We used $13.8 million and $16.0 million in cash from operations during the years ended June 30, 2019 and 2018, respectively.

Results of Operations

Comparison of the years ended June 30, 2019 and 2018

	Year Ended June 30,		
	2019	2018	Change
Revenues			
Product revenue, net	$ 7,314,581	$ 3,660,120	$ 3,654,461
License revenue, net	5,776	-	5,776
Total product revenue	7,320,357	3,660,120	3,660,237
Operating expenses			
Cost of sales	2,202,041	2,050,544	151,497
Research and development	589,072	167,595	421,477
Selling, general and administrative	18,887,783	17,732,490	1,155,293
Selling, general and administrative - related party (Note 14)	351,843	-	351,843
Impairment of intangible assets	-	1,856,020	(1,856,020)
Amortization of intangible assets	2,136,255	1,553,705	582,550
Total operating expenses	24,166,994	23,360,354	806,640
Loss from operations	(16,846,637)	(19,700,234)	2,853,597
Other (expense) income			
Other (expense), net	(535,500)	(749,423)	213,923
(Loss) / gain from contingent consideration	(9,830,550)	6,277,873	(16,108,423)
Gain from warrant derivative liability	80,779	3,983,921	(3,903,142)
Total other (expense) income	(10,285,271)	9,512,371	(19,797,642)
Net loss	$ (27,131,908)	$ (10,187,863)	$ (16,944,045)

Product revenue. During the year ended June 30, 2019, we recognized revenue of $7.3 million associated with the sale of our products, an increase of approximately $3.7 million compared to the same period ended June 30, 2018. The increase was the result of the combination of increased overall product units sold during the 2019 fiscal year. Increased sales volumes were due to the combination of (i) increased Natesto sales due to our further commercialization of the Natesto product line and, (ii) the acquisition and deployment of the Tuzistra XR and ZolpiMist products during the year ended June 30, 2019. This was offset by the discontinuation of the Primsol, ProstaScint and Fiera product lines during the year ended June 30, 2018.

Cost of sales. Cost of sales increased approximately $0.2 million during the year ended June 30, 2019 compared to the same period ended June 30, 2018. The increase was the result of increased volumes of products due to continued commercialization efforts. The prior year cost of goods sold included write-offs of inventory related to the Fiera product line.

Research and Development. Research and development expenses increased $0.4 million, or 251.5%, in fiscal 2019 compared to fiscal 2018. The increase was due primarily to the prior year reversal of 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 2020 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.

Selling, General and Administrative. Selling, general and administrative costs increased $1.5 million, or 8.5%, for the year ended June 30, 2019 compared the same period in 2018. The primary increase was due to labor, occupancy, travel and other and sales & marketing related to expanding our commercial team, launching Tuzistra XR, and stock-based compensation. The impairment expense of $1.9 million recognized in fiscal 2018, represent the impairment of the Aytu Women's Health assets based upon sales performance and the manufacturer no longer supporting the product.

Selling, General and Administrative – Related Party. Selling, general and administrative costs – related party are relate to the cost of a services provided by TrialCard, of which one of our Directors, Mr. Donofrio, was an employee for a period of time during the year ended June 30, 2019.

Impairment of Intangible Assets. We did not incur any impairment losses on any intangible assets for the year ended June 30, 2019. We recognized an impairment loss of approximately $1.9 million for the year ended June 30, 2018 relating to the discontinuation of the Fiera product line as a result of lower than expected sales combined with the contract manufacturer ending production.

Amortization of Intangible Assets. Amortization expense for the remaining intangible assets was $2.1 million and $1.6 million for the years ended June 30, 2019 and 2018, respectively. This expense is related to corresponding amortization of our finite-lived intangible assets.

Liquidity and Capital Resources

	Year ended June 30,	
	2019	2018
Net cash used in operating activities	$ (13,831,377)	$ (15,940,322)
Net cash used in investing activities	$ (1,061,985)	$ (484,292)
Net cash provided by financing activities	$ 19,075,062	$ 22,659,599

Net Cash Used in Operating Activities

During fiscal 2019, net operating cash outflows totaled $13.8 million. The use of cash was approximately $13.3 million less than the net loss due primarily to non-cash charges for stock-based compensation, issuance of restricted stock, depreciation, amortization and accretion, other loss and an increase in accounts payable, accrued liabilities and accrued compensation. These charges were offset by an increase in accounts receivable, inventory, prepaid expenses, and derivative income.

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.

Net Cash Used in Investing Activities

During fiscal 2019, net investing cash outflows totaled $1.1 million was used to acquire $0.8 million of intangible assets relating to our products, paydown of $0.2 million of a contingent consideration obligation relating to our products, and the purchase of approximately $0.1 million in fixed assets.

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.

Net Cash from Financing Activities

Net cash of $19.1 million provided by financing activities during fiscal 2019 was primarily related to the October 2018 public offering of $15.2 million, offset by the offering cost of $1.5 million which was paid in cash. In addition, we received proceeds of $5 million from a collateralized promissory note issued to Armistice Capital (see Note 14). We also received proceeds of $375,000 from warrant exercises.

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.

Contractual Obligations and Commitments

Information regarding our Contractual Obligations and Commitments is contained in Note 16 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, 2019. 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, 2019, our internal control over financial reporting is effective based on these criteria.

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting, known to the chief executive officer or the chief financial officer that occurred during the period covered by this Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers, and Corporate Governance

The following table sets forth the names and ages of all of our directors and executive officers as of August 31, 2019. 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	44	Chairman and Chief Executive Officer
Jarrett T. Disbrow	44	Chief Operating Officer
David A. Green	57	Chief Financial Officer, Secretary, and Treasurer
Michael E. Macaluso	67	Director
Carl C. Dockery	56	Director
John A. Donofrio, Jr.	51	Director
Gary V. Cantrell	64	Director
Ketan Mehta	58	Director
Steven J. Boyd	38	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 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.

Ketan Mehta - Director

Ketan Mehta has been a member of our Board of Directors since November 2018. Mr. Mehta is the Founder, President, and Chief Executive Officer of Tris Pharma, a fully-integrated specialty pharmaceutical company focused on developing and commercializing advanced delivery technologies. Ketan founded Tris in 2,000 and has built the company into a leading specialty pharmaceutical company with over 500 employees.Tris develops, manufactures, licenses, and commercializes both branded and generic products directly and through commercial partnerships with both large and emerging pharmaceutical companies. Tris has developed many pharmaceutical technologies, including its extended-release platform LiquiXR® and holds over 150 patents in the U.S. and around the world. Before founding Tris Pharma, Ketan worked for Capsugel (formerly a division of Pfizer) in sales, marketing and business development for eight years. Prior to Capsugel, he spent approximately six years as a pharmaceutical scientist for three different large pharmaceutical companies. Ketan is a pharmacist by education and holds an MS degree in Pharmaceutical Sciences from the University of Oklahoma. Mr. Mehta's experience as a founder and CEO of a pharmaceutical company, led to the conclusion that he should serve as a director of our company in light of our business and structure.

Steven J. Boyd - Director

Ketan Mehta has been a member of our Board of Directors since April 2019. Mr. Boyd is the Founder and Chief Investment Officer of Armistice Capital, a healthcare equity hedge fund he founded in 2012. Prior to founding Armistice, Mr. Boyd was a Research Analyst at Senator Investment Group, York Capital, and SAB Capital Management, where he focused on healthcare. Mr. Boyd began his career as an Analyst at McKinsey & Company. Mr. Boyd has served as a member of the board of directors of Cerecor (NASDAQ: CERC), an integrated biopharmaceutical company focused on pediatric healthcare, since April 2017 and EyeGate Pharmaceuticals (NASDAQ: EYEG), a clinical-stage, specialty pharmaceutical company focused on disorders of the eye, since May 2018. Mr. Boyd received a B.S. in Economics and a B.A. in Political Science from The Wharton School of the University of Pennsylvania. Mr. Boyd's experience in the capital markets and strategic transactions, and his focus on the healthcare industry, 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 Master 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. Macaluso and Mr. Dockery. Our Compensation Committee consists of Mr. Macaluso (Chair), Mr. Cantrell, 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, 2019.

Name	Fees Earned or Paid in Cash	All Other Compensation (1)	Total
Gary V. Cantrell (2)	$ 41,875	$ 194,850	$ 236,725
Carl C. Dockery (2)	$ 45,000	$ 194,850	$ 239,850
John A. Donofrio Jr. (2)	$ 45,000	$ 194,850	$ 239,850
Michael E. Macaluso (2)	$ 28,125	$ 259,800	$ 287,925
Ketan Mehta (2)	$ 14,583	$ 84,435	$ 99,018
Steven J. Boyd (2)	$ –	$ –	$ –

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

(2) As of June 30, 2019, the number of restricted shares held by each non-employee director was as follows: 152,663 restricted shares for Mr. Cantrell; 152,663 restricted shares for Mr. Dockery; 152,663 restricted shares for Mr. Donofrio; 202,663 restricted shares for Mr. Macaluso; 65,000 restricted shares for Mr. Mehta.

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, 2019 and 2018 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	2019	$ 330,000	$ 135,000	$ 578,705	$ –	$ –	$ –	$ –	$ 1,043,705
since December 2012	2018	$ 303,000	$ –	$ 303,000	$ –	$ –	$ –	$ –	$ 606,000
Jarrett T. Disbrow									
Chief Operating Officer	2019	$ 250,000	$ 105,000	$ 438,413	$ –	$ –	$ –	$ –	$ 793,413
since April 2015	2018	$ 250,000	$ –	$ 202,000	$ –	$ –	$ –	$ –	$ 452,000
David A. Green (2)									
Chief Financial Officer, Secretary	2019	$ 250,000	$ 95,000	$ 340,988	$ –	$ –	$ –	$ –	$ 685,988
and Treasurer, since December 2017	2018	$ 135,000	$ –	$ 152,000	$ –	$ –	$ –	$ –	$ 287,000
Gregory A. Gould (3)									
Chief Financial Officer	2019	$ –	$ –	$ –	$ –	$ –	$ –	$ –	$ –
	2018	$ 96,000	$ –	$ –	$ –	$ –	$ –	$ –	$ 96,000

(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 9 — Fair Value Considerations .”

(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, 2019:

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	10/24/2018	445,500	$ 1.30	$ 578,705
Jarrett T. Disbrow	10/24/2018	337,500	$ 1.30	$ 438,413
David A. Green	10/24/2018	262,500	$ 1.30	$ 340,988

(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 2019

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2019.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)	Equity Incentie Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Named Executive Officers									
Joshua R. Disbrow	125	–	–	$ 328.00	11/11/2025	453,475	$ 857,068	–	$ –
Joshua R. Disbrow	100	50	–	$ 328.00	7/7/2026	–	$ –	–	$ –
Jarrett T. Disbrow	125	–	–	$ 328.00	11/11/2025	342,913	$ 648,106	–	$ –
Jarrett T. Disbrow	100	50	–	$ 328.00	7/7/2026	–	$ –	–	$ –
David A. Green	–	–	–	$ –		266,250	$ 503,213	–	$ –

(1) Based on $1.89 per share which was the closing price of our common stock on NASDAQ on June 28, 2019, 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 $330,000 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 15, 2019, 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 15, 2019, 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 1/24th 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, 2019, would be the acceleration of the vesting of all options held by them at that date. On June 30, 2019, 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, 2019 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, 2019. The percentage ownership information shown in the table is based upon 17,688,071 shares of common stock outstanding as of August 31, 2019.

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, 2019. 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.

		Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders			
Armistice Capital, LLC	(1)	16,504,008	57.06%
Directors and Named Officers			
Disbrow, Joshua	(2)	492,830	2.81%
Disbrow, Jarrett	(3)	377,256	2.15%
Green, Dave	(4)	274,580	1.57%
Macaluso, Michael	(5)	202,843	1.16%
Dockery, Carl	(6)	154,795	*
Cantrell, Gary	(7)	152,878	*
Donofrio, John	(8)	152,701	*
Ketan Mehta	(9)	65,000	*
All directors and executive officers as a group (either persons)		1,872,833	10.65%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 3,12,064 shares, (ii) 2,000,000 shares indirectly held by Armistice Capital, (iii) 2,751,148 preferred shares, and (iv) 8,632,796 shares issuable upon the exercise of warrants.

(2) Consists of (i) 16,573 shares, (ii) 453,475 restricted shares, (iii) 225 vested options to purchase shares of stock, and (iv) 22,557 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 (i) 16,562 shares, (ii) 342,913 restricted shares, (iii) shares underlying 225 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.

(4) Consists of (i) 5,000 shares, (ii) 266,250 restricted shares, (iii) 3,330 shares issuable upon the exercise of warrants.

(5) Consists of (i) 75 shares, (ii) 202,663 restricted shares, and (iii) vested options to purchase 105 shares of common stock.

(6) Consists of (i) 152,663 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.

(7) Consists of (i) 152,663 restricted shares, (ii) 177 shares, and (iii) vested options to purchase 38 shares of common stock.

(8) Consists of (i) 152,663 restricted shares, and (ii) vested options to purchase 38 shares of common stock.

(9) Consists of restricted 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.

Armistice

In February 2019, the Company waived its right to disallow Armistice from holding more than 4.99% of Aytu common stock and agreed to allow Armistice to hold up to 40% of the outstanding shares of our common stock. Also, in February 2019, Armistice converted 1.9 million shares of Series C preferred stock into Aytu common stock, resulting in Armistice holding more than 10% of the Company's common stock. The Company also had a promissory note to Armistice with a face value of $5.0 million, which was subsequently exchanged for a combination of common stock, preferred stock and warrants. Therefore, Armistice is now considered an affiliate of the Company.

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, Aytu will prefund certain amounts from which TCI will make disbursements to qualified patients presenting valid prescriptions for Natesto, Tuzistra XR 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. One of the Aytu directors, Mr. Donofrio, was an executive officer of TCI but has no direct interest in the arrangement. As of February 2019, Mr. Donofrio is no longer employed by TCI.

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.

Six of our seven directors are independent under the definition of NASDAQ. Josh Disbrow is not independent under either definition due to being an executive officer of our Company.

Item 14. Principal Accountant Fees and Services

Plante Moran, PLLC, or Plante Moran, (formerly known as 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, 2019.

The following table presents aggregate fees for professional services rendered by our independent registered public accounting firm, Plante Moran, for the audit of our annual financial statements for the respective periods.

	Year Ended June 30,	
	2019	2018
Audit fees (1)	$ 154,000	$ 223,000
Audit related fees (2)	55,000	52,000
Tax fees (3)	–	–
Total fees	$ 209,000	$ 275,000

(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 2019 and 2018 were comprised of fees related to registration statements, including for our August 2017 private offering, S-3 filing, our March 2018 public offering, and October 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.

- Reports of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of June 30, 2019 and 2018
- Consolidated Statements of Operations for the years ended June 30, 2019 and 2018
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2019 and 2018
- Consolidated Statements of Cash Flows for the years ended June 30, 2019 and 2018
- 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 effective June 3, 2015	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 Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed on March 2, 2018	S-1/A	2/27/18	3.6	
3.7	Certificate of Amendment to the Restated of Certificate of Incorporation, effective August 10, 2018	8-K	8/10/18	3.1	
3.8	Amended and Restated Bylaws	8-K	6/09/15	3.2	
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock,	10-Q	2/7/19	10.4	
4.1	Form of Placement Agent Warrant issued in 2015 Convertible Note Financing	8-K	7/24/15	4.2	
4.2	Warrant Agent Agreement, dated May 6, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC	8-K	5/6/16	4.1	
4.3	First Amendment to May 6, 2016 Warrant Agent Agreement between Aytu BioScience, Inc. and VStock Transfer LLC	S-1	9/21/16	4.5	
4.4	Warrant Agent Agreement, dated November 2, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC	8-K	11/2/16	4.1	
4.5	Form of Amended and Restated Underwriters' Warrant (May 2016 Financing)	8-K	3/1/17	4.1	
4.6	Form of Amended and Restated Underwriters' Warrant (October 2016 Financing)	8-K	3/1/17	4.2	
4.7	Form of Common Stock Purchase Warrant issued on August 15, 2017	8-K	8/16/17	4.1	
4.8	Form of Common Stock Purchase Warrant for March 2018 Offering	S-1	2/27/18	4.8	
10.2#	Asset Purchase Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Valeant International (Barbados) SRL, effective as of December 2, 2011	8-K/A	6/08/15	10.4	
10.3#	Manufacturing and Supply Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Ethypharm S.A., dated September 10, 2012	8-K/A	6/08/15	10.5	
10.4	License, Development and Commercialization Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Daewoong Pharmaceuticals Co., Ltd., effective as of August 23, 2011				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

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
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	
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	8/31/2017	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	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.31	Amended and Restated Exclusive License Agreement, dated June 11, 2018, between Aytu BioScience, Inc. and Magna Pharmaceuticals, Inc.				X
10.32	Promissory Note, dated November 29, 2018, between Aytu BioScience, Inc. and Armistice Capital Master Fund Ltd	8-K	11/29/18	10.1	
10.33	Waiver of Blocker	10-Q	2/7/19	10.6	
10.34	Common Stock Purchase Warrant	10-Q	2/7/19	10.5	
10.35	Exchange Agreement, dated February 5, 2019	10-Q	2/7/19	10.3	
10.36	License, Development,Manufacturing and Supply Agreement, dated November 2, 2018	10-Q	2/7/19	10.2	
10.37	Amendment No.1 to Securities Purchase Agreement	8-K	4/26/19	10.1	
10.38	Independent Contractor Services Agreement	8-K	5/2/19	10.1	
10.39	Second Amendment to Lease Agreement, dated April 4, 2019	10-Q	5/14/19	10.3	
10.40	Empolyment Agreement with Jarret T. Disbrow, dated April 16, 2019	10-Q	5/14/19	10.2	
10.41	Employment Agreement with Joshua R. Disbrow, dated April 16, 2019	10-Q	5/14/19	10.1	
10.42	Amended and restated License and Supply Agreement with Acerus Pharmaceuticals, dated July 29, 2019	8-K	8/2/19	10.1	
23.1	Consent of Plante & Moran, PLLC, Independent Registered Public Accounting Firm.				X
23.2	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 26, 2019

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, 2019.

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
/s/ Steven Boyd Steven Boyd	Director
/s/ Ketan Mehta Ketan Mehta	Director

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS
AYTU BIOSCIENCE, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Aytu BioScience, Inc (the "Company") as of June 30, 2019, the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2019, and the results of its operations and its cash flows for the year then ended, 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

The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on the Company's financial statements based on our audit. 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 audit 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 audit 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 audit 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 audit provides a provides a reasonable basis for our opinion.

Change in Accounting Principle

As discussed in Note 1 to the financial statements, the Company adopted Accounting Standards Codification (ASC) Topic 606, "Revenue from Contracts with Customers," using the modified retrospective adoption method on July 1, 2018.

/s/ Plante & Moran, PLLC

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

Denver, CO
September 26, 2019

Report of Independent Public Accounting Firm

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

OPINIONS ON THE FINANCIAL STATEMENTS

We have audited the accompanying consolidated balance sheet of Aytu BioScience, Inc. (the "Company") as of June 30, 2018, and the related consolidated statements of operations, stockholders' equity, and cash flows, for the year ended June 30, 2018, and the related notes (collectively referred to as the "financial statements").

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2018, and the results of its operations and its cash flows for the year 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

We conducted our audit 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.

/s/ EKS&H LLLP

September 6, 2018
Denver, Colorado

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Balance Sheets

	June 30, 2019	June 30, 2018
Assets		
Current assets		
Cash and cash equivalents	$ 11,044,227	$ 7,012,527
Restricted cash	250,000	100,000
Accounts receivable, net	1,740,787	578,782
Inventory, net	1,440,069	1,338,973
Prepaid expenses and other	957,781	440,009
Total current assets	15,432,864	9,470,291
Fixed assets, net	203,733	218,684
Licensed assets, net	18,861,983	11,120,086
Patents, net	220,611	245,944
Deposits	2,200	5,088
Total long-term assets	19,288,527	11,589,802
Total assets	$ 34,721,391	$ 21,060,093
Liabilities		
Current liabilities		
Accounts payable and other	$ 2,297,270	$ 2,119,672
Accrued liabilities	1,147,740	185,882
Accrued compensation	849,498	540,674
Current deferred rent	–	1,450
Current contingent consideration	1,078,068	547,100
Total current liabilities	5,372,576	3,394,778
Long-term contingent consideration	22,247,796	4,146,829
Warrant derivative liability	13,201	93,981
Total liabilities	27,633,573	7,635,588
Commitments and contingencies (Note 16)		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; shares issued and outstanding 3,594,981 and 0, respectively as of June 30, 2019 and 2018	359	–
Common Stock, par value $.0001; 100,000,000 shares authorized; shares issued and outstanding 17,538,071 and 1,794,762, respectively as of June 30, 2019 and 2018	1,754	179
Additional paid-in capital	113,475,205	92,681,918
Accumulated deficit	(106,389,500)	(79,257,592)
Total stockholders' equity	7,087,818	13,424,505
Total liabilities and stockholders' equity	$ 34,721,391	$ 21,060,093

See the accompanying Notes to the Consolidated Financial Statements.

AYTU BIOSCIENCE, INC. AND SUBSIDIARY
Consolidated Statements of Operations

	Year Ended June 30,	
	2019	**2018**
Revenues		
Product revenue, net	$ 7,314,581	$ 3,660,120
License revenue, net	5,776	–
Total product revenue	7,320,357	3,660,120
Operating expenses		
Cost of sales	2,202,041	2,050,544
Research and development	589,072	167,595
Selling, general and administrative	18,887,783	17,732,490
Selling, general and administrative - related party (Note 14)	351,843	–
Impairment of intangible assets	–	1,856,020
Amortization of intangible assets	2,136,255	1,553,705
Total operating expenses	24,166,994	23,360,354
Loss from operations	(16,846,637)	(19,700,234)
Other (expense) income		
Other (expense), net	(535,500)	(749,423)
(Loss) / gain from change in fair value of contingent consideration	(9,830,550)	6,277,873
Gain from warrant derivative liability	80,779	3,983,921
Total other (expense) income	(10,285,271)	9,512,371
Net loss	$ (27,131,908)	$ (10,187,863)
Weighted average number of common shares outstanding	7,794,489	665,605
Basic and diluted net loss per common share	$ (3.48)	$ (15.31)

See the accompanying Notes to the Consolidated 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, 2017	–	$ –	41,244	$ 4	$ 73,069,541	$ (69,069,729)	$ 3,999,816
Stock-based compensation	–	–	38,350	4	596,930	–	596,934
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
Stock-based compensation	–	$ –	2,681,422	$ 270	$ 1,021,931	$ –	$ 1,022,201
Common stock issued to employee	–	–	9,000	1	11,689	–	11,690
Issuance of preferred, common stock and warrants, net of $1,479,963 in cash issuance costs	8,342,993	834	1,777,007	178	11,810,373	–	11,811,385
Warrants issued in connection with the registered offering	–	–	–	–	1,827,628	–	1,827,628
Warrants issued in connection with the registered offering to the placement agents, non-cash issuance costs	–	–	–	–	61,024	–	61,024
Preferred stock converted into common stock	(7,899,160)	(790)	7,899,160	789	1	–	–
Issuance of preferred stock	400,000	40	–	–	519,560	–	519,600
Issuance of preferred, common stock related to debt conversion	2,751,148	275	3,120,064	312	4,666,897	–	4,667,484
Warrants issued in connection with debt conversion	–	–	–	–	499,183	–	499,183
Warrants exercised	–	–	250,007	25	375,001	–	375,026
Rounding from reverse stock split	–	–	6,649	–	–	–	–
Net loss	–	–	–	–	–	(27,131,908)	(27,131,908)
BALANCE - June 30, 2019	3,594,981	$ 359	17,538,071	$ 1,754	$ 113,475,205	$ (106,389,500)	$ 7,087,818

See the accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended June 30,	
	2019	2018
Operating Activities		
Net loss	$ (27,131,908)	$ (10,187,863)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	2,727,067	2,591,270
Impairment of intangible assets	–	1,856,020
Stock-based compensation expense	1,022,202	596,934
Loss / (gain) from change in fair value of contingent consideration	9,830,550	(6,277,873)
Warrants issuance and amendments	–	183,920
Issuance of common stock to employee	11,690	–
Derivative income	(80,779)	(3,983,921)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(1,162,005)	(50,743)
(Increase) decrease in inventory	(101,096)	(26,752)
(Increase) in prepaid expenses and other	(517,772)	(129,249)
Increase / (decrease) in accounts payable and other	134,775	(109,707)
Increase / (decrease) in accrued liabilities	961,858	(596,654)
Increase in accrued compensation	308,824	200,970
Increase in interest payable - related party	166,667	–
(Decrease) in deferred rent	(1,450)	(6,674)
Net cash used in operating activities	(13,831,377)	(15,940,322)
Investing Activities		
Deposit	2,888	(2,200)
Purchases of fixed assets	(59,848)	(74,707)
Contingent consideration payment	(505,025)	(7,385)
Purchase of assetsÏ	(500,000)	(400,000)
Net cash used in investing activities	(1,061,985)	(484,292)
Financing Activities		
Issuance of preferred, common stock and warrants	15,180,000	11,839,995
Issuance costs related to preferred, common stock and warrants	(1,479,964)	(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	375,026	677,100
S-3 registered offering cost	–	(60,450)
Proceeds of debt - related party	5,000,000	–
Net cash provided by financing activities	19,075,062	22,659,599
Net change in cash, restricted cash and cash equivalents	4,181,700	6,234,985
Cash,restricted cash and cash equivalents at beginning of period	7,112,527	877,542
Cash,restricted cash and cash equivalents at end of period	$ 11,294,227	$ 7,112,527
Supplemental disclosures of cash and non-cash investing and financing transactions		
Warrants issued to investors and underwriters (see Note 13)	$ 1,888,652	$ 4,117,997
Warrant exercise of derivative warrants	–	40,096
Contingent consideration included in accounts payable	42,821	8,980
Earn-out payment to Nuelle Shareholders	–	250,000
Purchase of asset included in contingent consideration	–	293,216
Contingent consideration related to product acquisition (Note 4)	8,833,219	2,553,169
Issuance of preferred stock related to purchase of assets	519,600	–
Conversion of debt to equity	5,166,667	–

There was no cash paid for interest for the years ended

See the accompanying Notes to the Consolidated Financial Statements.

1. Nature of Business and Financial Condition

Nature of Business. Aytu BioScience, Inc. ("Aytu", or the "Company", which, unless otherwise indicated, refers to Aytu, Inc. and its subsidiaries) was incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado. Aytu was re-incorporated in the state of Delaware on June 8, 2015. Aytu is a specialty pharmaceutical company focused on global commercialization of novel products addressing significant medical needs such as hypogonadism (low testosterone), cough and upper respiratory symptoms, insomnia, and male infertility and plans to expand opportunistically into other therapeutic areas.

The Company is currently focused on commercialization of four products, (i) Natesto®, a testosterone replacement therapy, or TRT, (ii) Tuzistra ® XR, a codeine–based antitussive, (iii) ZolpiMist™, a short-term insomnia treatment and (iv), MiOXSYS ®, a novel in vitro diagnostic system for male infertility assessment. In the future the Company will look to acquire additional commercial-stage or near-market products, including existing products we believe can offer distinct commercial advantages. The 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.

Financial Condition. The Company's operations have historically consumed cash and are expected to continue to require cash, but at a declining rate. Revenues have increased 100% and 14% for each of the years ended June 30, 2019 and 2018, respectively, and is expected to continue to increase, allowing the Company to rely less on its existing cash and cash equivalents, and proceeds from financing transactions. Despite increased revenue, cash used in operations during fiscal year 2019 was $13.8 million compared to $16.0 million in 2018, due to the Company completing the build-out of the Company's commercial infrastructure in 2019.

As of the date of this Report, the Company expects its commercial costs to remain approximately flat or to increase modestly as the Company continues to focus on revenue growth. The Company's current asset position of $34.8 million plus the proceeds expected from ongoing product sales will be used to fund operations. The Company will access the capital markets to fund operations if and when needed, and to the extent it becomes probable that existing cash and cash equivalents, 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 the Company considers to be favorable to the Company and its stockholders, or at all. However, the Company has been successful in accessing the capital markets in the past and is confident in its ability to access the capital markets again, if needed. Since the Company does not have sufficient cash and cash equivalents on-hand as of June 30, 2019, to cover potential net cash outflows for the twelve months following the filing date of this Annual Report, ASU 2014-15, *Presentation of Financial Statements—Going Concern* (Subtopic 205-40) requires the Company to report that there exists an indication of substantial doubt about its ability to continue as a going concern.

If the Company is unable to raise adequate capital in the future when it is required, the Company can adjust its operating plans to reduce the magnitude of the capital need under its 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 the Company's commercialization programs, or reductions to its research and development programs. Without sufficient operating capital, the Company could be required to relinquish rights to product candidates on less favorable terms than it would otherwise choose. This may lead to impairment or other charges, which could materially affect the Company's balance sheet and operating results.

The Company has incurred accumulated net losses since inception, and at June 30, 2019, we had an accumulated deficit of $106.4 million. Our net loss increased to $27.1 million from $10.2 million for fiscal 2019 and 2018, respectively. The Company used $13.8 million and $16.0 million in cash from operations during fiscal 2019 and 2018.

Reverse Stock Split. The Company's common stock began trading on the Nasdaq Capital Market on October 20, 2017. On August 13, 2018, we effected a reverse stock split of the outstanding shares of our common stock by a ratio of one-for-twenty (the "Reverse Stock Split"). Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth herein have, where applicable, been adjusted retroactively to reflect the Reverse Stock Split.

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.

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").

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.

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 amounts held in certificate of deposit investments to maintain certain credit amount for Aytu's business credit cards. 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, 2019, Aytu has maintained balances in excess of federally insured limits.

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 reserve, accordingly. The Company did not recognize a reserve as of June 30, 2019 and 2018, respectively.

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 no reserve for slow moving inventory as of June 30, 2019 and 2018, respectively.

Fixed Assets. Fixed assets are recorded at cost, less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the assets' estimated useful lives. Leasehold improvements are amortized over the term of the lease agreement or the service lives of the improvements, whichever is shorter. The Company begins depreciating assets when they placed into service. Maintenance and repairs are expenses as incurred.

Fair Value of Financial Instruments. The carrying amounts of financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, and accounts payable 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.

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 was calculated using a lattice valuation model. Changes in the fair value in subsequent periods was recorded as 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.

Revenue Recognition. The Company generates revenue from product sales and license sales. The Company recognizes revenue when all of the following criteria are satisfied: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when, or as the Company satisfies each performance obligation.

Product sales consist of sales of the Company's four products: (i) Natesto, (ii) Tuzistra XR, (iii) ZolpiMist, and (iv), MiOXSYS. Products are generally shipped "free-on-board" destination. Collectibility of revenue is reasonably assured based on historical evidence of collectibility between the Company and its customers, or for new customers, upon review of customer financial condition and credit history. Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates. The Company constrains revenue by giving consideration to factors that could otherwise lead to a probable reversal of revenue. Provision balances related to estimated amounts payable to direct customers are netted against accounts receivable from such customers. Balances related to indirect customers are included in accounts payable and accrued liabilities. Where appropriate, the Company utilizes the expected value method to determine the appropriate amount for estimates of variable consideration based on factors such as the Company's historical experience and specific known market events and trends.

License sales consist of amounts generated from the Company's sublicense agreement to a third-party for certain of its patented products. Revenue is recognized when earned, based on sales of products under the specified sub-license agreement.

Customer Concentrations. The following customers contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2019 and 2018, respectively. The customers, sometimes referred to as partners or customers, are large wholesale distributors that resell our products to retailers. As of June 30, 2019, four customers accounted for 87% of gross revenue. The revenue from these customers as a percentage of gross revenue was as follows:

	Year Ended June 30,	
	2019	2018
Customer A	19%	32%
Customer C	26%	30%
Customer B	20%	19%
Customer D	22%	0%

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. 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, 2019, four customers accounted for 88% of gross accounts receivable. As of June 30, 2018, four customers accounted for 93% of gross accounts receivable.

	Year Ended June 30,	
	2019	2018
Customer A	9%	27%
Customer B	20%	19%
Customer C	36%	35%
Customer E	23%	0%
Other	0%	12%

Estimated Sales Returns and Allowances. Aytu records estimated reductions in revenue for potential returns of products by customers. As a result, the Company must make estimates of potential future product returns and other allowances related to current period product revenue. In making such estimates, the Company analyzes historical returns, current economic trends and changes in customer demand and acceptance of our products. If the Company 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, 2019 and 2018, the Company accrued $99,000 and $17,000, respectively, in our estimated returns allowance. Estimates of potential returns and allowances are recorded each quarter for the difference between estimates and actual results that become available.

Costs of Goods Sold. Costs of goods sold consists primarily of the direct costs of the Company's products acquired from third-party manufacturers as well as certain royalties owed on certain of the Company's products. Shipping and handling costs are also included in costs of goods sold for all periods presented.

Stock-Based Compensation. Aytu accounts for stock-based payments by recognizing compensation expense based upon the estimated fair value of the awards on the date of grant over the period of service. Stock option grants are valued on the grant date using the Black-Scholes option pricing model and recognizes compensation costs ratably over the period of service using the graded method. Restricted stock grants are valued based on the estimated grant date fair value of the Company's common stock, and recognized ratable over the requisite service period. Forfeitures are adjusted for as they occur.

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

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; which relates to the RedoxSYS and MiOXSYS products; 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.

Impairment of Long-lived Assets. The Company assesses impairment of its long-lived assets when events or changes in circumstances indicates that their carrying value amount may not be recoverable. The Company's long-lived assets consist of (i) fixed assets, net, (ii) licensed assets, net, and (ii) patents, net. Circumstances which could trigger a review include, but are not limited to: (i) significant decreases in the market price of the asset; significant adverse changes in the business climate or legal or regulatory factors; or expectations that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life.

The Company evaluated its long-lived assets for impairment as of June 30, 2019 and 2018 respectively, and there was $0 and $1.9 million of impairment recorded.

Income Taxes. Deferred tax assets and liabilities are recognized based on the difference between the carrying amounts of assets and liabilities in the financial statements and their respective tax bases. Deferred tax assets and liabilities are measured using currently enacted tax rates in effect in the years in which those temporary differences are expected to reverse. Deferred tax assets should be reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. At June 30, 2019 and 2018, respectively, the Company had recorded a valuation allowance against its deferred tax assets of $23.3 million $16.7 million, respectively.

Net 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 2019 and 2018, they were not included in the calculation of the diluted net loss per share because they would have been anti-dilutive.

The following table sets-forth securities that could be potentially dilutive, but as of the years ended June 30, 2019 and 2018 are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share.

		Year Ended June 30,	
		2019	2018
Warrants to purchase common stock - liability classified	(Note 13)	240,755	240,755
Warrant to purchase common stock - equity classified	(Note 13)	16,218,908	1,641,906
Employee stock options	(Note 12)	1,607	1,798
Employee unvested restricted stock	(Note 12)	2,347,754	38,740
Convertible preferred stock	(Note 11)	3,594,981	–
		22,404,005	1,923,199

Adoption of New Accounting Pronouncements

Revenue from Contracts with Customers ("ASU 2014-09"). In May 2014, the FASB issued ASU 2014-09, Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The amendments in this ASU provide a single model for use in accounting for revenue arising from contracts with customers and supersedes prior revenue recognition guidance, including industry-specific revenue guidance. The core principle of the new ASU is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. Disclosures about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers are also required. ASC 606 and Topic 340-40 *Contracts with Customers*, also require the deferral of incremental costs of obtaining contracts with customers and subsequent amortization of those costs of the period of anticipated benefit.

Effective July 1, 2018, the Company adopted ASC 606 through the modified retrospective method and did not result in a cumulative adjustment to retained earnings or accumulated deficit as of the adoption date. This is due to the fact 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 contracts with our customers.

We adopted the new standard through applying the following conclusions (resulting from a thorough analysis of all contract types): (1) The new guidance did not materially change our existing policy and practice for identifying contracts with customers, nor did it 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, (3) the new guidance did not change our existing policy and practice regarding the recording of variable consideration, and (4) we did not identify any customer acquisition costs that are incremental and that are expected to be recovered at a future time.

As mentioned above, the modified retrospective method of transition did not result in a cumulative adjustment as of July 1, 2018. The Company did not utilize either the (i) significant financing component practical expedient, or the (ii) contract cost practical expedient, as these did not apply to the Company's contracts, and there was no impact to the financial statements. Additionally, no other line items in the statement of operations or the balance sheet reflect any changes due to the adoption of the new standard. Adoption of the standards related to revenue recognition had no impact to cash from or used in operating, financing, or investing on our consolidated cash flows statement.

Recent Accounting Pronouncements

Fair Value Measurements ("ASU 2018-03"). In August 2018, the FASB issued ASU 2018-13, "Fair Value Measurement (Topic 820) Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement." The amendments in the standard apply to all entities that are required, under existing GAAP, to make disclosures about recurring or nonrecurring fair value measurements. ASU 2018-13 removes, modifies, and adds certain disclosure requirements in ASC 820, Fair Value Measurement. The standard is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019.

The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of ASU 2018-13. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is currently assessing the impact that ASU 2018-13 will have on its financial statements.

Financial Instruments – Credit Losses ("ASU 2016-03"). 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.

Leases ("ASU 2016-02"). In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02 – *Topic 842 Leases.* ASU 2016-02 requires that most leases be recognized on the financial statements, specifically the recognition of right-to-use assets and related lease liabilities, and enhanced disclosures about leasing arrangements. The objective is to provide improved transparency and comparability among organizations. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The standard requires using the modified retrospective transition method and apply ASU 2016-02 either at (i) latter of the earliest comparative period presented in the financial statements or commencement date of the lease, or (ii) the beginning of the period of adoption. The Company has elected to apply the standard at the beginning period of adoption, July 1, 2019 with a cumulative adjustment to retained earnings, if any, as opposed to retrospectively adjusting prior periods presented in the financial statements.

Future minimum lease obligations for leases accounted for as operating leases at June 30, 2019 totaled approximately $0.3 million. While the Company has not yet completed its evaluation, it anticipates that the adoption of ASU 2016-02 will require the Company to recognize approximately $0.4 - $0.5 million of right-to-use assets and related lease liabilities related to the Company's corporate office leases. The Company has not yet completed its determination whether leases qualify as (i) operating or (ii) financing under the new standard. The Company has elected to apply the short-term scope exception for leases with terms of 12 months or less at the inception of the lease, and will continue to recognize rent expense on a straight-line basis. The impact from electing this scope exception is expected to be less than $0.1 million.

3. Revenues from Contracts with Customers

The Company sells its products principally to a limited number of wholesale distributors and pharmacies in the United States, which account for the largest portion of our total revenue. International sales are made primarily to specialty distributors, as well as hospitals, laboratories, and clinics, some of which are government owned or supported (collectively, its "Customers"). The Company's Customers in the United States subsequently resell the products to patients and pharmacies. Revenue from product sales is recorded at the net sales price, or "transaction price," which includes estimates of variable consideration that result from coupons, discounts, chargebacks and distributor fees, processing fees, as well as allowances for returns and government rebates.

In accordance with ASC 606, the Company recognizes net revenues from product sales when the Customer obtains control of the Company's product, which typically occurs upon delivery to the Customer. The Company's payment terms are between 30 to 60 days in the United States and consistent with prevailing practice in international markets.

Revenues by Geographic location. The following table reflects our product revenues by geographic location as determined by the billing address of our customers:

	Year Ended June 30,	
	2019	2018
U.S.	$ 6,462,000	$ 3,213,000
International	858,000	447,000
Total net revenue	$ 7,320,000	$ 3,660,000

4. Product Licenses

The Company currently licenses three of its existing product offerings from third parties: (i) Natesto; (ii) ZolpiMist, and (ii) Tuzistra XR. Each of these license agreements are subject to terms and conditions specific to each agreement. The Company capitalized the acquisition cost of each license, which included a combination of both upfront considerations, as well as the estimated future contingent consideration estimated at the acquisition date.

License and Supply Agreement—Natesto.

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

In addition to the previously disclosed upfront payments made to Acerus, we agreed to make one-time, non-refundable milestone payments to Acerus within 45 days of the occurrence of certain agreed upon milestones. The maximum aggregate amount payable under such milestone payments is $37.5 million.

The fair value of the net identifiable Natesto asset acquired was determined to be $10.5 million, which is being amortized over eight years. The aggregate amortization expense for fiscal 2019 and fiscal 2018 was $1.3 million, respectively.

The estimated future amortization of Natesto after June 30, 2019 is as follows:

	Year-Ended June 30,
2020	$ 1,319,000
2021	1,319,000
2022	1,319,000
2023	1,319,000
2024	1,318,000
	$ 6,594,000

The contingent consideration was initially valued at $3.2 million using a Monte Carlo simulation, as of June 30, 2016. As of June 30, 2019, the contingent consideration was revalued at $5.1 million using the same Monte Carlo simulation methodology. The contingent consideration accretion expense for fiscal 2019 and fiscal 2018 was $0.07 million, and $0.7 million respectively. As of June 30, 2019, no milestone payments have been made.

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 $0.4 million to Magna upon execution of the agreement. In July 2018, we paid an additional $0.3 million of which, $297,000 was included in current contingent consideration at June 30, 2018. We also agreed to make certain royalty payments to Magna which will be calculated as a percentage of ZolpiMist net sales and are payable within 45 days of the end of the quarter during which the applicable net sales occur.

The ZolpiMist license agreement was valued at $3.2 million and will be amortized over the life of the license agreement up to seven years. The amortization expense for fiscal 2019 and fiscal 2018 was $0.5 million and $0.04 million, respectively.

The estimated future amortization of ZolpiMist after June 30, 2019 is as follows:

	Year Ended June 30,
2020	$ 464,000
2021	464,000
2022	464,000
2023	464,000
2024	464,000
Thereafter	424,000
	$ 2,744,000

The contingent consideration, related to these royalty payments, was valued at $2.6 million using a Monte Carlo simulation, as of June 11, 2018. As of June 30, 2019, the contingent consideration was revalued at $2.3 million (Note 9). The contingent consideration accretion expense for fiscal 2019 and 2018 was $0.3 million and $0.02 million, respectively.

License, Development, Manufacturing and Supply Agreement—Tuzistra XR

On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tris License Agreement") with TRIS Pharma, Inc. ("TRIS"). Pursuant to the Tris License Agreement, TRIS granted the Company an exclusive license in the United States to commercialize Tuzistra XR. In addition, TRIS granted the Company an exclusive license in the United States to commercialize a complementary antitussive referred to as "CCP-08" (together with Tuzistra XR, the "Products") for which marketing approval has been sought by TRIS under a New Drug Application filed with the Food and Drug Administration ("FDA"). As consideration for the Products license, the Company: (i) made an upfront cash payment to TRIS; (ii) issued shares of Series D Convertible preferred stock to TRIS; and (iii) will pay certain royalties to TRIS throughout the license term in accordance with the Tris License Agreement.

The Tris License Agreement was valued at $9.9 million and will be amortized over the life of the Tris License Agreement up to twenty years. The amortization expense for fiscal 2019 and 2018 was $0.3 million and $0, respectively. The estimated future amortization of Tuzistra after June 30, 2019 is as follows:

	Year Ended June 30,
2020	$ 493,000
2021	493,000
2022	493,000
2023	493,000
2024	493,000
Thereafter	7,059,000
	$ 9,524,000

We also agreed to make certain quarterly royalty payments to TRIS which will be calculated as a percentage of our Tuzistra XR net sales, payable within 45 days of the end of the applicable quarter.

As of November 2, 2018, the contingent consideration, related to this asset, was valued at $8.8 million using a Monte Carlo simulation. As of June 30, 2019, the contingent consideration was revalued at $16.0 million. The contingent consideration accretion expense for fiscal 2019 and 2018 was $0.2 million, and $0, respectively (Note 9).

5. Inventories

Inventory balances consist of the following:

	June 30,	
	2019	2018
Raw materials	$ 117,000	$ 239,000
Finished goods	1,323,000	1,100,000
	$ 1,440,000	$ 1,339,000

There was no work-in-process inventory as of June 30, 2019 or 2018, respectively.

6. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Lives in years	June 30,	
		2019	2018
Manufacturing equipment	2 - 5	$ 83,000	$ 213,000
Leasehold improvements	3	112,000	112,000
Office equipment, furniture and other	2 - 5	315,000	344,000
Lab equipment	3 - 5	90,000	90,000
Less accumulated depreciation and amortization		(396,000)	(540,000)
Fixed assets, net		$ 204,000	$ 219,000

During the year ended June 30, 2019, the Company derecognized the fully impaired fixed assets related to the Fiera product line, which was discontinued during the year ended June 30, 2018.

Aytu recorded depreciation and amortization expense of $0.1 million and $0.3 million for the years ended June 30, 2019 and 2018, respectively.

7. Patents

Aytu recorded the amortization expense totaling $0.03 and $0.03 million for the years ended June 30, 2019 and 2018, respectively.

Patents consist of the following:

	June 30,	
	2019	2018
Patents	$ 380,000	$ 380,000
Less accumulated amortization	(159,000)	(134,000)
Patents, net	$ 221,000	$ 246,000

Future amortization from the year ended June 30, 2019 is as follows:

Fiscal Year	Year Ended June 30,
2020	$ 25,000
2021	25,000
2022	25,000
2023	25,000
2024	25,000
Thereafter	96,000
	$ 221,000

8. Accrued liabilities

Accrued liabilities consist of the following:

	June 30,	
	2019	2018
Accrued accounting fee	$ 85,000	$ 71,000
Accrued legal-related fees	–	26,000
Accrued program liabilities	736,000	–
Accrued product-related fees	295,000	–
Customer overpayment	–	43,000
Other accrued liabilities*	32,000	46,000
Total accrued liabilities	$ 1,148,000	$ 186,000

* Other accrued liabilities consist of employee relocation expense, samples and consultants, none of which individually represent greater than five percent of total current liabilities.

9. Fair Value Considerations

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 on a recurring basis 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, 2019 and 2018, by level within the fair value hierarchy:

		Fair Value Measurements at June 30, 2019		
	Fair Value at June 30, 2019	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs(Level 2)	Significant Unobservable Inputs(Level 3)
Recurring:				
Warrant derivative liability	$ 13,000	$ –	$ –	$ 13,000
Contingent consideration	23,326,000	–	–	23,326,000
	$ 23,339,000	$ –	$ –	$ 23,339,000

		Fair Value Measurements at June 30, 2018		
	Fair Value at June 30, 2018	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs(Level 2)	Significant Unobservable Inputs(Level 3)
Recurring:				
Warrant derivative liability	$ 94,000	$ –	$ –	$ 94,000
Contingent consideration	4,694,000	–	–	4,694,000
	$ 4,788,000	$ –	$ –	$ 4,788,000

Warrant Derivative Liability. 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, 2019:

	As of June 30, 2019	As of June 30, 2018	At Issuance
Warrant Derivative Liability			
Volatility	163.2%	173.4%	188.0%
Equivalent term (years)	3.13	4.13	5.00
Risk-free interest rate	1.71%	2.69%	1.83%
Dividend yield	0.00%	0.00%	0.00%

The following table sets forth a reconciliation of changes in the warrant derivative liability for the period ended June 30, 2019:

	Liability Classified Warrants
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
Change in fair value included in earnings	(81,000)
Balance as of June 30, 2019	$ 13,000

Contingent Consideration. We classify our contingent consideration liability in connection with the acquisition of Natesto, ZolpiMist, and Tuzistra XR 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 following table sets forth a summary of changes in the contingent consideration for the period ended June 30, 2019:

	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
Increase due to purchase of assets	8,833,000
Increase due to accretion	516,000
Decrease due to contractual payment	(548,000)
Increase due to remeasurement	9,831,000
Balance as of June 30, 2019	$ 23,326,000

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.

Significant assumptions in valuing the contingent consideration were as follows as of June 30, 2019 and as of June 30, 2018:

	As of June 30, 2019	As of June 30, 2018
Natesto		
Relevered Beta	0.83	0.99
Maket risk premium	5.50%	5.50%
Risk-free interest rate	3.50%	4.00%
Discount	10.20%	10.40%

	As of June 30, 2019	As of June 30, 2018
ZolpiMist		
Relevered Beta	1.16	1.07
Maket risk premium	5.50%	5.00%
Risk-free interest rate	3.50%	3.50%
Discount	10.20%	10.40%

	As of June 30, 2019	At Issuance
Tuzistra XR		
Relevered Beta	1.19	1.49
Maket risk premium	5.50%	5.00%
Risk-free interest rate	3.50%	3.50%
Discount	20.20%	20.40%

10. Income Taxes

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.

	June 30,			
	2019		2018	
Benefit at statutory rate	$ (5,698,000)	-21.00%	$ (2,807,000)	-12.47%
State income taxes, net of federal benefit	(1,077,000)	-3.97%	(585,000)	-2.60%
Stock based compensation	3,000	0.01%	22,000	0.10%
Contingent consideration	–	0.00%	(465,000)	-2.07%
Change in tax rate	12,000	0.04%	(31,000)	-0.14%
Remeasurement of deferred taxes	–	0.00%	6,648,000	29.54%
Effect of phased-in tax rate	–	0.00%	891,000	3.96%
Change in valuation allowance	6,584,000	24.27%	(2,745,000)	-12.20%
Derivative income	(16,000)	-0.06%	(1,029,000)	-4.57%
Other	192,000	0.72%	101,000	0.45%
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:

	June 30,	
	2019	2018
Deferred tax assets (liabilities):		
Accrued expenses	$ 234,000	$ 136,000
Net operating loss carry forward	18,085,000	14,458,000
Intangibles	3,377,000	651,000
Share-based compensation	1,210,000	1,044,000
Fixed assets	86,000	139,000
Capital loss carry forward	203,000	204,000
Contribution carry forward	31,000	29,000
Warrant liability	51,000	53,000
Inventory	25,000	4,000
Total deferred income tax assets	23,302,000	16,718,000
Less: Valuation allowance	(23,302,000)	(16,718,000)
Net deferred income tax assets	$ –	$ –

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. A significant piece of objective negative evidence evaluated was the cumulative loss incurred since inception. Such objective evidence limits the ability to consider other subjective evidence such as the Company's projection for future growth. On the basis of this evaluation the company has recorded a full valuation allowance on its deferred tax assets.

The Company has federal net operating losses of approximately $73.9 million and $59.3 million as of June 30, 2019 and June 30, 2018, respectively that, subject to limitation, may be available in future tax years to offset taxable income. Of the available federal net operating losses, approximately $31.4 million can be carried forward indefinitely while the balance will begin to expire in 2031. The Company has state net operating losses of approximately $63.9 million and $50.3 million as of June 30, 2019 and June 30, 2018, 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 2038. 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, 2019 and 2018, the Company has no liability for gross unrecognized tax benefits or related interest and penalties. Aytu has made its best estimates of certain income tax amounts included in the financial statements. Application of the Company's accounting policies and estimates, however, involves the exercise of judgement and use of assumptions as to future uncertainties and, as a result, could differ from these estimates. In arriving at its estimates, factors the Company considers include how accurate the estimates or assumptions have been in the past, how much the estimates or assumptions have changed and how reasonably likely such changes may have a material impact. Aytu has been historically included in the Ampio consolidated tax return. Under the general statute of limitations, the Company would not be subject to federal or Colorado income tax examinations for tax years prior to 2015 and 2014, respectively. However, given the net operating losses generated since inception, all tax years since inception are subject to examination

11. Capital Structure

At June 30, 2019 and June 30, 2018, Aytu had 17,538,071 and 1,794,762 shares of common stock outstanding, respectively, and 3,594,981 and 0 shares of preferred stock outstanding, respectively. The Company has 100 million shares of common stock authorized with a par value of $0.0001 per share.

The Company has 50 million shares of non-voting, non-cumulative preferred stock authorized with a par value of $0.0001 per share, of which, 293,833 are designated as Series C Convertible preferred stock, 400,000 are designated as Series D Convertible preferred stock, and 2,751,148 are designated as Series E Convertible preferred stock as of June 30, 2019. Liquidation rights for all series of preferred stock are on an as-converted basis.

Included in the common stock outstanding are 2,551,024 shares of restricted stock issued to executives, directors, employees and consultants.

Year Ended June 30, 2019

On October 9, 2018, we completed an underwritten public offering for, total gross proceeds of $15.2 million which includes the full exercise of the underwriters' over-allotment option to purchase additional shares and warrants, before deducting underwriting discounts, commissions and other offering expenses payable by the Company.

The securities offered by the Company consisted of: (i) an aggregate of 457,007 shares of its common stock; (ii) an aggregate of 8,342,993 shares of its Series C Convertible preferred stock convertible into an aggregate of 8,342,993 shares of common stock at a conversion price of $1.50 per share; and (iii) warrants to purchase an aggregate of 8,800,000 shares of common stock at an exercise price of $1.50 per share. The securities were issued at a public offering purchase price of $1.50 per fixed unit consisting of: (a) one share of common stock and one warrant; or (b) one share of Series C preferred stock and one warrant. The common stock issued had a relative fair value of $533,000 in the aggregate and a fair value of $594,000 in the aggregate. The Series C preferred stock issued had a relative fair value of $9.7 million in the aggregate and a fair value of $10.8 million in the aggregate. The warrants are exercisable upon issuance and will expire five years from the date of issuance. The warrants have a relative fair value of $1.6 million in the aggregate, a fair value of $1.8 million in the aggregate, and generated gross proceeds of $88,000. The conversion price of the Series C preferred stock in the offering as well as the exercise price of the warrants are fixed and do not contain any variable pricing features, or any price based anti-dilution features.

In connection with this offering, the underwriters exercised their over-allotment option in full, purchasing an additional 1,320,000 shares of common stock and 1,320,000 warrants. The common stock issued had a relative fair value of $1.5 million and a fair value of $1.7 million. The warrants have the same terms as the Warrants sold in the registered offering. These warrants have a relative fair value of $238,000, a fair value of $265,000, and gross proceeds of $13,000, which was the purchase price per the underwriting agreement.

In October 2018, Aytu issued 9,000 shares of common stock to a former employee at a fair value of $12,000.

On November 2, 2018, the Company issued 400,000 shares of Series D Convertible preferred stock as consideration for a purchased asset valued at $520,000.

On April 18, 2019, pursuant to the exchange agreement between Aytu and Armistice, which was approved by the stockholders of the Company on April 12, 2019, Aytu exchanged the Armistice Note into: (1) 3,120,064 shares of common stock of the Company, (2) 2,751,148 shares of Series E Convertible preferred stock of the Company, and (3) a Common Stock Purchase Warrant exercisable for 4,403,409 shares of common stock of the Company.The aggregate fair value of shares issued was approximately $4.7 million.

As of June 30, 2019, warrants issued from the October registered offering to purchase an aggregate of 250,007 shares of common stock were exercised for aggregate gross proceeds to our Company of approximately $375,000.

As of June 30, 2019, investors holding shares of Series C preferred stock exercised their right to convert 7,899,160 shares of Series C preferred stock into 7,899,160 shares of common stock. As of June 30, 2019, Aytu has 443,833 shares of Series C preferred stock outstanding.

Year Ended June 30, 2018

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.

During the year ended June 30, 2018, warrants issued from the March 2018 registered offerings to purchase an aggregate of 80,750 shares of common stock were exercised for aggregate gross proceeds to the Company of approximately $677,000.

12. Equity Incentive Plan

2015 Stock Option and Incentive Plan. 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, 2019, we have 652,179 shares that are available for grant under the 2015 Plan.

Stock Options

Employee Stock Options: There were no grants of stock options to employees during the years ended June 30, 2019 and 2018, respectively, therefore, no assumptions are used for fiscal 2019.

Non-Employee Stock Options: During the year ended June 30, 2019, the Company issued 75,000 performance-based stock options out of the 2015 Plan to a consultant. These options vest based on meeting certain market criteria with an exercise price of $1.00. At June 30, 2019, the first of three market targets were not achieved, and all 75,000 performance stock options were forfeited.

Market options that require specific events before they begin to vest are valued at grant date. The fair value of the options granted has been calculated using a Monte Carlo simulation. The significant assumptions at issuance in valuing the non-employee performance stock options were as follows:

	As of June 30, 2019
Expected volatility	164.0%
Expected term (years)	5.00
Risk-free interest rate	2.99%
Dividend yield	0.00%

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2017	1,947	$ 326.20	8.40
Granted	–	–	
Exercised	–	–	
Forfeited/Cancelled	(149)	328.00	
Outstanding June 30, 2018	1,798	325.97	6.95
Granted	75,000	1.00	
Exercised	–	–	
Forfeited/Cancelled	(75,036)	1.16	
Expired	(155)	328.00	
Outstanding June 30, 2019	1,607	325.73	6.13
Exercisable at June 30, 2019	1,471	$ 325.52	6.07

The following table details the options outstanding at June 30, 2019 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	7.85	76	$ 280.00
328.00	1,531	328.00	6.05	1,395	328.00
	1,607	$ 325.73	6.13	1,471	$ 325.52

As of June 30, 2019, there was $7,000 of total unrecognized stock-based compensation expense related to employee non-vested stock options. The Company expects to recognize this expense over a weighted-average period of 0.32 years. There was no unrecognized stock-based compensation expense related to non-employee performance options, as these were fully forfeited at June 30, 2019.

Restricted Stock

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	–	40.40	
Forfeited	(1,950)	40.40	
Unvested at June 30, 2018	37,200	$ 39.80	9.4
Granted	2,772,022	1.30	
Vested	–	–	
Forfeited	(463,008)	1.23	
Unvested at June 30, 2019	2,346,214	$ 1.83	9.1

Activity During the Year Ended June 30, 2019

- In October 2018, the Company issued 2,707,022 shares of restricted stock to executives, directors, employees pursuant to the 2015 Plan, which vest in October 2028.
- In February 2019, The Company issued 65,000 shares of restricted stock to a director pursuant to the 2015 Plan, which vest in February 2029.
- 372,408 shares of restricted stock were exchanged with common stock, and the Company recognized an increase in aggregate stock compensation expense of $371,000
- 90,600 shares of restricted stock were forfeited due to employee turnover.

Activity during Year Ended June 30, 2018

- In September 2017, The Company issued 10,000 shares of restricted stock to employees pursuant to the 2015 Plan, which vest in September 2027.
- November 2017, the Company 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, The Company issued 3,750 shares of restricted stock to an officer pursuant to the 2015 Plan, which vest in January 2028.
- In March 2018, The Company issued 650 shares of restricted stock to employees pursuant to the 2015 Plan, which vest in March 2028.
- 1,150 shares of restricted stock were exchanged with common stock due to employee turnover, , and the Company recognized an increase in aggregate stock compensation expense of $14,000.
- 800 shares of restricted stock were forfeited due to employee turnover.

Under the 2015 Plan, there was $3,874,000 of total unrecognized stock-based compensation expense related to the non-vested restricted stock as of June 30, 2019. The Company expects to recognize this expense over a weighted-average period of 9.07 years.

The Company previously issued 1,540 shares of restricted stock outside the Company's 2015 Plan, which vest in July 2026. The unrecognized expense related to these shares was $1,397,000 as of June 30, 2019 and is expected to be recognized over the weighted average period of 7.03 years.

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 service period which is commensurate with vesting period. The following table summarizes stock-based compensation expense for the stock option and restricted stock issuances for fiscal 2019 and 2018:

Selling, general and administrative:	2019	2018
Stock options	$ 125,000	$ 349,000
Restricted stock	897,000	248,000
Total stock-based compensation expense	$ 1,022,000	$ 597,000

13. Warrants

A summary of the Company's warrant activity is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
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
Warrants issued in connection with the October 2018 public offering	10,120,000	1.50	
Warrants issued to underwriters in connection with the October 2019 public offering	303,600	1.50	
Warrants issued in connection with the Armistice debt exchange	4,403,409	1.00	
Warrants exercised	(250,007)	1.50	
Outstanding June 30, 2019	16,459,663	$ 4.16	4.34

In connection with the Company's August 2017 private offering, the Company 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 9).

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 during the year ended June 30, 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 the Company issued to the placement agent, in connection with the Company's 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.

In connection with the Company's October 2018 registered offering, we issued warrants to investors and underwriters to purchase an aggregate of 10,423,600 shares of the Company's common stock at an exercise price of $1.50 and a term of five years. These warrants are accounted for under equity treatment. These warrants had a relative fair value of $1.8 million and a fair value of $2.0 million.

In connection with the Armistice exchange agreement, the Company issued warrants to Armistice to purchase an aggregate of 4,403,409 shares of the Company's common stock at an exercise price of $1.00 and a term of 5 years. These warrants are accounted for under equity treatment. These warrants had a fair value of $499,000.

During the year ended June 30, 2019, warrants issued from the October registered offering to purchase an aggregate of 250,007 shares of common stock were exercised for aggregate gross proceeds to the Company of approximately $375,000.

14. Related Party Transactions

Armistice

In February 2019, the Company waived its right to disallow Armistice from holding more than 4.99% of Aytu common stock and agreed to allow Armistice to hold up to 40% of the outstanding shares of our common stock. Also, in February 2019, Armistice converted 1.9 million shares of Series C preferred stock into Aytu common stock, resulting in Armistice holding more than 10% of the Company's common stock. The Company also had a promissory note to Armistice with a face value of $5.0 million, which was subsequently exchanged for a combination of common stock, preferred stock and warrants. Therefore, Armistice is now considered an affiliate of the Company.

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, Aytu will prefund certain amounts from which TCI will make disbursements to qualified patients presenting valid prescriptions for Natesto, Tuzistra XR and ZolpiMist on behalf of Aytu. Disbursements will be based upon business rules determined by the Company. 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. One of the the Company's directors, Mr. Donofrio, was an executive officer of TCI but has no direct interest in the arrangement. As of February 2019, Mr. Donofrio is no longer employed by TCI.

15. 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 2019, the Company's match was $148,000.

16. Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of June 30, 2019:

	Total	2020	2021	2022	2023	2024	Thereafter
Prescription database	$ 1,613,000	$ 567,000	$ 534,000	$ 512,000	$ –	$ –	$ –
Product Milestone Payments	5,500,000	–	–	–	5,500,000	–	–
Office leases	494,000	112,000	113,000	118,000	121,000	30,000	–
	$ 7,607,000	$ 679,000	$ 647,000	$ 630,000	$ 5,621,000	$ 30,000	$ –

Prescription Database

In May 2016, the Company entered into an agreement with a vendor that will provide it with prescription database information. The Company agreed to pay approximately $1.6 million over three years for access to the database of prescriptions written for Natesto. The payments have been broken down into quarterly payments.

Milestone Payments

In connection with the Company's intangible assets, Aytu has certain milestone payments, totaling $5.5 million, payable at a future date, are not directly tied to future sales, but upon other events certain to happen. These obligations are included in the valuation of the Company's contingent consideration (see Note 9).

Office Lease

In June 2018, the Company entered into a 12-month operating lease, beginning on August 1, 2018, for office space in Raleigh, North Carolina. 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 had 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, extending the lease for an additional 24 months beginning October 1, 2018. The base rent remained $9,000 per month. In April 2019, the Company extended the lease for an additional 36 months beginning October1, 2020. Rent expense totaled $0.1 and $0.1 million for the years ended June 30, 2019 and 2018 respectively.

17. Segment Information

Operating segments, as defined by Accounting Standards Codification, or ASC, 280 *Segment Reporting*, are components of an enterprise for which separate financial information is available and is evaluated regularly by the Chief Operating Decision Maker, or CODM, in deciding how to allocate resources and in assessing performance. ASC 280 also requires disclosures about products, services, geographic areas and significant customers.

The Company's CODM operates the business as one reportable operating segment comprised of all four products.

Geographic Revenues. See Note 3.

18. Armistice Note Exchange

On November 29, 2018, Aytu issued a $5.0 million promissory note (the "Note") to Armistice Capital Master Fund Ltd. ("Armistice"). The Note was collateralized by the future revenue stream from the products licensed to the Company under the Tris License Agreement between the Company and TRIS. The Note carried an annual interest rate of 8% and had a three-year term with principal and interest payable at maturity. The Company had the right, in its sole discretion, to repay the Note without penalty at any time after December 29, 2018. During the quarter ended June 30, 2019, the Company and Armistice agreed to, and the shareholders approved to, exchange the entire Note for (i) 3.2 million shares of common stock, (ii) 2.75 million of shares of non-voting Series E preferred stock, and (iii) 4.4 million warrants (see Notes 11 and 13).

19. Subsequent Events

Acerus Pharmaceuticals SRL

On July 29, 2019, the Company agreed to amend and restate the License and Supply Agreement with Acerus Pharmaceuticals, SRL ("Acerus"). The effectiveness of the amended Agreement is conditioned upon Acerus obtaining new financing within six months of signing of the amended Agreement. The Company will continue to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus will receive performance-based commissions on prescriptions generated by urology and endocrinology specialties. Acerus will assume regulatory and clinical responsibilities and associated expenses and will serve a primary role in the development of key opinion leaders in urology and endocrinology. The Company will focus on commercial channel management, sales to wholesalers and other purchasing customers, and will direct sales efforts in all other physician specialties.

Innovus Pharmaceuticals, Inc.

On September 12, 2019, the Company signed a definitive merger agreements with Innovus Pharmaceuticals, Inc. (“Innovus”), a specialty pharmaceutical company commercializing, licensing and developing consumer health products. The Company will retire all outstanding common stock of Innovus for an aggregate of up to $8 million in shares of Aytu common stock, less certain deductions, at the time of closing. This initial consideration to Innovus common shareholders is estimated to consist of approximately 4.2 million shares of the Company’s common stock. Additional consideration for up to $16 million in milestone payments in the form of contingent value rights (CVRs) may be paid to Innovus shareholders in cash or stock over the next five years if certain revenue and profitability milestones are achieved.

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 2019 consolidated financial statements that appear in this Annual Report on Form 10-K.

Our report dated September 26, 2019 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/ Plante & Moran, PLLC

September 26, 2019
Denver, Colorado

Exhibit 23.2

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, 333-223385 and 333-227243) of our report dated September 6, 2018, relating to the 2018 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

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua R. Disbrow, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended June 30, 2019 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 26, 2019

/s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David A. Green, certify that:

(1) I have reviewed this annual report on Form 10-K for the year ended June 30, 2019 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 26, 2019

/s/ David A. Green

David A. Green
Chief Financial Officer (Principal Financial Officer and
Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO 18 U.S. C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Aytu BioScience, Inc. (the "Company") for the fiscal year ended June 30, 2019, 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 26, 2019

/s/ Joshua R. Disbrow
Joshua R. Disbrow
Chief Executive Officer (Principal Executive Officer)

Dated: September 26, 2019

/s/ David A. Green
David A. Green
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)