SECURITIES & EXCHANGE COMMISSION EDGAR FILING

AYTU BIOSCIENCE, INC

Form: 10-K

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

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2020

☐ **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 complying with any new or revised financial accounting standards provided pursuant to Section 13a) of the Exchange Act. ☐

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

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, 2019 was $10.1 million based on the closing price of $0.97 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 September 15, 2020, there were 125,837,357 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 Apeaz, Aytu, Diabasens, FlutiCare, Innovus Pharma, MiOXSYS, Natesto, Poly-Vi-Flor, Regoxidine, Tri-Vi-Flor, Tuzistra, Urivarx, Zestra, and ZolpiMist 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.

PART I

Item 1. Business

Company Overview

We are a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant healthcare needs in both prescription and consumer health categories. Through our heritage prescription business, we currently market a portfolio of prescription products addressing large primary care and pediatric markets. The Company's Primary Care Portfolio (the "Primary Care Portfolio") includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), (ii) ZolpiMist(R), the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup.

We acquired on November 1, 2020, the prescription pediatric portfolio (the "Pediatric Portfolio") which includes (i) Cefaclor, a second- generation cephalosporin antibiotic suspension; (ii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iii) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency.

In February 2020, we acquired Innovus Pharmaceuticals, Inc. ("Innovus"), a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve people's health and vitality. Innovus commercializes over twenty-two consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness, and respiratory health. The Innovus product portfolio is commercialized through direct-to-consumer marketing channels utilizing the Company's proprietary Beyond Human® marketing and sales platform.

On March 10, 2020, we announced the licensing of a COVID-19 IgG/IgM Rapid Test from L.B. Resources, Ltd. The test is intended for professional use and delivers clinical results between 2 and 10 minutes at the point-of-care. This agreement grants Aytu the right to distribute the product in the United States, Canada and Mexico for a period of three years, with additional three-year autorenewals thereafter. The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood,serum or plasma. We have made an additional investment to further our interest in fighting the COVID-19 pandemic by signing an exclusive worldwide licensing agreement with Cedars-Sinai Medical Center for a medical device platform technology called Healight™. This technology, which has been studied in the laboratory setting, is being investigated as a potential treatment for COVID-19 in hospitalized, intubated patients. In collaboration with researchers from the Medically Associated Science and Technology Program (MAST) at Cedars- Sinai Medical Center, we expect to advance the development of Healight in the near term.

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 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.

At our special meeting of shareholders held on January 24, 2020, our shareholders approved the proposal to amend our Certificate of Incorporation to increase the number of our authorized shares of common stock, par value $0.0001 per share, from 100,000,000 to 200,000,000 shares of common stock.

Our Products and Markets

Our products are sold and distributed through multiple channels, including sales to pharmaceutical wholesalers, on a sell-through basis using third-party logistics enterprises and direct to consumers.

Primary Care Portfolio

Prior to November 1, 2019, we were primarily focused on the commercial development of the Primary Care Portfolio:

- *Natesto®* – In 2016, we acquired exclusive U.S. rights to Natesto® (testosterone) nasal gel, a novel formulation of testosterone delivered via a discreet, easy-to-use nasal gel, including a license to four Orange Book-listed patents. The recorded chain of title from the inventor to the assignee of these four patents is incomplete, but the licensor Acerus is obligated to complete it. Natesto is approved by the U.S. Food and Drug Administration, or FDA, for the treatment of hypogonadism (low testosterone) in men and is the only testosterone replacement therapy, or TRT, delivered via a nasal gel. Natesto offers multiple advantages over currently available TRTs and competes in a $1.7 billion market accounting for nearly 7 million prescriptions annually. Importantly, as Natesto is delivered via the nasal mucosa and not the skin, there is no risk of testosterone transference to others, a known potential side effect and black box warning associated with topically applied TRTs.

  On July 29, 2019, we agreed to amend and restate the License and Supply Agreement with Acerus. The effectiveness of the amended Agreement was conditioned upon Acerus obtaining new financing within six months of signing of the amended Agreement, which was achieved on December 1, 2019. Aytu continues to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus receives performance-based commissions on prescriptions generated by urology and endocrinology specialties. Acerus assumed regulatory and clinical responsibilities and associated expenses and serves a primary role in the development of key opinion leaders in urology and endocrinology. Aytu continues to focus on commercial channel management, sales to wholesalers and other purchasing customers, and directs sales efforts in all other physician specialties.

  On December 1, 2019, we officially launched the co-promotion program and transferred five of our dedicated sales employees to Acerus until such time they could establish their own dedicated sales force. In July 2020, Acerus launched its dedicated sales team to promote Natesto to urologists and endocrinologists across the United States.

- *ZolpiMist ®* – In June 2018, we acquired an exclusive U.S. license to ZolpiMist ®. ZolpiMist is an FDA-approved prescription product that is indicated for the short-term treatment of insomnia, and is the only oral spray formulation of zolpidem tartrate, the most widely prescribed prescription sleep aid in the U.S. ZolpiMist® is not covered by any U.S. patents, is commercially available and competes in the non-benzodiazepine prescription sleep aid category, a $1.8 billion prescription drug category with over 43 million prescriptions written annually. Thirty million prescriptions of zolpidem tartrate (Ambien®, Ambien® CR, Intermezzo®, Edluar®, ZolpiMist®, and generic forms of immediate-release, controlled release, and orally dissolving tablet formulations) are written each year in the U.S., representing almost 70% of the non-benzodiazepine sleep aid category. Approximately 2.5 million prescriptions are written for novel formulations of zolpidem tartrate products (controlled release and sublingual tablets). We have integrated ZolpiMist® into our sales force's promotional efforts as an adjunct product to Natesto as there is substantial overlap of physician prescribers of both testosterone and prescription sleep aids.

- *Tuzistra® XR* – In November 2018 we acquired U.S. rights to distribute and market Tuzistra® XR from Tris Pharma, Inc. ("TRIS"), 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. Tuzistra® XR is a patented combination of codeine, an opiate agonist antitussive, and chlorpheniramine, a histamine-1 receptor antagonist, indicated for relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults aged 18 years and older. Tuzistra® XR is protected by two Orange Book-listed patents extending to 2027 and 2029 owned by TRIS, subject to a security interest to Deerfield Management, and has multiple pending patents. Aytu benefits from the patent portfolio through its supply and marketing relationship with TRIS and not by license or ownership of the patents. According to MediMedia, the US cough cold prescription market is worth in excess of $3 billion at current brand pricing, with 30-35 million annual prescriptions. This market is dominated by short-acting treatments, which require dosing 4-6 times a day. Tuzistra® XR was developed using TRIS's liquid sustained release technology, LiquiXR®, which allows for extended drug delivery throughout a 12-hour dosing period.

The Pediatric Portfolio

In November 2019, we acquired the Pediatric Portfolio in order to expand our portfolio of commercial-stage products and further leverage our commercial infrastructure. Through this acquisition we now commercialize seven core prescription products and market directly to pediatric and primary care physicians and sell to wholesalers and pharmacies throughout the U.S.

The combined Primary Care Portfolio and the Pediatric Portfolio (together, the "Commercial Portfolio") contains established prescription products competing in markets exceeding $8 billion in annual U.S. sales. Our products have unique clinical features and patient-friendly benefits and are indicated to treat common pediatric and primary care conditions. The Pediatric Portfolio consists of the following:

- *Poly-Vi-Flor® and Tri-Vi-Flor®* – Poly-Vi-Flor and Tri-Vi-Flor are two complementary prescription fluoride-based supplement product lines containing combinations of vitamins and fluoride in various oral formulations. These prescription supplements are prescribed for infants and children to treat or prevent fluoride deficiency due to poor diet or low levels of fluoride in drinking water and other sources. While Aytu does not own or license any patents covering these products, we have an exclusive supply relationship for the use of Metafolin® in pediatric products. Metafolin® is a patented and trademarked ingredient in Poly-Vi-Flor and Tri-Vi-Flor.

- *Karbinal® ER (carbinoxamine maleate extended-release oral suspension)* – Karbinal ER is an H1 receptor antagonist (antihistamine) indicated to treat various allergic conditions including seasonal and perennial allergic rhinitis, vasomotor rhinitis, and other common allergic conditions. Aytu does not own or license any patents covering this product.

- *Cefaclor (cefaclor oral suspension)* – Cefaclor for oral suspension is a second-generation cephalosporin antibiotic suspension and is indicated for the treatment of numerous common infections caused by Streptococcus pneumoniae, Haemophilus influenzae, staphylococci, Streptococcus pyogenes, and others. Aytu does not own or license any patents covering this product.

Aytu Consumer Health Portfolio

Our consumer health subsidiary, Innovus Pharmaceuticals, markets over 22 products in the U.S. and Canada and more than 7 products outside the U.S. through five international commercial partners. The following represents the core Innovus products:

- Diabasens® / NeuriteRx®
- UriVarx®
- FlutiCare®
- Apeaz®
- Vesele®
- Prostagorx®
- Sensum+®
- Trexar®

In addition, we currently expect to launch the following products in 2021 in the US, subject to the applicable regulatory approvals, if required:

- KetoGorx® Glucometer and Test Strips is a blood ketone monitoring device to help monitor blood ketone levels for self-testing/in-vitro diagnostic use only (first half 2021) and
- OmepraCare DR™ is an acid reducer which treats frequent heartburn. The OmepraCare DR™ delayed-release capsules are taken over a 14-day treatment period. OmepraCare DR™ is an over-the-counter proton pump inhibitor indicated to treat heartburn (first half 2021).

  Aytu owns 50 tradenames for products in its consumer health portfolio and owns or licenses patents covering 14 of these products.

The COVID-19 IgG/IgM Rapid Test

In March 2020, the Company signed an agreement to distribute a COVID-19 IgG/IgM rapid test with L.B. Resources Limited (a Hong Kong Corporation). This test is a serology-based rapid test detecting IgG and IgM antibodies specific to the COVID-19 virus. Aytu does not own or license any patents covering the COVID-19 IgG/IgM rapid test.

This test is intended for professional use and delivers clinical results between 2 and 10 minutes.

The COVID-19 IgG/IgM rapid test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the COVID-19 virus in human whole blood, serum or plasma. The test has been clinically validated and can be distributed in the United States, Canada and Mexico.

Features of the COVID-19 IgG/IgM Rapid Test:

- Results reported rapidly
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- Small specimens, only 5 µL of serum/plasma or 10 µL of whole blood specimens required
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

We have extensive experience across a wide range of business development activities and have in-licensed or acquired products from enterprises in the United States and abroad. Through an assertive product and business development approach, we expect that we will continue to build a substantial portfolio of complementary products.

Healight Medical Device Platform Technology

In April 2020 the Company signed an exclusive worldwide license with Cedars-Sinai (“Cedars-Sinai”) in Los Angeles, CA, to develop and commercialize the Healight platform technology ("Healight" or the “Healight Platform”), a novel endotracheal catheter. This medical device technology platform, discovered and developed by scientists at Cedars-Sinai, is being studied as a potential first-in-class treatment for coronavirus and other respiratory infections. The Healight Platform has been in development since 2016 by the Medically Associated Science and Technology (MAST) team at Cedars-Sinai. We are engaging with the MAST team and the FDA to determine an expedited regulatory process to potentially enable near-term use of the technology initially as a coronavirus intervention for critically ill intubated patients. We also entered into an agreement with Sterling Medical Devices ("Sterling") to finalize the development of Healight and produce prototypes.

Our Strategy

In the near-term, we expect to create value for shareholders by implementing a focused strategy of increasing sales of our prescription therapeutics while leveraging our commercial infrastructure. Further, we expect to increase sales of our recently acquired consumer healthcare product portfolio. Additionally, we expect to expand both our Aytu BioScience and Aytu Consumer Health product portfolios through continuous business and product development. Finally, we expect to identify operational efficiencies identified through our recent transactions and implement expense reductions accordingly.

Impact of COVID-19 on our Business and Strategy

The Company’s overall strategy of commercializing and increasing sales of our prescription therapeutics has been impacted by the COVID-19 global pandemic (the “Pandemic”), due in large part to a combination of “shelter-in-place” orders, restricted or reduced access of our sales force to physician offices and pharmacies, as well as a reduction in consumer spending as the United States economy has experienced a severe economic downturn as a result of the Pandemic. However, as the United States has begun to re-open, the Company’s commercial sales force has begun to return to near pre-Pandemic levels of sales activity, in order to continue the Company’s strategy to increase sales. The Pandemic also impacted the Company’s MiOXSYS device business, as demand declined internationally and domestically for our MiOXSYS devices as overall demand for infertility treatments and/or research using such devices declined.

However, the Company was able to successfully pivot and enter into licensing agreements for both (i) COVID-19 Test Kits and (ii) the Healight Platform to provide current testing solutions and a potential future treatment for COVID-19 and other respiratory diseases. Sales of our COVID-19 Test Kits helped bolster revenues from our Primary Care Portfolio, Pediatric Portfolio, and MiOXSYS product offerings.

The Pandemic also had an impact on our Aytu Consumer Health segment's operations as access to raw materials for manufacturing products became limited and its manufacturers reduced their workforce, thus delaying the production processes. As a result, our Aytu Consumer Health segment has accelerated the timing of future purchase orders to ensure sufficient inventory levels in the near term. Additionally, Aytu Consumer Health is reliant on certain services, especially the US postal service, for its direct-to-consumer campaigns. During the Pandemic, Innovus experienced delays reaching prospective customers due to United States Postal Service operational challenges.

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 product candidates if such efforts are necessary to achieve our strategic goals. Currently, we are developing one medical device candidate for approval by the FDA, the Healight Platform, for which regulatory approval or Emergency Use Authorization (EUA) 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 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 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, 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 Reconciliation Act of 2010 or the Affordable Care Act of 2010, 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 be done farther down the distribution chain including, (i) wholesalers' verification and tracking in November 2019, (ii) pharmacy verification and tracking 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.

Some of the products in our Commercial Portfolio are covered by commercial insurance providers and pharmacy benefit management companies and are dependent upon reimbursement for continued sales in the U.S. market. Additionally, some of our products are also covered by Medicaid, Medicare Part D and other government plans.

In the event we are able to successfully develop and commercialize the Healight Platform, we anticipate that sales of Healight, if approved for sale in the U.S., will be dependent upon reimbursement by government and commercial third-party payors in the U.S. Traditionally, sales of pharmaceuticals, medical diagnostics, and medical devices 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.

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

DEA Regulation

Our Primary Care Portfolio products, which are 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 Administration, or DEA, have Natesto and Tuzistra XR listed and regulated as Schedule III controlled substances, while ZolpiMist is listed and regulated as a Schedule IV controlled substance. None of our Pediatric Portfolio Rx products are considered "controlled substances."

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 theft 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. 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 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. Additionally, the Company uses third-party logistics ("3PL") firms to store inventory and fill sales orders for the Commercial Portfolio. As a result, the Company does not handle any controlled substances at its facilities.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for the technology and know-how upon which our products are based, in order to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights.

Aytu BioScience Segment

Our Aytu BioScience Segment includes our Primary Care Portfolio, Pediatric Portfolio and Medical Device product offerings. We hold ownership, trademark rights and/or exclusivity to develop and commercialize our products and product candidates covered by patents and patent applications. Our portfolio of patents includes patents or patent applications with claims directed to compositions of matter, including compounds, pharmaceutical formulations, methods of use, methods of manufacturing the compounds, or a combination of these claims. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. Similar extensions to patent term may be available in other countries for particular patents in our portfolio.

License Rights – Primary Care Portfolio and Pediatric Portfolio

We have 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 exclusive commercialization agreement with TRIS, 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 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 have exclusive license rights with third parties to develop, commercialize and promote our Primary Care Portfolio and Pediatric Portfolio products within the United States of America, including but not limited to, (i) Natesto, (ii) Poly-Vi-Flor and Tri-Vi-Flor, (iii) Karbinal ER, (iv) ZolpiMist and (v) Tuzistra XR. Each of these agreements come with royalties ranging from 0% to 23.5% based on net product revenue or gross profit (as defined by each agreement). In addition, certain licensing agreements include forms of contingent consideration, make-whole payments or both.

License Rights – COVID-19 Test Kits

During March 2020, we signed an exclusive distribution agreement for the right to commercialize a clinically validated coronavirus 2019 (COVID-19) IgG/IgM Rapid Test. The test has been licensed from L.B. Resources, Limited (a Hong Kong Corporation), which licensed North American rights from product developer Zhejiang Orient Gene Biotech Co., Ltd. The test is intended for professional use and delivers results between 2 and 10 minutes. This agreement grants Aytu the exclusive right to distribute the product in the United States, Canada and Mexico for a period of three years, with additional three-year autorenewals thereafter. The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma.

License Rights – Healight

In April 2020, we signed an exclusive worldwide license with Cedars-Sinai to develop and commercialize the Healight Platform. This medical device technology platform, discovered and developed by scientists at Cedars-Sinai, is being studied as a potential first-in-class treatment for coronavirus and other respiratory infections. The Healight Platform employs proprietary methods of administering intermittent ultraviolet (UV) A light via a novel endotracheal medical device. Pre-clinical findings indicate the technology's significant impact on eradicating a wide range of viruses and bacteria, inclusive of coronavirus. The data have been the basis of discussions with the FDA for a near-term path to enable human use for the potential treatment of coronavirus in intubated patients in the intensive care unit (ICU). Beyond the initial pursuit of a coronavirus ICU indication, additional data suggest broader clinical applications for the technology across a range of viral and bacterial pathogens. This includes bacteria implicated in ventilator associated pneumonia (VAP).

The Company believes the Healight Platform has the potential to positively impact outcomes for critically ill patients infected with coronavirus and severe respiratory infections. The Company licensed exclusive worldwide rights to the technology from Cedars-Sinai for all endotracheal and nasopharyngeal indications. Patents have been filed by Cedars-Sinai Department of Technology Transfer, and Aytu will manage all aspects of intellectual property prosecution and filing globally. Aytu BioScience expects to partner the product outside the U.S.

Patents - MiOXSYS

Our patent portfolio related to MiOXSYS and the underlying oxidation-reduction potential (ORP) technology is focused on the U.S. and certain foreign jurisdictions which include Europe, Canada, Israel, Japan and China. The portfolio consists of 44 issued patents and 1 pending application. During the fourth quarter ended June 30, 2020, we wrote-down the fair value of the MiOXSYS patent portfolio to $0 as a result of the Company's analysis indicating that the expected forecasted future cash flows from MiOXSYS sales would be unable to support the carrying value of the MiOXSYS patent portfolio.

Aytu Consumer Health Segment

Our Aytu Consumer Health Segment consists of those products acquired as part of the February 2020 merger with Innovus. We currently hold 8 patents in the U.S. and 18 patents registered outside the U.S. We currently have 13 patent applications pending in the U.S. and 16 patent applications pending in countries other than the U.S.

We own or license 68 trademark registrations in the U.S. and have 32 trademark applications pending in the U.S. We also own or license 104 trademarks registered outside of the U.S. (including 21 Madrid Protocol registrations), with 69 applications currently pending.

We have established business procedures designed to maintain the confidentiality of our proprietary information, including the use of confidentiality agreements and assignment-of-inventions agreements with employees, independent contractors, consultants and companies with which we conduct business.

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 pharmaceutical company compared to other companies. 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 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.

Competition – Primary Care Portfolio and Pediatric Portfolio

Natesto

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

Tuzistra XR

Tuzistra XR competes in the approximately $3.0 billion antitussive category and has an advantage over the existing codeine-based antitussives. The greatest point of differentiation of Tuzistra XR is the patented LiquiXR Technology that allows for extended release and flexible BID dosing Tuzistra XR is the only liquid codeine antitussive with a 12-hour duration, 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.

Karbinal ER

Karbinal ER faces competition from over-the-counter ("OTC") products such as non-sedating antihistamines, sedating antihistamines as well as nasal steroids. Karbinal ER's greatest point of differentiation is the patented LiquiXR Technology that allows for extended release and flexible BID dosing. This feature makes Karbinal ER the only BID first generation antihistamine. Additionally, Karbinal ER has a significant anticholinergic / drying effect on the symptoms associated with seasonal, perennial, as well as vasomotor allergic rhinitis.

Poly-Vi-Flor and Tri-Vi-Flor

Poly-Vi-Flor and Tri-Vi-Flor primarily compete in the generic prescription multi-vitamin fluoride market and with the brands of FLORIVA and QFLORA. Our primary point of differentiation is Metafolin and that our form of Metafolin is a body-ready folate to aid in cell reproduction. As well, we offer formulations that are patient friendly in terms of size of tablet and taste of medication, ensuring compliance of daily fluoride vitamin supplementation.

Cefaclor

Cefaclor (cefaclor oral suspension) faces significant competition from the generic antibiotic amoxicillin as well as Omnicef, Ceftin and others. The key point of differentiation for Cefaclor is our clinical positioning for appropriate patients who have failed first line therapies. Cefaclor is the best choice as a second line treatment for antibiotics that have failed with patients suffering from streptococcus, urinary tract infections and otitis media. Cefaclor is a second generation antibiotic indicated against a broad range of pathogens with a broad range of indications.

Competition – Devices

COVID-19 Test Kits

Our COVID-19 IgG/IgM Rapid Test (COVID-19 Test Kits) were licensed from Hong Kong based L.B. Resources, which licensed North American rights from product developer Zhejiang Orient Gene Biotech Co., Ltd. Our COVID-19 Test Kit is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma, otherwise known as a serology test. In addition to other serology-based antibody test kits, our COVID-19 Test Kits compete with two other forms of tests, (i) molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and (ii) antigen tests that detect specific proteins on the surface of the virus.

Healight Medical Device Platform Technology

The Healight Platform has been in development since 2016 by the Medically Associated Science and Technology (MAST) team at Cedars-Sinai Medical Center. We are engaging with the research team at Cedars-Sinai and the FDA to determine an expedited regulatory process to potentially enable near-term use of the technology initially as a coronavirus intervention for critically ill intubated patients. We also entered into an agreement with Sterling Medical Devices ("Sterling") to finalize the product development of Healight.. To date, there is no FDA-approved treatment for COVID-19 or conventional means to reduce secondary infections in mechanically ventilated patients.

Competition – Consumer Health

The OTC pharmaceutical market is highly competitive with many established manufacturers, suppliers and distributors that are actively engaged in all phases of the business. We believe that competition in the sale of our products will be based primarily on efficacy, regulatory compliance, brand awareness, availability, product safety and price. Our brand name OTC pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. All of our existing products compete with generic and other competitive products in the marketplace.

Competing in the branded product business requires us to identify and quickly bring to market new products embodying technological innovations. Successful marketing of branded products depends primarily on the ability to communicate the efficacy, safety and value to consumers. We anticipate that our branded product offerings will support our existing lines of therapeutic focus. Based upon business conditions and other factors, we regularly reexamine our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities.

Some of our existing products compete with one or more products marketed by very large pharmaceutical companies that have much greater financial resources for marketing, selling and developing their products. These competitors, as well as others, have been in business for a longer period of time, have a greater number of products on the market and have greater financial and other resources than we do. If we directly compete with them for the same markets and/or products, their financial and market strength could prevent us from capturing a meaningful share of those markets.

Research and Development

The research and development required for FDA approval of the Primary Care Portfolio and the Pediatric Portfolio has been conducted by 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.

We financially supported a Natesto study conducted at the University of Miami, through which the investigators sought to demonstrate that Natesto improves hypogonadism while preserving fertility parameters. The study was led by Dr. Ranjith Ramasamy, MD, Director of Reproductive Urology at the University of Miami’s Department of Urology. In April 2020, we announced the results of the Phase IV single institution, prospective, clinical trial conducted between November 2017 and September 2019 at the University of Miami's Department of Urology by lead author and the study's principal investigator Dr. Ranjith Ramasamy, MD, the Director of Reproductive Urology. The study concluded that Natesto was effective in returning hypogonadal men to back to normal testosterone levels, significantly improve erectile function and quality of life, preserve gonadotropin hormones, and most importantly preserve semen parameters through 6 months of treatment.

Studies estimate ~12.4 - 15.6% of men under 39 years old receive prescribed testosterone therapy (TTh). The most commonly prescribed testosterone therapies, injections and topical gels, can impair semen parameters and can cause azoospermia in up to 65% of men. Additionally, off-label use of therapies such as selective estrogen receptor modulators (SERMs) are widely used to preserve spermatogenesis while simultaneously increasing testosterone. Many of these off-label products can have numerous additional adverse reactions, therefore identifying alternatives to increase testosterone in men without impacting fertility is paramount.

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.

Employees

As of September 15, 2020, we had 75 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 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, 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 specialty pharmaceutical 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. Since then, we have incurred losses in each year since our inception. Our net loss for the years ended June 30, 2020 and 2019 was $13.6 million and $27.1 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. 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 historical experience acquiring products and or businesses as we continue to strategically develop our product and business portfolio. We may be unable to adjust spending in a timely manner to compensate for any unexpected budgetary shortfall.

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 the Primary Care Portfolio, Pediatric Portfolio, the Consumer Health segment and COVID-19 Test Kits and investing in efforts to eventually commercialize the Healight Platform, 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. As of June 30, 2020, our cash, cash equivalents and restricted cash totaling $48.3 million, available to fund our operations, offset by an aggregate $20.0 million in accounts payable and other and accrued liabilities. During the twelve months ended June 30, 2020, the Company raised approximately $87.2 million proceeds, net of fees from a combination of common stock offerings and common stock warrant exercises.

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 may require additional capital to continue the expansion of commercialization efforts for our pharmaceutical, device and commercial health products, and to obtain regulatory approval for, and to commercialize, our current product candidate, the Healight Platform. Raising funds in the current economic environment, as well as our limited 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 could 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 our pharmaceutical, device and consumer health products, and/or be required to significantly curtail, delay or discontinue one or more of our research or development programs for the Healight Platform, 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.

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, 2020 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

Our Pharmaceutical, Device and Consumer Health products 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 our pharmaceutical, device and consumer health product offerings. 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 pharmaceutical products; 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 the Healight Platform.

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 our pharmaceuticals and consumer health product offerings . 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, our product candidates.

We may not be able to develop our current or 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.

For our more strictly regulated pharmaceutical products, such as our Primary Care Portfolio and Pediatric Portfolio product offerings, we are not permitted to market a pharmaceutical 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.

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 and Healight Platforms for clinical use.

The MiOXSYS System is subject to 510(k) 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. The Healight Platform is also subject to 510(k) De Novo clearance or Emergency Use Authorization (EUA) during the COVID-19 pandemic by the FDA prior to its marketing for commercial use in the U.S., and to regulatory approvals required by certain foreign governmental entities prior to its marketing outside of 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 510(k) De Novo clearance, pre-market approval, or foreign regulatory approvals. The 510(k) 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 510(k) 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 510(k) 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 Authorization Application, or MAA, to the European Medicines Agency, or EMA, which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining regulatory approvals from health authorities in countries outside the 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 our pharmaceutical and devices regulated by the FDA;
- 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.

Except for the Healight Platform, we compete with companies that design, manufacture and market treatments that compete with our products.

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 for some of our Primary Care and Pediatric portfolios 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 have 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 our pharmaceutical products are 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 all of our products, at the very least, in the near future. 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, we will face difficulty finding replacement suppliers, which could harm sales of those products. 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.

Certain of our products 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.

Certain of our products, such as Natesto, Tuzistra XR and ZolpiMist, which are approved by the FDA, are regulated by the DEA as Schedule III or Schedule IV 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. These requirements are applicable to us, to our third-party manufacturersand 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 are considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Natesto and Tuzistra XR are regulated by the DEA as a Schedule III controlled substances, 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 be 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 be done farther down the distribution chain including, (i) wholesaler authentication and verification in November 2019, (ii) pharmacy authentication 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.

Risks Related to COVID-19

Our business may be adversely affected by the effects of the COVID-19 pandemic.

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. It has since spread to multiple other countries; and, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. This pandemic has adversely affected or has the potential to adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate, our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, business partners and customers, and the demand for some of our marketed products.

The COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including governmental orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, maintain social distancing, and order cessation of non-essential travel. As a result of these recent developments, we have implemented work-from-home policies for a significant part of our employees. The effects of shelter-in-place and social distancing orders, government-imposed quarantines, and work-from-home policies may negatively impact productivity, disrupt our business, and delay our business timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Such restrictions and limitations may also negatively impact our access to regulatory authorities (which may be affected, among other things, by travel restrictions and may be delayed in responding to inquiries, reviewing filings, and conducting inspections). The COVID-19 pandemic may also result in the loss of some of our key personnel, either temporarily or permanently. In addition, our sales and marketing efforts may be impacted by postponement of face-to-face meetings and restrictions on access by non-essential personnel to hospitals or clinics, all of which could slow adoption and implementation of our marketed products, resulting in lower net product sales. For example, while the impact of shelter-in-place and social distancing orders, physicians' office closures, and delays in the treatment of patients following the COVID-19 pandemic on our net product sales of our products for the three months ended March 31, 2020 was limited, overall demand was lower in April 2020 compared to the same period of 2019. In addition to other potential impacts of the COVID-19 pandemic on net product sales, we expect to see continued adverse impact on new patient starts for all products while these measures remain in place. See Part III, Item 2. "Management's Discussion and Analysis of Financial Condition and Results of Operations - Results of Operations" for a discussion of our net product sales. Demand for some or all of our marketed products may continue to be reduced while the shelter-in-place or social distancing orders are in effect and, as a result, some of our inventory may become obsolete and may need to be written off, impacting our operating results. These and similar, and perhaps more severe, disruptions in our operations may materially adversely impact our business, operating results, and financial condition.

Quarantines, shelter-in-place, social distancing, and similar government orders (or the perception that such orders, shutdowns, or other restrictions on the conduct of business operations could occur) related to COVID-19 or other infectious diseases are impacting personnel at our research and manufacturing facilities, our suppliers, and other third parties on which we rely, and may impact the availability or cost of materials produced by or purchased from such parties, which could result in a disruption in our supply chain.

In addition, infections and deaths related to COVID-19 may disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay, FDA review and potential approval of our marketed products. It is unknown how long these disruptions could continue. Further, while we are focused on therapies to address the COVID-19 pandemic, our other product candidates may need to be de-prioritized. Any elongation or de-prioritization of our other products could materially affect our business.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for us to access capital if needed. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The global COVID-19 pandemic continues to rapidly evolve. The ultimate impact of this pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, healthcare systems, or the global economy as a whole. These effects could have a material impact on our operations. To the extent the COVID-19 pandemic adversely affects our business, prospects, operating results, or financial condition.

We are relying on FDA policies and guidance provisions that have changed very recently, and may continue to change, and relate directly to the COVID-19 health crisis. If we misinterpret this guidance or the guidance changes unexpectedly and/or materially, potential sales of the COVID-19 tests would be impacted.

The U.S. Food and Drug Administration (FDA) issued non-binding guidance for manufacturers relating to the pathway to enable FDA approval for devices related to testing for COVID-19 under an Emergency Use Authorization (EUA). Following the issuance of the initial published guidance, on March 16, 2020, revised guidance specific to COVID-19 "antibody tests" was issued. Newer guidance was published on May 4, 2020 and May 11, 2020 further describing the requirements for serology tests to continue to be marketed under an Emergency Use Authorization. If our interpretation of the newly revised guidance is incorrect or specifics around the guidance change, the sales of the COVID-19 test could be materially impacted. In addition, if we or our manufacturing partners are not able to obtain EUA on the COVID-19 tests or our manufacturing partners' EUAs do not cover us our potential sales of the COVID-19 tests would be impacted.

If the COVID-19 tests we distribute do not perform as expected or the reliability of the technology is questioned, we could experience delayed or reduced market acceptance of the tests, increased costs and damage to our reputation.

Our success depends on the market's confidence that we can provide reliable, high-quality COVID-19 diagnostic tests. We believe that customers in our target markets are likely to be particularly sensitive to product defects and errors. Our reputation and the public image of our licensed COVID-19 diagnostic tests may be impaired if they fail to perform as expected or are perceived as difficult to use. Despite quality control testing, defects or errors could occur with the tests.

In the future, if the COVID-19 diagnostic tests experience a material defect or error, this could result in loss or delay of revenues, delayed market acceptance, damaged reputation, diversion of development resources, legal claims, increased insurance costs or increased service and warranty costs, any of which could harm our business. Such defects or errors could also prompt us to amend certain warning labels or narrow the scope of the use of our diagnostic tests, either of which could hinder our success in the market. Even after any underlying concerns or problems are resolved, any widespread concerns regarding our technology or any manufacturing defects or performance errors in the test could result in lost revenue, delayed market acceptance, damaged reputation, increased service and warranty costs and claims against us.

If we become subject to claims relating to improper handling, storage or disposal of hazardous materials, we could incur significant cost and time to comply

Our research and development processes involve the controlled storage, use and disposal of hazardous materials, including biological hazardous materials. We are subject to foreign, federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. We may incur significant costs complying with both existing and future environmental laws and regulations. In particular, we are subject to regulation by the Occupational Safety and Health Administration, (OSHA), and the Environmental Protection Agency (EPA), and to regulation under the Toxic Substances Control Act and the Resource Conservation and Recovery Act in the United States. OSHA or the EPA may adopt additional regulations in the future that may affect our research and development programs. The risk of accidental contamination or injury from hazardous materials cannot be eliminated completely. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our workers' compensation insurance. We may not be able to maintain insurance on acceptable terms, if at all.

The COVID-19 tests we distribute have not been manufactured on a high-volume scale and could be subject to unforeseen scale-up risks.

While the manufacturers of the COVID-19 tests have experience manufacturing diagnostic tests, there can be no assurance that they can manufacture the COVID-19 diagnostic tests at a scale that is adequate for our current and future commercial needs. We may face significant or unforeseen difficulties in securing adequate supply of the COVID-19 diagnostic tests, relating to the manufacturing of the tests. These risks include but are not limited to:

- Technical issues relating to manufacturing components of the COVID-19 diagnostic tests on a high-volume commercial scale at reasonable cost, and in a reasonable timeframe;
- difficulty meeting demand or timing requirements for orders due to excessive costs or lack of capacity for part or all of an operation or process;
- changes in government regulations or in quality or other requirements that lead to additional manufacturing costs or an inability to supply product in a timely manner, if at all; and
- increases in raw material or component supply cost or an inability to obtain supplies of certain critical supplies needed to complete our manufacturing processes.

These and other difficulties may only become apparent when scaling up to the manufacturing process of the COVID-19 diagnostic tests to a more substantive commercial scale. In the event the tests cannot be manufactured in sufficient commercial quantities or manufacturing is delayed, our future prospects could be significantly impacted, and our financial prospects could be materially harmed.

Our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacturing of the COVID-19 diagnostic tests that could result in delays or shortfalls in our production. Suppliers may also face similar delays or shortfalls. In addition, suppliers' production processes may have to change to accommodate any significant future expansion of manufacturing capacity, which may increase suppliers' manufacturing costs, delay production of diagnostic tests, reduce our product gross margin and adversely impact our business. If we are unable to keep up with demand for the COVID-19 diagnostic test by successfully securing supply and shipping our diagnostic tests in a timely manner, our revenue could be impaired, market acceptance for the test could be adversely affected and our customers might instead purchase our competitors' diagnostic tests.

We have relied and expect to continue to rely on third parties to conduct studies of the COVID-19 diagnostic tests that will be required by the FDA or other regulatory authorities and those third parties may not perform satisfactorily.

Although we intend to sell the COVID-19 IgG/IgM rapid tests by virtue of recent FDA guidance allowing for reduced product clinical and analytical studies, we have relied on third parties, such as independent testing laboratories and hospitals, to conduct such studies. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for additional diagnostic tests.

If the manufacturers' delivery of the COVID-19 tests and the required clinical data is delayed, then our ability to obtain necessary regulatory approvals and/or authorizations to distribute the COVID-19 tests will be impaired, which will adversely affect our business plans.

While the FDA has provided a path forward to begin selling the COVID-19 tests on an expedited basis, we are still required to provide the FDA with data concerning the validation of the tests and to satisfy certain labeling conditions. If the manufacturers are delayed in delivering to us the COVID-19 tests and related validation data, we will, in turn, be delayed in obtaining FDA authorization or approval required before we can begin selling the COVID-19 tests. Any such delays will adversely affect our business plans.

We rely on third parties to manufacture the COVID-19 tests for us and if such third-party refuses or is unable to supply us with the COVID-19 test, our business will be materially harmed.

We rely on third parties to manufacture the COVID-19 diagnostic tests, which manufacturers licenses their rights from the owners of the intellectual property underlying the COVID-19 tests. If any issues arise with respect to the manufacturers' ability to manufacture and deliver to us the COVID-19 tests, our business could be materially harmed.

Risks Related to the Healight Technology

We must rely on a third party to develop the Healight Technology.

We must rely on Cedars-Sinai Medical Center to conduct testing and clinical trials of the Healight Technology (" ***Healight Platform***"). As a result, we are expected to remain dependent on a third party to conduct ongoing trials and the timing and completion of these trials will be partially controlled by such third party and may result in delays to the Healight development program. Nevertheless, we are responsible for ensuring that each of the trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards and our reliance on a third party does not relieve us of our regulatory responsibilities. If we or Cedars-Sinai Medical Center fail to comply with applicable requirements, the FDA may require us to perform additional clinical trials.

There is no guarantee that Cedars-Sinai Medical Center will devote adequate time and resources to the Healight development activities or perform as contractually required. Furthermore, Cedars-Sinai Medical Center may also have relationships with other entities, some of which may be our competitors. If Cedars-Sinai Medical Center fails to meet expected deadlines, adhere to our clinical protocols, meet regulatory requirements, or otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for the Healight technology development may be extended, delayed, suspended, or terminated.

The development of Healight faces uncertainties related to testing.

The development of Healight is based on scientific hypotheses and experimental approaches that may not lead to desired results. It is possible that the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic, and collaborator constraints. Success in one stage of testing is not necessarily an indication that the Healight program will succeed in later stages of testing and development. The discovery or unexpected side effects, inability to increase scale of manufacture, market attractiveness, regulatory hurdles, competition, as well as other factors may make the Healight technology unattractive of unsuitable for human use.

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 viewed 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

Our Amended and Restated Bylaws provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, including claims under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Amended and Restated Bylaws provides that the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and our directors, officers, employees and agents. Stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. Notwithstanding the foregoing, the exclusive provision shall not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the Exchange Act, or the Securities Act of 1933, as amended, or the Securities Act, or the respective rules and regulations promulgated thereunder.

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, our acquisition of the Pediatric Portfolio in November 2019 and the merger with Innovus Pharmaceuticals, Inc. in February 2020. 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 2020, 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.

Three customers contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2020 and four customers contributed greater than 10% of the Company's gross revenue during the year ended 2019, respectively. As of June 30, 2020, three customers accounted for 46% 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, 2020, four customers accounted for 61% of gross accounts receivable. As of June 30, 2019, four customers accounted for 88% 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, 2020, we had 75 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, 2020, we had federal net operating loss carryforwards of approximately $147.1 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, 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.

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 5.0 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, 2020, options to purchase 765,937 shares of common stock issued under our 2015 Stock Plan at a weighted average exercise price of $1.85 per share were outstanding. In addition, at June 30, 2020, there were outstanding warrants to purchase an aggregate of 23,125,293 shares of our common stock at a weighted average exercise price of $3.78. 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.

Shareholders approved a reverse stock split of up to 1-for-20 on April 24, 2020 which if the Board of Directors elected to effect, and enacted, may not achieve one or more of our objectives.

Historically, we have affected 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, the Company entered into a 37-month operating lease in Englewood, Colorado. This lease has an initial base rent of $9,000 a month with a total base rent over the term of the lease of approximately $318,000. In October 2017, the Company signed an amendment to the 37-month operating lease in Englewood, Colorado. The amendment extended the lease for an additional 24 months beginning October 1, 2018. The base rent will remain at $9,000 a month. In April 2019, the Company extended the lease for an additional 36 months beginning October 1, 2020.

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 terminated the lease agreement on July 31, 2020.

In July 2020, Aytu entered into a 24-month operating lease for office space in Raleigh, North Carolina. The lease has initial base rent of $792 a month, with the annual base rent of approximately $9,500.

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

In November and December 2019, four lawsuits were filed in connection with the Company's disclosure statement regarding the October 2019 financing transaction and the acquisition of the Pediatric Portfolio. As of the date of this 10-K Report, all plaintiffs have dismissed their claims after the Company amended its disclosure.

On November 20, 2019, an individual named Carl Pliscott, filed a Verified Class Action Complaint in Delaware Chancery Court, alleging that the Company's Board of Directors had breached its fiduciary duty to the Company stockholders by disseminating a proxy statement which, according to the Complaint, did not provide stockholders with sufficient information to allow stockholders to meaningfully assess the reasonableness or financial fairness of two transactions: (i) an Asset Purchase Agreement, entered on October 10, 2019, with Cerecor Inc., ("Cerecor") pursuant to which the Company had purchased certain assets, and assumed certain liabilities, from Cerecor; and (ii) Securities Purchase Agreements entered on October 11, 2019 with two investors pursuant to which the Company issued and sold $10.0 million of Aytu's Series F Convertible Preferred Stock.

After the Pliscott case was filed three additional cases making similar allegations were filed: Adam Franchi v. Aytu Bioscience, Inc., et al., was filed in U.S. District Court in Delaware on November 26, 2019; Adam Kirschenbaum v. Aytu Bioscience, Inc., et al., was filed in Delaware Chancery Court on December 10, 2019; and Michael Sebree v. Josh Disbrow, et al., was filed in Delaware Chancery Court on December 17, 2019.

Although the Company believed that its proxy statement provided stockholders with sufficient information, the Company determined that it would be most efficient and least costly to file an amended proxy statement making supplemental disclosures in order to moot the claims asserted in the Pliscott, Franchi, Kirschenbaum and Sebree plaintiffs.

After the amended proxy statement was filed, the Pliscott, Franchi, Kirschenbaum and Sebree plaintiffs agreed to dismiss their claims, and the Company agreed to pay attorney fees to the lawyers representing the plaintiffs in these cases.

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, 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

Fiscal Year ended June 30, 2020	High	Low
First Quarter (ended September 30, 2019)	$ 1.95	$ 1.21
Second Quarter (ended December 31, 2019)	$ 1.35	$ 0.67
Third Quarter (ended March 31, 2020)	$ 2.05	$ 0.35
Fourth Quarter (ended June 30, 2020)	$ 2.02	$ 1.19

On September 15, 2020, the closing price as reported on the NASDAQ of our common stock was $1.18. As of September 15, 2020, there were 1,026 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. At the special meeting of stockholders on January 24, 2020, the Aytu stockholders voted to increase the plan to 5.0 million shares. The following table displays equity compensation plan information as of June 30, 2020 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 (Column A)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column B)	Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Column C - Excluding Securities Reflected in Column (A))
Equity compensation plans approved by security holders	765,937	$ 1.85	4,837
Equity compensation plans not approved by security holders	1,624	$ 594.63	-
Total	767,561	$ 3.10	4,837

Dividend Policy

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

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

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

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

Item 6. Selected Financial Data

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing elsewhere in this Annual Report. Some of the information contained in this discussion and analysis, including information with respect to our plans and strategy for our business and related financing strategy, 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 commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant healthcare needs in both prescription and consumer health categories. Through our heritage prescription business, we currently market a portfolio of prescription products addressing large primary care and pediatric markets.

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 our equity securities. Since the formation of Aytu in June 2015, we have raised approximately $157.6 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 277% and 100% for each of the years ended June 30, 2020 and 2019, respectively, and are 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 the year ended June 30, 2020 was $28.4 million compared to $13.8 million for the year ended June 30, 2019. The increased cash use was due to funding existing operations as well as the funding required to consummate and integrate the operations of two significant transactions which substantially increased the size and scope of our commercial operations. Additional funds were required to license the Healight Platform and pursue its development. Revenue from our Covid-19 test kit sales has supplemented revenue from our core Rx and Consumer Health operations beginning in the fourth quarter of 2020. While this revenue and related cash flow has a positive impact on the Company's financial performance and reduces the amount of capital required from financings, we believe this revenue will be temporary, potentially limited to the period while the US is experiencing the Covid-19 pandemic. Additionally, our Covid-19 test kits are, serology test kits that do not provide confirmatory results. Our COVID-19 test kits are intended for patient screening purposes. This may limit the addressable market for our Covid-19 test kits. However, the utility of our Covid-19 test kits is high as they are a lower cost diagnostic tool and produce results quickly compared to other testing technologies. We believe these characteristics, allow for a substantial addressable market for our serology test kits. On September 22, 2020, we were informed by FDA that our Covid-19 serology test kits manufactured by Zhejiang Orient Gene Biotech Co., Ltd. are viewed by FDA as a distinct product from another Zhejiang Orient Gene Biotech Co., Ltd. test kit that was covered by an EUA (the "Healgen Scientific test kit") given the differences in labeling between the products. The FDA advised us that we could consider aligning our test kit labeling to the Healgen Scientific test kit labeling to be covered under their EUA, given that the tests are identical from a technical perspective, or that we could sell the test kit as currently configured under Section IV.D of the FDA's Policy for Coronavirus Disease-2019 Tests as already allowed for under the policy. Given what we expect to be the current and future market of serology based Covid-19 tests, we have decided to sell the remaining kits under Section IV.D of the FDA's Policy for Coronavirus Disease-2019 Tests rather relying on the Healgen Scientific EUA. The main difference between selling test kits under a Section IV.C and under Section IV.D of the FDA's Policy for Coronavirus Disease-2019 Tests is that purchasers of our serology test kits under Section IV.D of the FDA's Policy for Coronavirus Disease-2019 are required to have access to high complexity laboratories. Substantially all of our test kit customers have access to high complexity laboratories and therefore we expect a minimal impact on our sales outlook. However, this could limit the number of potential customers for the test kits which may impact our revenue and profitability.

As of the date of this Report, we expect costs for our current operation to stabilize as we integrate the acquisition of the Pediatrics Portfolio and Innovus (Aytu Consumer Health) and continues to focus on revenue growth through increasing product sales and the introduction of new products. Our total current asset position of approximately $75.0 million plus the proceeds expected from ongoing product sales will be used to fund operations. Since we have sufficient cash and cash equivalents on-hand as of June 30, 2020, to fund potential net cash outflows for the twelve months following the filing date of this Annual Report, in accordance with ASU 2014-15, Subtopic 205-40, we report that there does not exist any indication of substantial doubt about our ability to continue as a going concern.

The Company's business model involves in-licensing and/or acquiring new products, product lines, or businesses that are complementary to its current products and businesses. Because of this the Company is frequently engaged in ongoing discussions to evaluate and consider the acquisition or licensing of new products. At any given time, the Company may be exploring transactions inclusive of product-specific transactions or larger, strategic transactions. In fiscal 2020 the Company completed two transactions, a significant asset purchase and a merger, and may consider additional transactions of that size or larger.

While our capital is sufficient to fund our near-term operations, there is no guarantee that such capital resources will be sufficient until such time we reach profitability. We may access capital markets to fund strategic acquisitions or ongoing operations on terms management believes are favorable. 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. We may utilize debt or sell newly issued equity securities through public or private transactions, or through the use of an at the market facility. There is no guarantee that capital will be available on terms favorable to Aytu and our stockholders, or at all. However, we have been successful in accessing the capital markets in the past and are confident in our ability to access the capital markets again, if needed.

If we are unable to raise adequate capital in the future, if and when it is required, we can adjust our operating plans to reduce the magnitude of the capital need under our existing operating plans. Some of the adjustments that could be made include delays of and reductions to M&A plans and commercial programs, reductions in headcount, narrowing the scope of our commercial plans, or reductions to our research and development programs. Without sufficient operating capital, we could be required to relinquish rights to products or renegotiate to maintain such rights on less favorable terms than it would otherwise choose. This may lead to impairment or other charges, which could materially affect our balance sheet and operating results.

Nasdaq Listing Compliance. The Company's common stock is listed on The Nasdaq Capital Market (the "Nasdaq"). In order to maintain compliance with Nasdaq listing standards, the Company must, amongst other requirements, maintain a stockholders' equity balance of at least $2.5 million pursuant to Nasdaq Listing Rule 5550(b). In that regard, on June 30, 2020, the Company's stockholders' equity totaled approximately $95.0 million.

On September 30, 2019, the Company's stockholders' equity totaled approximately $2.3 million. However, subsequent to September 30, 2019, the Company completed (i) the Offering with the Investors, raising approximately $9.3 million, net in equity financing (see Note 1), and (ii) the "Asset Purchase Agreement" in which the Company issued approximately 9.8 million shares of Series G Convertible Preferred Stock worth approximately $5.6 million, resulting in an increase in stockholders' equity of approximately $14.8 million in the aggregate. Further, the Company raised additional funds including (i) $71.3 million in net proceeds from the March 10, 2020, March 12, 2020 and March 19, 2020 Offerings and exercises of warrants during March and April of 2020, and (ii) $6.6 million in net proceeds raised from our at the market facility during June 2020.

Accordingly, as of the filing of this Form 10-K, the Company's stockholders' equity balance significantly exceeds the minimum $2.5 million threshold and, therefore, the Company believes it is currently in compliance with all applicable Nasdaq Listing Requirements.

We have incurred accumulated net losses since inception, and at June 30, 2020, we had an accumulated deficit of $120.0 million. Our annual net loss decreased to $13.6 million for the year ended June 30, 2020 compared to a net loss of $27.1 million during our previous fiscal year ended June 30, 2019. We used $28.4 million and $13.8 million in cash from operations during the years ended June 30, 2020 and 2019, respectively.

Results of Operations

Comparison of the years ended June 30, 2020 and 2019

	Year Ended June 30,			
	2020	2019	$ Change	% Change
Revenues				
Product revenue, net	$ 27,632,080	$ 7,314,581	$ 20,317,499	278%
License revenue, net	-	5,776	(5,776)	-100%
Total product revenue	27,632,080	7,320,357	20,311,723	277%
Operating expenses				
Cost of sales	7,553,031	2,202,041	5,350,990	243%
Research and development	1,721,419	589,072	1,132,347	192%
Selling, general and administrative	34,802,432	18,887,783	15,914,649	84%
Selling, general and administrative - related party	-	351,843	(351,843)	-100%
Impairment of intangible assets	195,278	-	195,278	–
Amortization of intangible assets	4,490,466	2,136,255	2,354,211	110%
Total operating expenses	48,762,626	24,166,994	24,545,632	102%
Loss from operations	(21,130,546)	(16,846,637)	(4,283,909)	25%
Other (expense) income				
Other (expense), net	(2,606,487)	(535,500)	(2,070,719)	387%
(Loss) / gain from contingent consideration	10,430,252	(9,830,550)	20,260,802	-206%
Gain (Loss) on extinguishment of debt	(315,728)	-	(315,728)	–
Gain from warrant derivative liability	1,830	80,779	(78,949)	-98%
Total other (expense) income	7,509,867	(10,285,271)	17,795,138	-173%
Net loss	$ (13,620,679)	$ (27,131,908)	$ 13,511,229	-50%

Product revenue. During the year ended June 30, 2020, we recognized revenue of $27.6 million associated with the sale of our products, an increase of approximately $20.3 million compared to the same period ended June 30, 2019. This increase was primarily driven by revenues from (i) sales of the recently acquired Pediatric Portfolio and from sales of our COVID-19 Test Kits, and (ii) approximately $10.4 million from sales from our Consumer Health segment as a result of the Merger with Innovus on February 14, 2020.

Cost of sales. Cost of sales increased approximately $5.4 million during the year ended June 30, 2020 compared to the same period ended June 30, 2019. This increase was primarily driven by the additional costs of higher sales resulting from the (i) acquisition of the Pediatric Portfolio on November 1, 2019, (ii) the Merger with Innovus on February 14, 2020, and (iii) sales of our COVID-19 Test Kits during the three months ended June 30, 2020.

Research and Development. Research and development expenses increased $1.1 million, or 192%, in fiscal 2020 compared to fiscal 2019. The increase was due primarily to approximately $1.3 million related to costs associated with the Company's Healight Platform license and initial development and clinical costs.

Selling, General and Administrative. Selling, general and administrative costs increased $15.9 million, or 84%, for the year ended June 30, 2020 compared to the same period in 2019. This increase was primarily driven by the cost of personnel and the commercial support associated with generating additional revenues from the (i) acquisition of the Pediatric Portfolio on November 1, 2019 and (ii) the Merger with Innovus on February 14, 2020. Additionally, we incurred significant expenses associated with the execution of the Merger and Pediatric Portfolio transactions.

Selling, General and Administrative – Related Party. Selling, general and administrative costs – related party relate to the cost of services provided by TrialCard, one of our vendors that previously employed one of our Directors, Mr. Donofrio, for a period of time during the fiscal year ended June 30, 2019.

Impairment of Intangible Assets. We incurred an impairment loss of approximately $0.2 million for the year-ended June 30, 2020 as a result of the write-down of the carrying value of the MiOXSYS patent portfolio.

Amortization of Intangible Assets. Amortization expense for our intangible assets was $4.5 million for the year ended June 30, 2020 compared to $2.1 million for the year ended June 30, 2019. The increase of $2.4 million in amortization expense was the result of (i) the November 1, 2019 acquisition of the Pediatric Portfolio from Cerecor, Inc. and (ii) the February 14, 2020 Innovus Merger.

Other (expense) income, net. Other (expense) income, net for the year ended June 30, 2020 was income of approximately $7.5 million, compared to expenses of $10.3 million for the year ended June 30, 2019. The approximately $17.8 million difference was due to (i) a gain of approximately $10.4 million as a result of a decline in the fair value of the contingent consideration liability related to ZolpiMist and Tuzistra for the year ended June 30, 2020, compared to the prior year when we realized a loss of approximately $9.8 million for the year-ended June 30, 2019, and (ii) offset by an approximately $2.0 million increase in other expenses due to accretion and interest expense resulting from the assumed fixed payment obligations and other long-term liabilities that arose from the (i) November 1, 2019 acquisition of the Pediatric Portfolio from Cerecor, Inc. and (ii) the February 14, 2020 Merger with Innovus.

Liquidity and Capital Resources

	Year ended June 30,	
	2020	2019
Net cash used in operating activities	$ (28,373,887)	$ (13,831,377)
Net cash used in investing activities	$ (5,655,772)	$ (1,061,985)
Net cash provided by financing activities	$ 71,068,739	$ 19,075,062

Net Cash Used in Operating Activities

During fiscal 2020, net operating cash outflows totaled $28.4 million. The use of cash was approximately $14.8 million greater than the net loss due primarily to non-cash income/gains from change in fair value of contingent consideration and derecognition of contingent consideration. In addition, the Company's use of cash increased due to changes in working capital including increases in accounts receivable, inventory, prepaid and other assets. These charges were offset by depreciation, amortization and accretion and an increase in accrued liabilities and accrued compensation.

During fiscal 2019, our operating activities consumed $13.8 million of cash. Our cash use 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.

Net Cash Used in Investing Activities

During fiscal 2020, net investing cash outflows totaled $5.7 million as the result of (i) $1.4 million for the Innovus Merger, (ii) $4.5 million for the acquisition of the Pediatric Portfolio from Cerecor, (iii) payment of $0.2 million in contingent consideration and (iv) offset by cash of $0.4 million acquired due to the Innovus Merger.

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.

Net Cash from Financing Activities

Net cash provided by financing activities during fiscal 2020 was $71.1 million. This was primarily related to the (i) October 2019 Offering for gross proceeds of $10.0 million, offset by the offering cost of $0.7 million which was paid in cash; (ii) $49 million raised in the March 2020 Offerings, offset by offering costs of approximately $4.5 million, (iii) $27.0 million raised as the result of warrant exercises in March 2020, and (iv) gross proceeds of $6.8 million from the at-the-market offering program in June 2020, offset by offering cost of $0.2 million.

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 $5.0 million from a collateralized promissory note issued to Armistice Capital. We also received proceeds of $375,000 from warrant exercises.

Payroll Protection Plan. During the year ended June 30, 2020, the Company participated in the Paycheck Protection Program ("PPP"), a Small Business Administration ("SBA") loan program through a third-party financial institution in response to the COVID-19 global pandemic. The Company borrowed approximately $2.5 million during the three months ended June 30, 2020. However, the Company elected to return the proceeds to the SBA during the same three months ended June 30, 2020 after reviewing the Company's financial and liquidity position and taking into account the goals of the PPP.

Contractual Obligations and Commitments

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide information under this item.

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, 2020. 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, 2020, 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, except as described below, 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.

The Company's assessment over changes in our internal controls over financial reporting excluded those processes or controls that exist at our Aytu Consumer Health reporting unit which we acquired from the February 14, 2020 Innovus Merger. Aytu Consumer Health comprises approximately 37.6% of net revenues, 23.6% of net losses, and 17.4% of the total assets.

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 September 15, 2020. Our Board of Directors is currently comprised of seven 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	45	Chairman and Chief Executive Officer
David A. Green	57	Chief Financial Officer, Secretary, and Treasurer
Steven J. Boyd	39	Director
Gary V. Cantrell	65	Director
Carl C. Dockery	57	Director
John A. Donofrio, Jr.	52	Director
Michael E. Macaluso	68	Director
Ketan Mehta	59	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.

David A. Green – Chief Financial Officer, Executive Vice President, 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.

Steven J. Boyd - Director

Steven J. Boyd 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

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 biotechnology 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 2019, Mr. Donofrio was appointed President of EPI Health, a privately-held specialty pharmaceutical company focused on dermatology. From March 2018 through February 2019, Mr. Donofrio served as 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. MrDonofrio 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, a fully-integrated specialty pharmaceutical company focused on developing and commercializing advanced delivery technologies. Ketan founded Tris in 2000 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, 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.

Family Relationships

Jarrett T. Disbrow, our Executive VP, Corporate Development, 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 a 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 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 each non-employee director, $20,000 for the committee chair of the Audit and Compensation Committees, $10,000 for each other member of the Audit and Compensation Committees, $10,000 for the committee chair of the Nominating and Governance committee, and $5,000 for each other member of the Nominating and Governance committee; a grant of 65,000 restricted shares of stock upon appointment to the board; and an annual stock option grant or a combination of options and restricted stock units for each year of service thereafter.

The following table provides information regarding all compensation paid to non-employee directors of Aytu during the fiscal year ended June 30, 2020.

Name	Fees Earned or Paid in Cash	All Other Compensation (1)	Total
Carl C. Dockery (2)(3)	$ 74,400	$ 56,130	$ 130,530
John A. Donofrio Jr. (2)(3)	$ 74,400	$ 56,130	$ 130,530
Michael E. Macaluso (2)(3)	$ 69,400	$ 56,130	$ 125,530
Gary V. Cantrell (2)(3)	$ 64,400	$ 42,564	$ 106,964
Ketan Mehta (2)(3)	$ 44,600	$ 61,800	$ 106,400
Steven J. Boyd (2)(3)	$ –	$ –	$ –

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

(2) As of June 30, 2020, the number of restricted shares held by each non-employee director was as follows: (i) 152,663 restricted shares for Mr. Dockery; (ii) 152,663 restricted shares for Mr. Donofrio; (iii) 202,663 restricted shares for Mr. Macaluso; (iv) 162,663 restricted shares for Mr. Cantrell; and (v) 75,000 restricted shares for Mr. Mehta.

(3) As of June 30, 2020, the number of stock options held by each non-employee director was as follows: (i) 40,038 shares for Mr. Dockery; (ii) 40,038 shares for Mr. Donofrio; (iii) 40,105 shares for Mr. Macaluso; (iv) 20,038 shares for Mr. Cantrell and (v) 40,000 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, 2020 and 2019 to each of the following named executive officers.

Name and Principal Position (a)	Year (b)	Salary ($) (c)(3)	Bonus ($) (d)	Stock Award ($) (e)	Option Award ($)(1) (f)	Non-Equity Incentive Plan Compensation ($) (g)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($) (h)	All Other Compensation ($) (i)	Total ($) (j)
Named Executive Officers									
Joshua R. Disbrow									
Chief Executive Officer since December 2012	2020	$ 607,620	$ 185,000	$ 652,500	$ 140,330				$ 1,585,450
	2019	$ 330,000	$ 135,000	$ 578,705	$ –	$ –	$ –	$ –	$ 1,043,705
David A. Green (2)									
Chief Financial Officer, Secretary and Treasurer, since December 2017	2020	$ 400,046	$ 150,000	$ 362,500	$ 140,330	$	$	$	$ 1,052,876
	2019	$ 250,000	$ 95,000	$ 340,988	$ –	$ –	$ –	$ –	$ 685,988

(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 effective December 18, 2017.

(3) Salaries for the year ended June 30, 2020 include accrued deferred payments of $222,203 to Mr. Joshua R. Disbrow and $130,463 to Mr. David A. Green that were paid in July 2020.

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 most beneficial to our company and our shareholders. No interest is paid on amounts reimbursed to the executives.

Outstanding Equity Awards at Fiscal Year-End 2020

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2020.

	Option Awards					Stock Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (1)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)
Named Executive Officers									
Joshua R. Disbrow	125	–	–	$ 328.00	11/11/2025	-	$ -	–	$ -
Chief Executive Officer	150	–	–	$ 328.00	7/7/2026	-	$ -	–	$ -
	–	100,000		$ 1.45	6/8/2030	-	$ -		
	–	–	–	–	–	903,475	$ 1,282,935	–	$ -
David A. Green	–	100,000	–	$ 1.45	6/8/2030	-	$ -		
Chief Financial Officer	–	–	–	–	–	516,250	$ 733,075	–	$ -

(1) Based on $1.42 per share which was the closing price of our common stock on NASDAQ on June 28, 2020, 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 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.

On July 1, 2020, we entered into employment agreements with Joshua Disbrow (the "CEO Amendment") and David Green (the "CFO Amendment") The material terms of the respective amendments are as follows.

CEO Amendment

- Effective June 1, 2020, increase base salary to $500,000 and lower annual bonus % target from 100% to 60% of base salary
- Effective January 1, 2021, increase base salary to $590,000
- Granted 100,000 options on terms set forth in a separate option agreement
- Granted 450,000 shares of restricted stock on the terms set forth in a separate restricted stock agreement.

CFO Amendment

- Effective June 1, 2020, increase base salary to $375,000
- Effective January 1, 2021, increase base salary to $400,000
- Granted 100,000 options on terms set forth in a separate option agreement
- Granted 250,000 shares of restricted stock on the terms set forth in a separate restricted stock agreement.

The CEO Amendment and the CFO Amendment are filed as exhibits to this Form 10-K. The foregoing description of the CEO Amendment and the CFO Amendment is qualified in its entirety by reference to the text of the CEO Amendment and the CFO Amendment as attached to this Form 10-K.

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 David Green, had a Change in Control occurred as of June 30, 2020, would be the acceleration of the vesting of all equity securities held by them at that date. On June 30, 2020, the closing price of our common stock was below the exercise price for all of the options held by Joshua Disbrow and therefore there would have been no economic benefit to them upon the acceleration of vesting of those options. RSU acceleration is now a part of our contracts.

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 September 15, 2020 for:

- each beneficial owner of more than 10% 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 September 15, 2020. The percentage ownership information shown in the table is based upon 125,837,357 shares of common stock outstanding as of September 15, 2020.

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, 2020. 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			
None		-	0.00%
Directors and Named Officers			
Disbrow, Joshua	(1)	997,830	*
Green, David	(2)	524,580	*
Macaluso, Michael	(3)	202,843	*
Cantrell, Gary	(4)	162,878	*
Dockery, Carl	(5)	154,795	*
Donofrio, John	(6)	152,701	*
Ketan Mehta	(7)	75,000	*
All directors and executive officers as a group (either persons)		2,522,883	2.00%

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 71,573 shares, (ii) 903,475 restricted shares, (iii) 275 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.

(2) Consists of (i) 5,000 shares, (ii) 516,250 restricted shares, and (iii) 3,330 shares issuable upon the exercise of warrants.

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

(4) Consists of (i) 162,663 restricted shares, (ii) 177 shares, and (iii) vested options to purchase 38 shares of common stock.

(5) Consists of (i) 152,663 restricted shares, (ii) vested options to purchase 38 shares of common stock, and (iii) 2,094 shares held by Alpha Venture Capital Partners, L.P Mr. Dockery is the President of the general partner of Alpha Venture Capital Partners, L.P. and therefore may be deemed to beneficially own the shares beneficially owned by Alpha Venture Capital Partners, L.P.

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

(7) Consists of 75,000 shares of restricted stock.

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 two 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.

Tris Pharma, Inc.

On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tris License Agreement") with 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 License") 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 as well as product minimum make-whole payments in the event the Company fails to achieve certain volume targets.

On November 1, 2019, the Company acquired the rights to Karbinal as a result of the acquisition of the Pediatric Portfolio from Cerecor, Inc. As a result of this acquisition, the Company acquired the license and supply agreement with TRIS. (the "Karbinal License and Supply Agreement"), which grants us an exclusive license in the United States to commercialize Karbinal. Under the terms of the Karbinal License and Supply Agreement, the Company owes royalties on the net product revenues, as well as a royalty make-whole in the event the Company fails to achieve certain sales goals.

Mr. Ketan Mehta serves as a Director on the Board of Directors of the Company, and is also the Chief Executive Officer of TRIS. During the twelve-months ended June 30, 2020, the Company paid TRIS. approximately $1.3 and $1.2 million for the years ended June 30, 2020 and 2019, respectively for a combination of royalty payments, inventory purchases and other payments as contractually required. Our liability obligations to TRIS, including accrued royalties, contingent consideration and fixed payment obligations were $22.7 million and $16.0 million as of June 30, 2020 and 2019, respectively

In March 2020, TRIS converted all 400,000 Series D Convertible preferred stock into 400,000 shares of our common stock.

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 Audit Committee Charter and is available on our website at 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, has served as our independent auditor since April 2015 and has been appointed by our Audit Committee to continue as our independent auditor for the fiscal year ending June 30, 2020.

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,	
	2020	2019
Audit fees	$ 226,000	$ 154,000
Audit related fees (1)	67,512	55,000
Tax fees (2)	—	—
Total fees	$ 293,512	$ 209,000

(1) Audit-related fees for both fiscal year 2020 and 2019 were comprised of fees related to registration statements, including for our August 2017 private offering, S-3 & S-4 filings, our March 2018 public offering, our October 2018 public offering, our March 10, 2020, our March 12, 2020 and our March 19, 2020 offerings respectively.

(2) 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, 2020 and 2019
- Consolidated Statements of Operations for the years ended June 30, 2020 and 2019
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2020 and 2019
- Consolidated Statements of Cash Flows for the years ended June 30, 2020 and 2019
- 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
2.1	Agreement and Plan of Merger, dated as of September 12, 2019, by and among Aytu BioScience, Inc., Aytu Acquisition Sub, Inc. and Innovus Pharmaceuticals, Inc.	8-K	9/18/19	2.1	
2.2	Asset Purchase Agreement, dated October 10, 2019	8-K	10/15/19	2.1	
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	
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock	8-K	10/15/19	3.1	
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock	8-K	11/4/19	3.1	
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	
4.9	Form of Pre-Funded Purchase Warrant	8-K	3/13/20	4.1	
4.10	Form of Placement Agent's Warrant	8-K	3/13/20	4.2	
4.11	Form of Warrant	8-K	3/13/20	4.1	
4.12	Form of Placement Agent's Warrant	8-K	3/13/20	4.2	
4.13	Form of Warrant	8-K	3/20/20	4.1	
4.14	Form of Placement Agent's Warrants	8-K	3/20/20	4.2	
4.15	Form of Wainwright Warrant	8-K	7/2/20	4.1	
10.2#	Asset Purchase Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Valeant International (Barbados) SRL, effective as of December 2, 2011	8-K/A	6/08/15	10.4	
10.3#	Manufacturing and Supply Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Ethypharm S.A., dated September 10, 2012	8-K/A	6/08/15	10.5	

10.4	License, Development and Commercialization Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Daewoong Pharmaceuticals Co., Ltd., effective as of August 23, 2011 (incorporated by reference to Exhibit 10.1 of Ampio Pharmaceuticals Form 8-K/A filed October 5, 2011; File No. 001-25182)			
10.5#	Distribution Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and FBM Industria Farmaceutica, Ltda., dated as of March 1, 2012	8-K/A	6/08/15	10.7
10.6#	Distribution and License Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Endo Ventures Limited, dated April 9, 2014	8-K/A	6/08/15	10.8
10.7#	Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated September 1, 2009	8-K/A	6/08/15	10.9
10.8#	Addendum No. 4 to Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated March 17, 2014	8-K	5/27/15	10.14

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 (incorporated by reference to Exhibit 10.1 to Ampios Form 8-K filed April 22, 2015; File No. 001-35182)				
10.12	Asset Purchase Agreement between Jazz Pharmaceuticals, Inc. and Rosewind Corporation, dated May 20, 2015	8-K	5/27/15	10.14	
10.13	Form of Note Purchase Agreement for 2015 Convertible Note Financing	8-K	7/24/15	10.1	
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	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	
10.20	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	
10.21†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Joshua R. Disbrow	8-K	4/18/17	10.1	
10.22†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Jarrett T. Disbrow	8-K	4/18/17	10.2	
10.23	Asset Purchase Agreement, dated March 31, 2017, between Allegis Holdings, LLC and Aytu BioScience, Inc.	10-Q	5/11/17	10.1	
10.24#	Merger Agreement, dated May 3, 2017, between Nuelle, Inc. and Aytu BioScience, Inc.	10-K	8/31/2017	10.25	
10.25†	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	7/27/17	10.1	
10.26	Securities Purchase Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	8/16/17	10.1	
10.27	Registration Rights Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	8/16/17	10.2	
10.28†	Employment Agreement with David A. Green, dated December 18, 2017	8-K	12/19/2017	10.1	
10.29	Warrant Exercise Agreement dated March 23, 2018	8-K	3/28/18	10.1	
10.30	Amended and Restated Exclusive License Agreement, dated June 11, 2018, between Aytu BioScience, Inc. and Magna Pharmaceuticals, Inc.	10-K	09/06/18	10.31	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.31	Promissory Note, dated November 29, 2018, between Aytu BioScience, Inc. and Armistice Capital Master Fund Ltd	8-K	11/29/18	10.1	
10.32	Waiver of Blocker	10-Q	2/7/19	10.6	
10.33	Common Stock Purchase Warrant	10-Q	2/7/19	10.5	
10.34	Exchange Agreement, dated February 5, 2019	10-Q	2/7/19	10.3	
10.35	License, Development, Manufacturing and Supply Agreement, dated November 2, 2018	10-Q	2/7/19	10.2	
10.36	Amendment No.1 to Securities Purchase Agreement	8-K	4/26/19	10.1	
10.37	Independent Contractor Services Agreement	8-K	5/2/19	10.1	
10.38	Second Amendment to Lease Agreement, dated April 4, 2019	10-Q	5/14/19	10.3	
10.39†	Employment Agreement with Jarret T. Disbrow, dated April 16, 2019	10-Q	5/14/19	10.2	
10.40†	Employment Agreement with Joshua R. Disbrow, dated April 16, 2019	10-Q	5/14/19	10.1	
10.41†	Amended and restated License and Supply Agreement with Acerus Pharmaceuticals, dated July 29, 2019	8-K	8/2/19	10.1	
10.42	Form of Contingent Value Rights Agreement	8-K	9/18/19	10.1	
10.43	Registration Rights Agreement, dated October 11, 2019	8-K	10/15/19	10.3	
10.44	Securities Purchase Agreement, dated October 15, 2019	8-K	10/15/19	10.2	
10.45	Placement Agency Agreement with Ladenburg Thalmann & Co. Inc., dated October 15, 2019	8-K	10/15/19	10.1	
10.46	First Amendment to Asset Purchase Agreement with Cerecor, Inc., dated November 1, 2019	8-K	11/4/19	10.1	
10.47	Registration Rights Agreement with Cerecor, Inc., dated November 1, 2019	8-K	11/4/19	10.2	
10.48	Form of Cerecor Voting Agreement, dated November 1, 2019	8-K	11/4/19	10.3	
10.49	Form of Security Holder Voting Agreement, dated November 1, 2019	8-K	11/4/19	10.4	
10.50	Form of Officer Voting Agreement, dated November 1, 2019	8-K	11/4/19	10.5	
10.51	Transition Services Agreement, dated November 1, 2019	8-K	11/4/19	10.7	
10.52	Consent and Limited Waiver Agreement, dated November 1, 2019	8-K/A	11/4/19	10.6	
10.53	Consent and Limited Waiver Agreement, dated November 1, 2019	8-K/A	11/7/19	10.6	
10.54	Waiver and Amendment to the July 29, 2019 Amended and Restated License and Supply Agreement, dated November 29, 2019	8-K	12/2/19	10.1	
10.57	Form of Securities Purchase Agreement, dated March 10, 2020	8-K	3/13/20	10.1	
10.58	Form of Securities Purchase Agreement, dated March 12, 2020	8-K	3/13/20	10.1	
10.59	Form of Securities Purchase Agreement, dated March 19, 2020	8-K	3/20/20	10.1	
10.60	Early Payment Agreement, dated May 29, 2020	8-K	6/1/20	10.1	
10.61	Form of Restricted Stock Cancelation and Exchange Agreement	8-K	7/2/20	10.1	
10.62†	Amended Employment Agreement with Joshua R. Disbrow dated July 1, 2020				X
10.63†	Amended Employment Agreement with David A. Green dated July 1, 2020				X
21.1	List of Subsidiaries				X
23.1	Consent of Plante & Moran PLLC 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 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, 2020 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: October 6, 2020

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 October 6 , 2020.

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

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Aytu BioScience, Inc. and Subsidiaries (the "Company") as of June 30, 2020 and 2019, the related statements of operations, stockholders' equity, and cash flows for the years 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, 2020 and 2019 and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Plante & Moran, PLLC

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

Denver, CO

October 6, 2020

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Balance Sheets

	June 30, 2020	June 30, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 48,081,715	$ 11,044,227
Restricted cash	251,592	250,000
Accounts receivable, net	5,175,924	1,740,787
Inventory, net	9,999,441	1,440,069
Prepaid expenses and other	5,715,089	957,781
Other current assets	5,742,011	-
Total current assets	74,965,772	15,432,864
Fixed assets, net	258,516	203,733
Right-of-use asset	634,093	-
Licensed assets, net	16,586,847	18,861,983
Patents and tradenames, net	11,081,048	220,611
Product technology rights, net	21,186,666	-
Deposits	32,981	2,200
Goodwill	28,090,407	-
Total long-term assets	77,870,558	19,288,527
Total assets	$ 152,836,330	$ 34,721,391

See the accompanying Notes to the Consolidated Financial Statements.

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Balance Sheets, Cont'd

	June 30, 2020	June 30, 2019
Liabilities		
Current liabilities		
Accounts payable and other	$ 11,824,560	$ 2,133,522
Accrued liabilities	7,849,855	1,311,488
Accrued compensation	3,117,177	849,498
Debt	982,076	-
Contract liability	339,336	-
Current lease liability	300,426	-
Current portion of fixed payment arrangements	2,340,166	-
Current portion of CVR liabilities	839,734	-
Current portion of contingent consideration	713,251	1,078,068
Total current liabilities	28,306,581	5,372,576
Long-term contingent consideration, net of current portion	12,874,351	22,247,796
Long-term lease liability, net of current portion	725,374	-
Long-term fixed payment arrangements, net of current portion	11,171,491	-
Long-term CVR liabilities, net of current portion	4,731,866	-
Warrant derivative liability	11,371	13,201
Total liabilities	57,821,034	27,633,573
Commitments and contingencies (Note 17)		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; shares issued and outstanding 0 and 3,594,981, respectively as of June 30, 2020 and 2019	-	359
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 125,837,357 and 17,538,071, respectively as of June 30, 2020 and 2019	12,584	1,754
Additional paid-in capital	215,012,891	113,475,205
Accumulated deficit	(120,010,179)	(106,389,500)
Total stockholders' equity	95,015,296	7,087,818
Total liabilities and stockholders' equity	$ 152,836,330	$ 34,721,391

See the accompanying Notes to the Consolidated Financial Statements.

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Statements of Operations

	Year Ended June 30,	
	2020	2019
Revenues		
Product and service revenue, net	$ 27,632,080	$ 7,314,581
License revenue, net	-	5,776
Total product revenue	27,632,080	7,320,357
Operating expenses		
Cost of sales	7,553,031	2,202,041
Research and development	1,721,419	589,072
Selling, general and administrative	34,802,432	18,887,783
Selling, general and administrative - related party	-	351,843
Impairment of intangible assets	195,278	-
Amortization of intangible assets	4,490,466	2,136,255
Total operating expenses	48,762,626	24,166,994
Loss from operations	(21,130,546)	(16,846,637)
Other (expense) income		
Other (expense), net	(2,606,487)	(535,500)
(Loss) / gain from change in fair value of contingent consideration	10,430,252	(9,830,550)
Gain (Loss) on extinguishment of debt	(315,728)	-
Gain from warrant derivative liability	1,830	80,779
Total other (expense) income	7,509,867	(10,285,271)
Net loss	$ (13,620,679)	$ (27,131,908)
Weighted average number of common shares outstanding	45,192,010	7,794,489
Basic and diluted net loss per common share	$ (0.30)	$ (3.48)

See the accompanying Notes to the Consolidated Financial Statements.

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

	Preferred Stock		Common Stock		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	Deficit	Equity
BALANCE - June 30, 2018	-	$ -	1,794,762	$ 179	$ 92,681,918	$ (79,257,592)	$ 13,424,505
Stock-based compensation	-	$ -	2,681,422	$ 270	$ 11,021,931	$ -	$ 1,022,201
Common stock issued to employee	-	-	9,000	1	11,689	1	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 converted into common stock	(7,899,160)	(790)	7,899,160	789	1	-	-
Issued 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
Warrant exercise	-	-	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 SUBSIDIARIES
Consolidated Statements of Stockholders' Equity, Cont'd

	Preferred Stock		Common Stock		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	capital	Deficit	Equity
BALANCE - June 30, 2019	3,594,981	$ 359	17,538,071	$ 1,754	$ 113,475,205	$ (106,389,500)	$ 7,087,818
Stock-based compensation	-	$ -	1,952,912	$ 196	$ 1,079,115	$ -	$ 1,079,311
Issuance of Series H preferred stock and common stock due to acquisition of Innovus	1,997,902	200	3,809,712	381	4,405,603	-	4,406,184
Issuance of Series F preferred stock from October 2019 private placement financing, net of $741,650 issuance costs	10,000	1	-	-	5,249,483	-	5,249,484
Warrants issued in connection with the private placement	-	-	-	-	4,008,866	-	4,008,866
Issuance of common stock, net of $4,523,884 in cash issuance costs	-	-	36,365,274	3,637	33,275,119	-	33,278,756
Warrants issued in connection with the registered offering	-	-	-	-	9,723,161	-	9,723,161
Warrants issued in connection with the registered offering to the placement agents, non-cash issuance costs	-	-	-	-	1,458,973	-	1,458,973
Issuance of common stock, net of $1,860,194 in issuance costs	-	-	4,302,271	430	4,982,009	-	4,982,439
Preferred converted into common stock	(15,408,728)	(1,541)	25,398,728	2,540	91,881	-	92,880
Issuance of Series G preferred stock due to acquisition of Cerecor	9,805,845	981	-	-	5,558,933	-	5,559,914
Issuance of common stock related to debt conversion	-	-	1,842,046	185	2,578,679	-	2,578,864
Cashless warrant exercise	-	-	12,915,770	1,292	(1,292)	-	-
Warrant and option exercises	-	-	20,186,994	2,018	26,989,823	-	26,991,841
Common stock issued to consultants	-	-	165,000	16	230,984	-	231,000
Issuance of common stock related to settlement	-	-	122,375	12	173,602	-	173,614
CVR payouts	-	-	1,238,204	123	1,732,747	-	1,732,870
Rounding from reverse stock split	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	(13,620,679)	(13,620,679)
BALANCE - June 30, 2020	-	$ -	125,837,357	$ 12,584	$ 215,012,891	$ (120,010,179)	$ 95,015,296

See the accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended June 30,	
	2020	2019
Operating Activities		
Net loss	$ (13,620,679)	$ (27,131,908)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	6,245,827	2,727,067
Impairment of intangible assets	195,278	-
Stock-based compensation expense	1,079,311	1,022,202
Loss / (gain) from change in fair value of contingent consideration	(5,291,629)	9,830,550
Derecognition of contingent consideration	(5,199,806)	-
Gain on the change in fair value of CVR payout	(267,130)	-
Changes in allowance for bad debt	404,549	-
Loss / (gain) from change in fair value of CVR	352,782	-
Loss / (gain) from note conversion	315,728	-
Loss / (gain) from settlement payment	(24,469)	-
Issuance of common stock to employee	48,083	11,690
Derivative income	(1,830)	(80,779)
Changes in operating assets and liabilities:		
(Increase) in accounts receivable	(3,560,860)	(1,162,005)
(Increase) in inventory	(6,950,624)	(101,096)
(Increase) in prepaid expenses and other	(2,315,881)	(517,772)
(Increase) in other current assets	(3,749,846)	-
(Decrease) / increase in accounts payable and other	(1,376,521)	134,775
Increase in accrued liabilities	4,330,856	961,858
Increase in accrued compensation	1,124,624	308,824
(Decrease) in contract liabilities	(111,650)	-
Increase in interest payable - related party	-	166,667
(Decrease) in deferred rent	-	(1,450)
Net cash used in operating activities	(28,373,887)	(13,831,377)
Investing Activities		
Deposit	6,000	2,888
Purchases of fixed assets	-	(59,848)
Contingent consideration payment	(202,688)	(505,025)
Cash received from acquisition	390,916	-
Purchase of assets	(5,850,000)	(500,000)
Net cash used in investing activities	$ (5,655,772)	$ (1,061,985)

See accompanying Notes to Consolidated Financial Statements

AYTU BIOSCIENCE, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows, Cont'd

	Year Ended June 30,	
	2020	2019
Financing Activities		
Issuance of preferred, common stock and warrants	$ 65,729,900	$ 15,180,000
Issuance costs related to preferred, common stock and warrants	(5,404,151)	(1,479,964)
Warrant exercises	26,991,841	375,026
Payments made to borrowings	(19,436,779)	-
Proceeds from borrowings	2,547,928	-
Issuance of note payable	640,000	-
Issuance of debt - related party	-	5,000,000
Net cash provided by financing activities	71,068,739	19,075,062
Net change in cash, restricted cash and cash equivalents	37,039,080	4,181,700
Cash, restricted cash and cash equivalents at beginning of period	11,294,227	7,112,527
Cash, restricted cash and cash equivalents at end of period	$ 48,333,307	$ 11,294,227
Supplemental disclosures of cash and non-cash investing and financing transactions		
Warrants issued to investors and underwriters	$ -	$ 1,888,652
Contingent consideration included in accounts payable	16,014	42,821
Contingent consideration related to product acquisition	-	8,833,219
Issuance of preferred stock related to purchase of assets	-	519,600
Conversion of debt to equity	-	5,166,667
Cash paid for interest	1,040,276	-
Fair value of right-to-use asset and related lease liability	334,895	-
Issuance of Series G preferred stock due to acquisition of the Pediatric Portfolio of therapeutics	5,559,941	-
Issuance of Series H preferred stock due to acquisition of the Innovus	12,805,263	-
Fixed payment arrangements included in accounts payable	894,900	-
Exchange of convertible preferred stock into common stock	2,540	-
Reclass of par from APIC to Common Stock for issuance of stock for equity classified instruments	1,488	-
Issuance cost related to S-3	1,531,190	-
Issuance of common stock for settlement	125,531	-
Issuance of common stock for note conversion	2,578,864	-
Issuance of common stock to consultants	231,000	-
CVR payout for calendar year 2019	$ 2,000,000	$ -

See 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 BioScience, 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, various pediatric conditions and the Company's plans to expand opportunistically into other therapeutic areas.

The Company is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant healthcare needs in both prescription and consumer health categories.

The Primary Care Portfolio that existed at the beginning of the year ended June 30, 2020 includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), (ii) ZolpiMist®, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup.

On November 1, 2019, the Company acquired the portfolio of pediatric products from Cerecor, Inc (the "Pediatric Portfolio"). The Pediatric Portfolio includes; (i) Cefaclor, a second-generation cephalosporin antibiotic suspension; (ii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iii) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various forms for infants and children with fluoride deficiency.

On February 14, 2020, the Company acquired Innovus Pharmaceuticals Inc. ("Innovus"), a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve health and vitality. Innovus commercializes over twenty-two consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness and respiratory health (the "Consumer Health Portfolio"). The Consumer Health Portfolio is commercialized through direct-to-consumer marketing channels utilizing Innovus' proprietary Beyond Human® marketing and sales platform.

The Company recently acquired exclusive U.S., Canada and Mexico distribution rights to a COVID-19 IgG/IgM rapid test. The coronavirus test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. The rapid test has been validated in multi-center clinical trials. Most recently, the Company signed a licensing agreement with Cedars-Sinai Medical Center for worldwide rights to various potential uses of Healight, an investigational medical device platform technology. Healight has demonstrated safety and efficacy in pre-clinical studies, and the Company plans to advance this technology and assess its safety and efficacy in human studies.

The Company's strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets.

Financial Condition. As of June 30, 2020, the Company had approximately $48.3 million of cash, cash equivalents and restricted cash. The Company's operations have historically consumed cash and are expected to continue to require cash, but at a declining rate. Revenues have increased 277% and 100% for each of the years ended June 30, 2020 and 2019, respectively, and are 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 2020 was $28.4 million compared to $13.8 million in 2019. The increased cash use was due to funding existing operations as well as the funding required to consummate and integrate the operations of two significant transactions which substantially increased the size and scope of the Company's commercial operations. Additional funds were required to license the Healight Platform and pursue its development. As of the date of these financial statements, the Company expects its commercial costs to increase but at a rate lower than revenue increases as we continue to focus on realizing cost savings from efficiencies in scale and on revenue growth.

On November 1, 2019, the Company closed an asset acquisition with Cerecor, Inc. (“Cerecor”) whereby the Company acquired certain of Cerecor’s portfolio of pediatric therapeutics (the “Pediatric Portfolio”) for $4.5 million in cash, approximately 9.8 million shares of Series G Convertible Preferred Stock, the assumption of Cerecor’s financial and royalty obligations, which includes not more than $3.5 million of Medicaid rebates and products returns as they come due, and other assumed liabilities associated with the Pediatric Portfolio (see Note 2). As of June 30, 2020, the Company has paid down approximately $3.5 million of those assumed liabilities.

In addition, the Company assumed obligations in connection with the Pediatric Portfolio acquisition due to an investor including fixed and variable payments. The Company assumed fixed monthly payments equal to $0.1 million from November 2019 through January 2021 plus $15 million due in January 2021. Monthly variable payments due to the same investor are equal to 15% of net revenue generated from a subset of the Pediatric Portfolio, subject to an aggregate monthly minimum of $0.1 million, except for January 2020, when a one-time payment of $0.2 million was paid. The variable payment obligation continues until the earlier of: (i) aggregate variable payments of approximately $9.5 million have been made, or (i) February 12, 2026. On May 29, 2020, the Company, Armistice and the Deerfield Parties entered into an Early Payment Agreement and Escrow Instruction (the “Early Payment Agreement”) pursuant to which, (i) the Company agreed to transfer the sum of $15 million to the Deerfield Parties in early satisfaction of the Balloon Payment Obligation (ii) the Deerfield Parties, jointly and severally, acknowledged receipt and payment in full of the Balloon Payment and (iii) the Deerfield Parties and Armistice agreed to deliver to the Escrow Agent the joint written instruction to release the Escrow Funds to Armistice. The parties to the Early Payment Agreement acknowledged and agreed that the remaining fixed payments set forth on Schedule I of the Waiver other than the Balloon Payment Obligation remain due and payable pursuant to the terms of the Waiver, and that nothing in the Early Payment Agreement alters, amends, or waives any provisions or obligations in the Waiver or the Deerfield agreement other than as expressly set forth therein. As further consideration for the early payment of the Balloon Payment Obligation contemplated by the Early Payment Agreement, Armistice agreed (i) to pay to the Company, in immediately available funds, an amount equal to $200,000 and (ii) to reimburse the Company for all reasonable out–of-pocket legal expenses and fees incurred in connection with the Early Payment Agreement and the transactions contemplated thereby. On April 3, 2020, a majority of the Company’s disinterested board of directors approved the Company entering into an agreement whereby the Company would either assume the Escrow Agreement pursuant to an assignment and assumption agreement or paying the Balloon Payment Obligation. In early June 2020, the Company paid down the $15 million Balloon Payment Obligation, leaving a remaining fixed minimum commitment of approximately $7.3 million.

On February 14, 2020, the Company completed a merger with Innovus after approval by the stockholders of both companies on February 13, 2020 (the “Merger”). Upon closing the Merger, the Company merged with and into Innovus and all outstanding Innovus common stock was exchanged for approximately 3.8 million shares of the Company’s common stock and up to $16 million of Contingent Value Rights (“CVRs”). The outstanding Innovus warrants with cash out rights were exchanged for approximately 2.0 million shares of Series H Convertible Preferred stock of Aytu and retired. The remaining Innovus warrants outstanding at the time of the Merger continue to be outstanding, and upon exercise, retain the right to the merger consideration offered to Innovus stockholders, including any remaining claims represented by CVRs at the time of exercise. Innovus will continue as a wholly owned subsidiary of the Company.

In addition, as part of the Merger, the Company assumed approximately $3.1 million of notes payable, $0.8 million in lease liabilities, and other assumed liabilities associated with Innovus. Of the $3.1 million of notes payable, approximately $2.2 million was converted into approximately 1.8 million shares of the Company’s common stock during the quarter ended June 30, 2020.

During the three months ended March 31, 2020, the Company completed three separate equity offerings, on March 10, 2020, March 12, 2020 and March 19, 2020 (the “March Offerings”), in which the Company issued a combination of common stock and warrants. The following summarizes the March Offerings, including total capital raised from both the issuance of common stock and subsequent warrant exercises.

On March 19, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 12,539,197 shares of the Company’s common stock (the “Common Stock”) at a purchase price per share of $1.595 and (ii) warrants to purchase up to 12,539,197 shares of Common Stock (the “March 19, 2020 Warrants”) at an exercise price of $1.47 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company. The March 19, 2020 Warrants are exercisable immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued warrants with an exercise price of $1.9938 per share to purchase up to 815,047 shares of common stock (the “March 19, 2020 Placement Agent Warrants”) as a portion of the fees paid to the placement agent. The March 19, 2020 Placement Agent Warrants have a term of five year from the issuance date.

Since March 19, 2020, a total of 1.2 million March 19, 2020 Warrants have been exercised, for total proceeds of $1.7 million, of which 0.7 million March 19, 2020 Warrants were exercised, for total proceeds of $1.1 million.

On March 12, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 16,000,000 shares of the Company’s common stock at a purchase price per share of $1.25 and (ii) warrants to purchase up to 16,000,000 shares of Common Stock (the “March 12, 2020 Warrants”) at an exercise price of $1.25 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the “Registered Offering”). The March 12, 2020 Warrants are exercisable immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued warrants with an exercise price of $1.5625 per share to purchase up to 1,040,000 shares of common stock (the “March 12, 2020 Placement Agent Warrants”) as a portion of the fees paid to the placement agent. The March 12, 2020 Placement Agent Warrants have a term of five year from the issuance date.

Since March 12, 2020, a total of 13 million March 12, 2020 Warrants have been exercised, for total proceeds of approximately $16.3 million, of which approximately 10.5 million March 12, 2020 Warrants were exercised through March 31, 2020, for total proceeds of $13.1 million.

On March 10, 2020, Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 4,450,000 shares of the Company's common stock (the "Common Stock") at a purchase price per share of $1.15 and (ii) pre-funded warrants to purchase up to 3,376,087 shares of Common Stock (the "Pre-Funded Warrants") at an effective price of $1.15 per share ($1.1499 paid to the Company upon the closing of the offering and $0.0001 to be paid upon exercise of such Pre- Funded Warrants), for aggregate gross proceeds to the Company of approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the "Registered Offering"). The Pre-Funded Warrants were immediately exercised upon close. In addition, the Company issued warrants with an exercise price of $1.4375 per share to purchase up to 508,696 shares of common stock (the "March 10, 2020 Placement Agent Warrants"). The March 10, 2020 Placement Agent Warrants have a term of five year from the issuance date.

Since March 10, 2020, a total of 6.0 million shares of the Company's October 2018 $1.50 Warrants (the "October 18 $1.50 Warrants") were exercised, resulting in proceeds of approximately $9.0 million.

In total, the Company has raised net proceeds of approximately $71.3 million from the March Offerings and related warrant exercises, as well as exercises of the October 2018 $1.50 Warrants. The net proceeds received by the Company from the March Offerings and related warrant exercise will be used for general corporate purposes, including working capital.

On October 11, 2019, the Company entered into Securities Purchase Agreements (the "Purchase Agreement") with two institutional investors (the "Investors") providing for the issuance and sale by the Company (the "October 2019 Offering") of $10.0 million of, (i) 10,000 shares of the Company's Series F Convertible Preferred Stock (the "Preferred Stock") which are convertible into 10,000,000 shares of common stock (the "Conversion Shares") for a stated value of $1,000 per unit and (ii) 10,000,000 warrants (the "October 2019 Warrants") which are exercisable for shares of common stock (the "Warrant Shares"), which expire January 10, 2025,. The closing of the October 2019 offering occurred on October 16, 2019. The Warrants had an exercise price equal to $1.25 and contain a cashless exercise provision. This provision was dependent on (i) performance of the Company's stock price between October 11, 2019 and the date of exercise of all, or a portion of the Warrants, and (ii) subject to shareholder approval of the October 2019 Offering, which was approved January 24, 2020.

During March 2020, all of the Series F Convertible Preferred Stock were converted into 10 million shares of the Company's common stock, and 5.0 million of the October 2019 Warrants were exercised using the cashless exercise provision to acquire 5.0 million shares of the Company's common stock. In April of 2020, the remaining 5 million October 2019 Warrants were exercised using the cashless exercise provision into 5.0 million shares of the Company's common stock.

The net proceeds that the Company received from the October 2019 Offering were approximately $9.3 million. The net proceeds received by the Company from the October 2019 Offerings have been used for general corporate purposes, including working capital.

In June 2020, we completed an at-the-market offering program, which allows us to sell and issue shares of our common stock from time-to-time. The company issued 4,302,271 shares of common stock, with total gross proceeds of $6.8 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company.

As of the date of this Report, the Company expects its costs for its current operation to stabilize as the Company integrates the acquisition of the Pediatrics Portfolio and Innovus and continues to focus on revenue growth through increasing product sales and the introduction of new products. The Company's total current asset position of approximately $75.0 million plus the proceeds expected from ongoing product sales will be used to fund operations. Since the Company has sufficient cash and cash equivalents on-hand as of June 30, 2020, to fund potential net cash outflows for the twelve months following the filing date of this Annual Report, in accordance with ASU 2014-15, Subtopic 205-40, the Company reports that there does not exist any indication of substantial doubt about its ability to continue as a going concern.

As of the date of this report, while the Company has adequate capital resources to complete its near-term operations, there is no guarantee that such capital resources will be sufficient until such time the Company reaches profitability. The Company may access capital markets to fund strategic acquisitions or ongoing operations on terms the Company believes are favorable. 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. The Company may utilize debt or sell newly issued equity securities through public or private transactions, or through the use of an at the market facility. There is no guarantee that capital will be available on terms 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 are confident in its ability to access the capital markets again, if needed.

If the Company is unable to raise adequate capital in the future, and if and 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 merger, acquisition and commercial programs, reductions in headcount, narrowing the scope of the Company's commercial plans, or reductions to its research and development programs. Without sufficient operating capital, the Company could be required to relinquish rights to products or renegotiate to maintain such rights 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, 2020, we had an accumulated deficit of $120.1 million. Our net loss decreased to $13.6 million from $27.1 million for fiscal 2020 and 2019, respectively. The Company used $28.4 million and $13.8 million in cash from operations during fiscal 2020 and 2019.

2. Summary of Significant Accounting Policies

Basis of Presentation. The audited consolidated financial statements include the operations of Aytu and its wholly-owned subsidiaries, Aytu Women's Health, LLC, Aytu Therapeutics, LLC and Innovus Pharmaceuticals, Inc. 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").

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 consists primarily of amounts held in certificate of deposit investments to maintain certain credit amounts for the Company's business credit cards. The Company'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, 2020, the Company has maintained balances in excess of federally insured limits.

Accounts Receivable. Accounts receivable are recorded at their estimated net realizable value. The Company evaluates collectability of accounts receivable on a quarterly basis and records a reserve, if any, accordingly. The Company recognized a reserve of $0.4 million and $0.0 million as of June 30, 2020 and 2019, respectively. The Company does not charge interest on its outstanding trade receivables as its standard trade practices. However the Company does reserve the right to such charges as circumstances arise.

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. Therefore, we currently have $1.3 million and $0 reserved for slow moving inventory as of June 30, 2020 and 2019, 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 are placed into service. Maintenance and repairs are expensed as incurred.

Fair Value of Financial Instruments.

Cash, cash equivalents, restricted cash, accounts receivable, and accounts payable. 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.

Contingent consideration. The Company classifies its contingent consideration liability in connection with the acquisition of Tuzistra XR, ZolpiMist and Innovus, within Level 3 as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity. The Company estimates the fair value of our contingent consideration liability based on projected payment dates, discount rates, probabilities of payment, and projected revenues. Projected contingent payment amounts are discounted back to the current period using a discounted cash flow methodology.

Liability and equity classified warrants. The Company accounts for liability classified 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 liability classified derivative financial instruments were calculated using a lattice valuation model. Equity classified financial instruments are valued using a Black-Scholes model. Changes in the fair value of liability classified derivative financial instruments in subsequent periods were recorded as derivative income or expense for the warrants and reported as a component of cash flows from operations. During the year ended June 30, 2020, such changes in the fair value of the Company's liability classified derivative liabilities was less than $0.1 million.

Contingent value rights. The fair value of the contingent value rights was based on a model in which each individual payout was deemed either (a) more likely than not to be paid out or (b) less likely than not to be paid out. From there, each obligation was then discounted at a 30% discount rate to reflect the overall risk to the contingent future payouts pursuant to the CVRs. This value is then remeasured both for future expected payout at well as the increase fair value due to the time value of money. These gains or losses, if any, are included as a component of operating cash flows.

Fixed Payment Arrangements. Fixed payment arrangements are comprised of minimum product payment obligations relating to either make whole payments or fixed minimum royalties arising from the acquisition of the Pediatric Portfolio. These were recognized at their amortized cost basis using a market appropriate discount rate and are accreted up to their ultimate face value over time. These are one-time measurements and remeasurement at each reporting period is not recognized at as a component of earnings each reporting period. However, if the Company determines the circumstances have changed such that the fair value of these fixed payment obligations would have changed due to changes in company specific circumstances or interest rate environments, such changes would be reflected in the Company's footnote disclosures..

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.

Aytu BioScience Segment (Note 19)

Product sales consist of sales of its prescription related products from both the (i) Pediatric Portfolio and (ii) Primary Care Portfolio principally to a limited number of wholesale distributors and pharmacies in the United States, which account for the largest portion of our total prescription products revenue. International sales are made primarily to specialty distributors, as well as to hospitals, laboratories, and clinics, some of which are government owned or supported (collectively, its "Customers").

Products are generally shipped "free-on- board" destination when shipped domestically within the United States and if shipped internationally, products are shipped "free-on-board" shipping point, as those are the agreed-upon contractual terms.

Collectability of revenue is reasonably assured based on historical evidence of collectability 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.

Aytu Consumer Health Segment (Note 19)

The Company generates revenues from its Consumer Health Portfolio from product sales and the licensing of the rights to market and commercialize our products. Sales from the Company's Aytu Consumer Health division are generally recognized "free-on-board" shipping point, as those are the agreed-upon contractual terms. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by us from a customer, are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of sales.

Customer Contract Costs. The Company has elected to adopt the practical expedient on expensing the incremental costs to obtain a contract, given the expectation that any amounts attributable to obtaining such a contract would be satisfied within one year.

Customer Concentrations. The following customers contributed greater than 10% of the Company's gross revenue during the year ended June 30, 2020 and 2019, respectively. The customers, sometimes referred to as partners or customers, are large wholesale distributors that resell our products to retailers. As of June 30, 2020, three customers accounted for 46% of gross revenue. 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,	
	2020	2019
Customer A	16%	19%
Customer B	16%	20%
Customer C	14%	26%
Customer D	–	22%

The loss of one or more of the Company's significant partners or customers 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, 2020, four customers accounted for 61% of gross accounts receivable. As of June 30, 2019, four customers accounted for 88% of gross accounts receivable.

	Year Ended June 30,	
	2020	2019
Customer A	19%	9%
Customer B	16%	20%
Customer C	14%	36%
Customer E	0%	23%
Customer F	12%	0%

In addition, the Company is owed approximately $3.6 million as of June 30, 2020 by Cerecor that arose as a result of certain transition processes that caused customer payments on the Pediatric Portfolio products to continue to be deposited in Cerecor’s account. The Company and Cerecor are expected to finalize the settlement of these amounts in the first half of the fiscal year ended June 30, 2021.

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, 2020, and 2019, the Company accrued $1.3 million and $0.1 million, 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 Sales. Costs of sales 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 sales 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 and tradenames. 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 life of approximately 15 years, which expires in March 2028.

Patents and tradenames subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. Impairment losses are measured and recognized to the extent the carrying value of such assets exceeds their fair value. In June 2020, the Company decided to write off the entire remaining balance of the Luoxis patents.

On February 14, 2020, upon completion of the Merger with Innovus, the Company recognized the fair value of the rental of the customer lists for $390,000 and amortizes the asset over a useful life of 1.5 years.

The Company recognized the fair value of trademarks, patents or a combination of both for 18 distinct products that Innovus markets, distributes and sells for $11,354,000 and amortizes the asset over a useful life of 5 years.

Advertising Costs. Advertising costs consist of the direct marketing activities related to the Company's Aytu Consumer Health reportable segment that arose from the February 14, 2020 acquisition of Innovus Pharmaceuticals, Inc. The Company expenses all advertising costs as incurred. The Company incurred $4.7 million and $0 for the years ended June 30, 2020 and 2019, respectively.

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, (iii) patents and tradenames, net and (iv) Products technology rights. Circumstances which could trigger a review include, but are not limited to: (i) significant decreases in the market price of the asset; (ii) significant adverse changes in the business climate or legal or regulatory factors; (iii) 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, 2020 and 2019 respectively, and there was $0.2 million and $0 million of impairment recorded.

Income Taxes. Deferred taxes are provided on an asset and liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carryforwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred taxes are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

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

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. As the Company incurred losses in both 2020 and 2019, basic and diluted loss per share was the same and 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, 2020 and 2019 are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share.

		Year Ended June 30,	
		2020	2019
Warrants to purchase common stock - liability classified	(Note 15)	240,755	240,755
Warrant to purchase common stock - equity classified	(Note 15)	22,884,538	16,238,657
Employee stock options	(Note 14)	765,937	1,607
Employee unvested restricted stock	(Note 14)	4,186,056	2,551,024
Convertible preferred stock	(Note 13)	-	3,594,981
		28,077,286	22,627,024

Adoption of New Accounting Pronouncements

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 which resulted in no cumulative adjustment to retained earnings.

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. As a result of the adoption, on July 1, 2019, the Company recognized a lease liability of approximately $0.4 million, which represented the present value of the remaining minimum lease payments using an estimated incremental borrowing rate of 8%. As of July 1, 2019, the Company recognized a right-to-use asset of approximately $0.4 million. Lease expense did not change materially as a result of the adoption of ASU 2016-02.

In addition, in conjunction with the Innovus Merger, the Company recognized a lease liability of approximately $0.8 million relating to Innovus' corporate offices and related warehouse as part of the purchase price allocation (see Note 2 and Note 22).

Leases ("ASU 2018-11"). On July 30, 2018, the FASB issued ASU 2018-11 to provide entities with relief from the costs of implementing certain aspects of the new leasing standard, ASU 2016-02 (codified as ASC 842). Specifically, under the amendments in ASU 2018-11: (i) Entities may elect not to recast the comparative periods presented when transitioning to ASC 842 (Issue 1), and (ii) Lessors may elect not to separate lease and nonlease components when certain conditions are met (Issue 2). The Company adopted this standard and elected not to recast prior comparative periods when presented, including the year ended June 30, 2019, which is included in this Form 10-K.

Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) ("ASU 2017- 11") . In July 2017, the FASB issued ASU No. 2017-11 — *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815)*. Part I to ASU 2017-11 eliminates the requirement to consider "down round" features when determining whether certain equity-linked financial instruments or embedded features are indexed to an entity's own stock. In addition, entities will have to make new disclosures for financial instruments with down round features and other terms that change conversion or exercise prices. Part I to ASU 2017-11 is effective for fiscal years beginning after December 31, 2018. The Company adopted this standard update as a result of the issuance of the Series F Preferred stock as a result of the October 2019 Offering. There were no "down-round" features present in the financial instruments issued in conjunction with the March 2020 Offerings.

Compensation – Stock Compensation (Topic 718) ("ASU 2018-07"). On June 20, 2018, the FASB issued ASU 2018-07, Improvements to Nonemployee Share-Based Payment Accounting, as part of its ongoing Simplification Initiative. Currently, share-based payments to nonemployees are accounted for under Subtopic 505-50 which significantly differs from the guidance for share-based payments to employees under Topic 718. This ASU supersedes Subtopic 505-50 by expanding the scope of Topic 718 to include nonemployee awards and generally aligning the accounting for nonemployee awards with the accounting for employee awards (with limited exceptions). The Company issued stock to certain former Innovus Directors to compensate them for consulting services. Those grants were fully vested at the time of grant and an approximately $0.2 million charge was recognized as a current period expense.

Business Combinations (Topic 805) — Clarifying the Definition of a Business ("ASU 2017-01"). In January 2017, the FASB issued ASU 2017-01, which sets out a new framework for classifying transactions as acquisitions (disposals) of assets versus businesses. The new guidance provides a framework to evaluate when an input and a substantive process are present as well as provide more stringent criteria for sets without outputs to be considered businesses. As a result, fewer transactions are expected to involve acquiring (or selling) a business. ASU 2017-01 is effective for public companies with fiscal years beginning after December 15, 2018. This standard is expected to reduce the number of acquisitions which are considered business combinations upon adoption, especially in both real estate and life science industries.

During the fiscal year ended June 30, 2020, the Company acquired both the Pediatric Portfolio from Cerecor and Consumer Health Portfolio from Innovus. The Company adopted this standard as a result of the acquisitions, and while ASU 2017-01 is expected to result in more asset acquisitions in life science industries, the Company came to the conclusion that both of the acquisitions qualified as business combinations.

Statement of Cash Flows (Topic 230) — Classification of Certain Cash Receipts and Cash Payments ("ASU 2016-15"). On August 26, 2016, the FASB issued ASU 2016-15, which amends Topic 230 to add or clarify guidance on the classification of certain cash receipts and payments in the statement of cash flows. One of the items ASU 2016-15 clarified was the treatment of cash payments on zero coupon debt or debt-like instrument. Under ASU 2016-15, cash paid on zero coupon bonds should be allocated between the interest and principal portion of the obligation at the time of payment, with the interest portion classified as operating in the Statement of Cash Flows and the principal portion classified as a financing cash outflow in the Statement of Cash Flows.

The Company has numerous obligations in which there is no stipulated interest rate, and the obligation is recognized at a discount from the ultimate obligation. These include certain notes and fixed payment arrangements. The Company adopted this standard in the year ended June 30, 2020 and classified cash payments, if any, in accordance with this standard.

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 2016-13"). 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 was originally effective for interim and annual reporting periods beginning after December 15, 2019 and early adoption is permitted for interim and annual reporting periods beginning after December 15, 2018. However, in November 2019, the Financial Accounting Standard Board (FASB) issued ASU 2019-10, *Financial Instruments—Credit Losses, (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) — Effective Dates* ("*ASU 2019-10*"). ASU 2019-10 deferred the adoption date for (i) public business entities that meet the definition of an SEC filer, excluding entities eligible to be "smaller reporting companies" as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and (2) all other entities for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. As of June 30, 2020, the Company qualified as a smaller reporting companies as defined by the SEC. 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.

3. Revenues from Contracts with Customers

Revenues by Product Portfolio. Net revenue disaggregated by significant product portfolio for the year ended June 30, 2020 and June 30, 2019 were as follows:

	Year Ended June 30,	
	June 30, 2020	June 30, 2019
Primary care and devices portfolio	$ 7,957,000	$ 7,320,000
Pediatric portfolio	9,292,000	-
Consumer Health portfolio	10,383,000	-
Consolidated revenue	$ 27,632,000	$ 7,320,000

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,	
	2020	2019
U.S.	$ 24,980,000	$ 6,462,000
Rest-of-the-World	2,652,000	858,000
Total net revenue	$ 27,632,000	$ 7,320,000

4. Acquisitions

The Pediatric Portfolio

On October 10, 2019, the Company entered into the Purchase Agreement with Cerecor, Inc. ("Cerecor") to purchase and acquire Cerecor's Pediatric Portfolio, which closed on November 1, 2019. The Pediatric Portfolio consists of four prescription products consisting of (i) Cefaclor for Oral Suspension, (ii) Karbinal® ER and, (iii) Poly-Vi-Flor® and Tri-Vi-Flor™. Total consideration transferred to Cerecor consisted of $4.5 million in cash and approximately 9.8 million shares of Series G Convertible Preferred Stock. The Company also assumed certain of Cerecor's financial and royalty obligations, and not more than $3.5 million of Medicaid rebates and products returns, of which $3.5 million has been incurred. The Company also retained the majority of Cerecor's workforce focused on sales, commercial contracts and customer relationships.

In addition, the Company assumed Cerecor obligations due to an investor that include fixed and variable payments aggregating to $25.6 million. The Company assumed fixed monthly payments equal to $0.1 million from November 2019 through January 2021 plus $15 million due in January 2021. Monthly variable payments due to the same investor are equal to 15% of net revenue generated from a subset of the Pediatric Portfolio, subject to an aggregate monthly minimum of $0.1 million, except for January 2020, when a one-time payment of $0.2 million was paid to the investor. The variable payment obligation continues until the earlier of: (i) aggregate variable payments of approximately $9.5 million have been made, or (ii) February 12, 2026. In early June 2020, the Company paid down the $15 million due in January 2021, leaving a remaining fixed minimum commitment of approximately $7.3 million.

Further, certain of the products in the Pediatric Portfolio require royalty payments ranging from 12% to 15% of net revenue. One of the products in the Pediatric Portfolio requires the Company to generate minimum annual sales sufficient to represent annual royalties of approximately $1.8 million, in the event the minimum sales volume is not satisfied.

While no equity was acquired by the Company, the transaction was accounted for as a business combination under the acquisition method of accounting pursuant to Topic 805. Accordingly, the tangible and identifiable intangible assets acquired and liabilities assumed were recorded at fair value as of the date of acquisition, with the remaining purchase price recorded as goodwill. The goodwill recognized is attributable primarily to strategic opportunities related to an expanded commercial footprint and diversified product portfolio that is expected to provide revenue and cost synergies. Goodwill is not amortizable for tax purposes. Transaction costs of $0.7 million were included as general and administrative expense in the consolidated statements of operations for the fiscal year 2020.

The following table summarizes the preliminary fair value of assets acquired and liabilities assumed at the date of acquisition. These estimates are preliminary, pending final evaluation of certain assets, and therefore, are subject to revisions that may result in adjustments to the values presented below:

	As of November 1, 2019
Consideration	
Cash and cash equivalents	$ 4,500,000
Fair value of Series G Convertible Preferred Stock	
Total shares issued	9,805,845
Estimated fair value per share of Aytu common stock	$ 0.567
	5,559,914
Total consideration transferred	**$ 10,059,914**
Recognized amounts of identifiable assets acquired and liabilities assumed	
Inventory, net	$ 459,123
Prepaid assets	1,743,555
Other current assets	2,525,886
Intangible assets - product marketing rights	22,700,000
Accrued liabilities	(300,000)
Accrued product program liabilities	(6,683,932)
Assumed fixed payment obligations	$ (29,837,853)
Total identifiable net assets	**(9,393,221)**
Goodwill	**$ 19,453,135**

The following table provides a reconciliation of the carrying value of the Company's goodwill associated with the acquisition of the Pediatric Portfolio:

	Goodwill – Pediatric Portfolio
Balance **as of November 1, 2019**	$ 15,387,064
Increase due to change in estimated fixed payment obligations	3,766,071
Increase to account for settlement with former product licensor	300,000
Balance **as of June 30, 2020**	$ 19,453,135

The Company recorded an adjustment to the previously reported identifiable net assets and goodwill of approximately $4.1 million, of which $3.8 million related to the Karbinal make-whole payment, and $0.3 million related to a settlement upon the closing of the Cerecor transaction. The amounts above represent the provisional fair value estimates as of June 30, 2020 and are subject to subsequent adjustment as the Company obtains additional information during the measurement period and finalizes its fair value estimates.

The fair values of intangible assets, including product technology rights were determined using variations of the income approach. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value (see Note 10).

	As of November 1, 2020
Acquired product technology rights	$ 22,700,000

The fair value of the net identifiable asset acquired was determined to be $22.7 million, which is being amortized over ten years. The aggregate amortization expense was $1.5 million and $0, for fiscal year 2020 and 2019 respectively.

Since the November 1, 2019 acquisition of the Pediatric Portfolio, the Pediatric Portfolio has contributed $9.3 million in net revenues and a net loss of approximately $0.4 million, excluding corporate, overhead and other costs not assigned to these products.

Innovus Merger (Consumer Health Portfolio)

On February 14, 2020, the Company completed the merger with Innovus Pharmaceuticals after approval by the stockholders of both companies on February 13, 2020. Upon the effectiveness of the Merger, the Company merged with and into Innovus and all outstanding Innovus common stock was exchanged for approximately 3.8 million shares of the Company's common stock and up to $16 million of Contingent Value Rights ("CVRs"). The outstanding Innovus warrants with cash out rights were exchanged for approximately 2.0 million shares of Series H Convertible Preferred stock of the Company and retired. The remaining Innovus warrants outstanding at the time of the Merger continue to be outstanding, and upon exercise, retain the right to the merger consideration offered to Innovus stockholders, including any remaining claims represented by CVRs at the time of exercise. Innovus is now a 100% wholly-owned subsidiary of the Company, ("Aytu Consumer Health").

On March 31, 2020, the Company paid out the first CVR Milestone in the form of approximately 1.2 million shares of the Company's common stock to satisfy the $2.0 million obligation as a result of Innovus achieving the $24 million revenue milestone for the calendar year ended December 31, 2019. As a result of this, the Company recognized a gain of approximately $0.3 million.

In addition, as part of the merger, the Company assumed approximately $3.1 million of notes payable, $0.8 million in lease liabilities, and other assumed liabilities associated with Innovus. Of the $3.1 million of notes payable, approximately $2.2 million was converted into approximately 1.8 million shares of the Company's common stock since February 14, 2020.

The following table summarized the preliminary fair value of assets acquired and liabilities assumed at the date of acquisition. As this was a tax-exempt transaction, goodwill is not tax deductible in future periods. These estimates are preliminary, pending final evaluation of certain assets acquired and liabilities assumed, and therefore, are subject to revisions that may result in adjustments to the values presented below. The estimates of the fair value of the assets acquired assumed at the date of the Acquisition are subject to adjustment during the measurement period (up to one year from the Acquisition date). While the Company believes that such preliminary estimates provide a reasonable basis for estimating the fair value of assets acquired, it evaluates any necessary information prior to finalization of the fair value. During the measurement period, the Company will adjust assets and liabilities if new information is obtained about facts and circumstances that existed as of the Acquisition date that, if known, would have resulted in the revised estimated values of those assets as of that date. The impact of all changes that do not qualify as measurement period adjustments, if applicable, and are included in current period earnings.

	As of February 14, 2020
Consideration	
Fair value of Aytu Common Stock	
Total shares issued at close	3,810,393
Estimated fair value per share of Aytu common stock	$ 0.756
Estimated fair value of equity consideration transferred	$ 2,880,581
Fair value of Series H Convertible Preferred Stock	
Total shares issued	1,997,736
Estimated fair value per share of Aytu common stock	$ 0.756
Estimated fair value of equity consideration transferred	$ 1,510,288
Fair value of former Innovus warrants	$ 15,315
Fair value of Contingent Value Rights	$ 7,049,079
Forgiveness of Note Payable owed to the Company	$ 1,350,000
Total consideration transferred	**$ 12,805,263**

	As of February 14, 2020
Total consideration transferred	**$ 12,805,263**
Cash and cash equivalents	$ 390,916
Accounts receivables, net	278,826
Inventory, net	1,149,625
Prepaid expenses and other current assets	1,692,133
Other long-term assets	36,781
Right-to-use assets	328,410
Property, plant and equipment	190,393
Trademarks and patents	11,744,000
Accounts payable and accrued other expenses	(7,202,309)
Other current liabilities	(629,601)
Debt	(3,056,361)
Lease liability	(754,822)
Total identifiable net assets	4,167,991
Goodwill	$ 8,637,272

The fair values of intangible assets, including product distribution rights were determined using variations of the income approach, specifically the relief-from-royalties method. It also includes customer lists using an income approach utilizing a discounted cash flow model. Varying discount rates were also applied to the projected net cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value (see Note 10).

	As of February 14, 2020
Acquired product distribution rights	$ 11,354,000
Acquired customer lists	390,000
Total intangible assets	$ 11,744,000

The fair value of the net identifiable assets acquired was determined to be $11.7 million, which is being amortized over a range between 1.5 to 10 years. The aggregate amortization expense was $0.7 million and $0, for the fiscal year ended June 30, 2020 and 2019, respectively.

The Company recorded an adjustment to the previously reported identifiable net assets and goodwill of approximately $0.2 million related to legal fee liabilities relating to a lawsuit which was settled prior to the merger date. The amounts above represent the provisional fair value estimates as of June 30, 2020 and are subject to subsequent adjustment as the Company obtains additional information during the measurement period and finalizes its fair value estimates.

	Goodwill - Innovus Merger
As of February 14, 2020	$ 8,374,269
Increase due to settlements related to lawsuit and product royalties	209,178
Increase due to additional bonus accrual	53,825
As of June 30, 2020	$ 8,637,272

Since the February 14, 2020 acquisition of Innovus, Innovus has contributed approximately $10.4 million in net revenues and net loss of approximately $3.2 million.

Pro Forma Impact due to Business Combinations

The following supplemental unaudited proforma financial information presents the Company's results as if the following acquisitions had occurred on July 1, 2018:

- Acquisition of the Pediatric Portfolio, effective November 1, 2019;
- Merger with Innovus effective February 14, 2020.

	Year ended June 30,	
	2020 Unaudited (aa)	2019 Pro forma Unaudited
Total revenues, net	$ 35,562,537	$ 39,044,357
Net loss	$ (16,325,078)	$ (37,939,908)
Net loss per share	$ (0.37)	$ (3.27)

(aa) Due to the absence of discrete financial information for Innovus, covering the period from February 1, 2020 through February 13, 2020, the Company did not include the impact of that stub-period for the pro forma results for the year ended June 30, 2020.

5. Inventories

Inventory balances consist of the following:

	June 30,	
	2020	2019
Raw materials	$ 397,000	$ 117,000
Finished goods, net	9,603,000	1,323,000
	$ 10,000,000	$ 1,440,000

There was no work-in-process inventory as of June 30, 2020 or 2019, respectively. As of June 30, 2020 and 2019, there was a $1.3 million and $0 reserve for excess and obsolete inventory.

6. Fixed Assets

Fixed assets consist of the following:

	Estimated Useful Lives in years	June 30,	
		2020	2019
Manufacturing equipment	2 - 5	$ 112,000	$ 83,000
Leasehold improvements	3	229,000	112,000
Office equipment, furniture and other	2 - 5	312,000	315,000
Lab equipment	3 - 5	90,000	90,000
Less accumulated depreciation and amortization		(484,000)	(396,000)
Fixed assets, net		$ 259,000	$ 204,000

Aytu recorded depreciation and amortization expense of $0.1 million for the years ended June 30, 2020 and 2019, respectively.

7. Leases, Right-to-Use Assets and Related Liabilities

In September 2015, the Company entered into a 37-month operating lease in Englewood, Colorado. In October 2017, the Company signed an amendment to extend the lease for an additional 24 months beginning October 1, 2018. In April 2019, the Company extended the lease for an additional 36 months beginning October 1, 2020. This lease has base rent of approximately $10,000 a month, with total rent over the term of the lease of approximately $0.4 million.

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 approximately $1,000 a month, with total rent over the term of the lease of approximately $13,000.

In October 2017, the Company's subsidiary, Innovus, entered into a commercial lease agreement for 16,705 square feet of office and warehouse space in San Diego, California that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent was $21,000 with an approximate 3% increase in the base rent amount on an annual basis, as well as, rent abatement for rent due from January 2018 through May 2018. The Company holds an option to extend the lease an additional 5 years at the end of the initial term. On November 18, 2019 ("decision date"), Innovus determined it would no longer utilize the warehouse portion of the lease space, representing approximately 9,729 square feet, and as of December 31, 2019 ("cease use date") ceased using any such space. In accordance with ASC 842, *Leases*, the Company assessed the asset value of the separate lease component and amortized such asset from the decision date through the cease use date.

As discussed within *Note 2*, the Company adopted the FASB issued ASU 2016-02, *"Leases (Topic 842)"* as of July 1, 2019. With the adoption of ASU 2016-02, the Company recorded an operating right-of-use asset and an operating lease liability on its balance sheet associated with its lease of its corporate headquarters. The right-of-use asset represents the Company's right to use the underlying asset for the lease term and the lease obligation represents the Company's commitment to make the lease payments arising from the lease. Right-of-use lease assets and obligations are recognized at the later of the commencement date or July 1, 2019; the date of adoption of Topic 842; based on the present value of remaining lease payments over the lease term. As the Company's lease does not provide an implicit rate, the Company used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of the lease payments. Rent expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. The lease liability is classified as current or long-term on the balance sheet.

	Total	2021	2022	2023	2024	2025	Thereafter
Remaining office leases	$ 1,193,000	$ 389,000	$ 403,000	$ 362,000	$ 36,000	$ 3,000	-
Less: discount adjustment	(167,000)	-	-	-	-	-	-
Total lease liability	1,026,000	-	-	-	-	-	-
Lease liability - current portion	301,000	-	-	-	-	-	-
Long-term lease liability	$ 725,000	-	-	-	-	-	-

Rent expense for fiscal 2020 and 2019 totaled $0.2 million and $0.1 million, respectively.

8. Intangible Assets — Amortizable

The Company currently holds three existing intangible asset portfolios as of June 30, 2020: (i) Licensed assets, which consist of pharmaceutical product assets that were acquired prior to July 1, 2020; (ii) Product technology rights, acquired from the November 1, 2019 acquisition of the Pediatric Portfolio from Cerecor; and (iii) Patents and tradenames, which as of June 30, 2020, consist entirely of patents, tradenames and customer lists acquired due to the February 2020 acquisition of Innovus.

If acquired in an asset acquisition, the Company capitalized the acquisition cost of each licensed patents or tradename, which can include a combination of both upfront considerations, as well as the estimated future contingent consideration estimated at the acquisition date. If acquired in a business combination, the Company capitalizes the estimated fair value of the intangible asset or assets acquired, based primarily on a discounted cash flow model approach or relief-from-royalties model.

The following table provides the summary of the Company's intangible assets as of June 30, 2020 and June 30, 2019, respectively.

	June 30, 2020				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted-Average Remaining Life (in years)
Licensed assets	$ 23,649,000	$ (7,062,000)	$ -	$ 16,587,000	11.88
MiOXSYS Patent	380,000	(185,000)	(195,000)	-	-
Acquired product technology right	22,700,000	(1,513,000)	-	21,187,000	9.34
Acquired product distribution rights	11,354,000	(565,000)	-	10,789,000	4.62
Acquired customer lists	390,000	(98,000)	-	292,000	1.12
	$ 58,473,000	$ (9,423,000)	$ (195,000)	$ 48,855,000	9.11

	June 30, 2019				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted-Average Remaining Life (in years)
Licensed assets	$ 23,649,000	$ (4,787,000)	$ -	$ 18,862,000	12.31
MiOXSYS Patent	380,000	(159,000)	-	221,000	8.70
	$ 24,029,000	$ (4,946,000)	$ -	$ 19,083,000	12.27

The following table summarizes the estimated future amortization expense to be recognized over the next years and periods thereafter:

	Licensed Assets	Product Technology Rights	Product Distribution Rights (Patents & Trademarks)	Total
2021	$ 2,276,000	$ 2,270,000	$ 1,768,000	$ 6,314,000
2022	2,276,000	2,270,000	1,540,000	6,086,000
2023	2,276,000	2,270,000	1,500,000	6,046,000
2024	2,275,000	2,270,000	1,488,000	6,033,000
2025	917,000	2,270,000	1,292,000	4,479,000
Thereafter	6,567,000	9,837,000	3,493,000	19,897,000
	$ 16,587,000	$ 21,187,000	$ 11,081,000	$ 48,855,000

Certain of the Company's amortizable intangible assets include renewal options, extending the expected life of the asset. The renewal periods range between approximately 1 to 20 years depending on the license, patent, or other agreement. Renewals are accounted for when they are reasonably assured.

Licensed Assets.

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 license and supply agreement was formally amended and restated on December 1, 2019. 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.

The fair value of the net identifiable Natesto asset acquired was determined to be $10.6 million, which is being amortized over eight years. The aggregate amortization expense for fiscal 2020 and fiscal 2019 was $1.3 million, respectively.

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 the Company'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. In addition, the Company also agreed to periodic royalties to Magna as a percentage of ZolpiMist net sales, which was factored into the initial fair value of the license agreement.

The ZolpiMist license agreement was valued at $3.2 million and is amortized over the life of the license agreement up to seven years. The amortization expense for fiscal 2020 and fiscal 2019 was $0.5 million and $0.5 million, respectively.

Tuzistra XR. On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tuzistra 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. 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, which were converted into 0.4 million shares of the Company's common stock during the year ended June 30, 2020; and (iii) will pay certain royalties to TRIS throughout the license term in accordance with the Tris License Agreement and (iv) could incur future payments if certain milestones are achieved.

The Tuzistra License Agreement was valued at $9.9 million and is amortized over the life of the Tris License Agreement up to twenty years. The amortization expense for fiscal 2020 and 2019 was $0.5 million and $0.3 million, respectively. The Company 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.

Product Technology Rights

In November 2019, Aytu Therapeutics, LLC., acquired the Pediatric Portfolio. This transaction expanded our product portfolio with the addition of four prescription products, (i) Cefaclor for Oral Suspension, (ii) Karbinal® ER, (iii) Poly-Vi-Flor® and Tri-Vi-Flor™. The fair value of the acquired Product Technology Rights (the "Product Technology Rights") utilized a Multiple-Period Excess Earnings Method model. The Company amortizes the Product Technology Rights over ten years, with total amortization expense of approximately $1.5 million and $0 for the years ended June 30, 2020 and June 30, 2019 respectively.

Karbinal ER. The Company acquired and assumed all rights and obligations pursuant to the Supply and Distribution Agreement, as Amended, with TRIS for the exclusive rights to commercialize Karbinal® ER in the United States (the "TRIS Karbinal Agreement"). The TRIS Karbinal Agreement's initial term terminates in August of 2033, with an optional initial 20-year extension. The Company owes periodic royalties on sales of Karbinal as a percent of net revenues on a quarterly basis. As part of the agreement, the Company has agreed to pay TRIS a product make-whole payment of approximately $2.1 million per year through July 2023, totaling a minimum of $10.7 million as of June 30, 2020 (see Note 17).

Poly-vi-Flor & Tri-vi-Flor. The Company acquired and assumed all rights and obligations pursuant to a Supply and License Agreement and various assignment and release agreements, including a previously agreed to Settlement and License Agreements (the "Poly-Tri Agreements") for the exclusive rights to commercialize Poly-Vi-Flor and Tri-Vi-Flor in the United States. The Company owes royalties to multiple parties based on a percentage of net revenues on a quarterly basis. There are no milestones, make-whole payments other otherwise any contingencies related to these agreements.

Cefaclor (cefaclor oral suspension). Cefaclor for oral suspension is a second-generation cephalosporin antibiotic suspension and is indicated for the treatment of numerous common infections caused by Streptococcus pneumoniae, Haemophilus influenzae, staphylococci, and Streptococcus pyogenes, and others. Aytu does not own or license any patents covering this product. The Company acquired the License, Supply and Distribution Agreement for rights to promote and commercialize Cefaclor within the United States. The Company is required to pay periodic royalties based on a percent of net revenues.

Patents and Trademarks Tradenames – Acquired from Innovus

On February 14, 2020, the Company and Innovus Pharmaceuticals, Inc. ("Innovus") completed the Merger after successful approval of the Merger by the shareholders of the Company and Innovus at separate special meetings held on February 13, 2020. Upon completion of the Merger, the Company obtained 22 products with a combination of over 300 registered trademarks and/or patent rights including, but not limited to the following:

Patented Products

- *Sensum* – a male moisturizer cream to increase gland sensitivity.
- *Vesele* – A dietary supplement formulated for healthy blood flow.
- *Zestra* - Patented blend of botanical oils and extracts, scientifically formulated to support women's sexual satisfaction.

Trademarks

- *Diabasens* – Topical cream formulated to relieve cutaneous pain associated with conditions such as Postherpetic Neuralgia and Diabetic Neuropathy.
- *FlutiCare* – 24-hour nasal allergy relief that helps fight indoor and outdoor allergens causing congestion, sneezing and a runny nose.
- *UriVarx* – a dietary supplement to support bladder tone and function.
- *Beyond Human Testosterone Booster* - A daily dietary supplement that naturally increases testosterone Levels, supporting natural stamina, endurance and strength.
- Trexar – a dietary supplement to support healthy nerves in men and women.

On February 14, 2020, upon completion of the Merger with Innovus, the Company recognized the fair value of the rental of the customer lists for $0.4 million and amortizes the asset over a useful life of 1.5 years.

The Company recognized the fair value of trademarks, patents or a combination of both for 18 distinct products that the Company markets, distributes and sells for approximately $11.4 million and amortizes the asset over a useful life of 3 – 10 years.

Patents and Tradenames – MiOXSYS

The cost of the oxidation-reduction potential ("ORP") technology related patents for the MiOXSYS Systems was $0.4 million when they were acquired and are being amortized over the remaining U.S. patent life of approximately 15 years as of the date, which expires in March 2028. Aytu recorded the amortization expense totaling $0.03 and $0.03 million for the years ended June 30, 2020 and 2019, respectively. In June 2020, the Company decided to write off the entire remaining balance of the MiOXSYS patents, resulting in a loss of approximately $0.2 million for the year ended June 30, 2020, presented as *Impairment of intangible assets* in the Statement of Operations. This charge was a part of the Aytu BioScience reportable segment (see Note 18) The Company's decision was based on the fact that the product demand has declined due to pandemic caused by the Coronavirus Disease 2019 ("COVID-19"). COVID-19 has caused a decline in demand for fertility services, which creates downstream impacts on demand for products such as MiOXSYS.

9. Accrued liabilities

Accrued liabilities consist of the following:

	As of June 30, 2020	As of June 30, 2019
Accrued settlement expense	$ 315,000	$ -
Accrued program liabilities	959,000	736,000
Accrued product-related fees	2,471,000	295,000
Credit card liabilities	510,000	–
Medicaid liabilities	1,842,000	61,000
Return reserve	1,329,000	98,000
Sales taxes payable	175,000	–
Other accrued liabilities*	249,000	121,000
Total accrued liabilities	$ 7,850,000	$ 1,311,000

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

10. 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 those inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company'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.

The Company'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. The Company 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 Company's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2020 and 2019, by level within the fair value hierarchy:

	Fair Value Measurements at June 30, 2020			
	Total	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	$ 11,000	–	–	$ 11,000
Contingent consideration	13,588,000	–	–	13,588,000
CVR liability	5,572,000	–	–	5,572,000
	$ 19,171,000	–	–	$ 19,171,000

	Fair Value Measurements at June 30, 2019			
	Total	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

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, 2020:

	As of June 30, 2020	As of June 30, 2019	At Issuance
Warrant Derivative Liability			
Volatility	163.2%	163.2%	188.0%
Equivalent term (years)	2.13	3.13	5.00
Risk-free interest rate	0.16%	1.83%	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, 2020:

	Liability Classified Warrants
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
Change in fair value included in earnings	(2,000)
Balance as of June 30, 2020	$ 11,000

Contingent Consideration.

The Company classifies its contingent consideration liability in connection with the acquisition of Tuzistra, ZolpiMist and Innovus within Level 3 factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity.

Natesto. On July 29, 2019, the Company and Acerus agreed to an Amended and Restated License and Supply Agreement (the "Acerus Amendment"), subject to certain conditions being satisfied prior to the Acerus Amendment becoming effective and enforceable. The Acerus Amendment eliminated the previously disclosed revenue-based milestone payments to Acerus that were expected to occur. The maximum aggregate milestones payable under the original agreement was $37.5 million. Upon the effectiveness of the Acerus Amendment on December 1, 2019, all royalty and milestone liabilities were eliminated. Upon the effectiveness of the Acerus Amendment, Acerus was granted the right to earn commissions on certain filled Natesto prescriptions. Additionally, Acerus assumed certain ongoing sales, marketing and regulatory obligations from the Company. This Acerus Amendment became effective December 1, 2019, resulting in a $5.2 million unrealized gain for the fiscal year 2020, due to the elimination of the revenue-based product milestones.

ZolpiMist. 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 10). As of June 30, 2020, the contingent consideration was revalued at $0.2 million (Note 10). The contingent consideration accretion expense for fiscal 2020 and 2019 was $0.2 million and $0.3 million, respectively.

Tuzistra XR. At the November 2, 2018 acquisition date, the contingent consideration, related to this licensed asset, was initially valued at $8.8 million using a Monte Carlo simulation. The contingent consideration was revalued at $13.2 million and $16.0 million as of June 30, 2020 and 2019, respectively. The contingent consideration accretion expense for the year ended June 30, 2020 and 2019 was $0.4 million and $0.2 million, respectively.

Innovus. The Company recognized approximately $0.2 million in contingent consideration as a result of the February 14, 2020 Innovus Merger. The fair value was based on a discounted value of the future contingent payment using a 30% discount rate based on the estimates risk that the milestones are achieved. There was no material change in this valuation as of June 30, 2020.

The following table sets forth a summary of changes in the contingent consideration for the period ended June 30, 2020:

	Contingent Consideration
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
Increase due to purchase of assets	183,000
Increase due to accretion	789,000
Decrease due to contractual payment	(180,000)
Decrease due to amended license agreement	(5,200,000)
Decrease due to remeasurement	(5,330,000)
Balance as of June 30, 2020	$ 13,588,000

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, 2020 and 2019, respectively:

	As of June 30, 2020	As of June 30, 2019
Natesto		
Relevered Beta	–	0.83
Market risk premium	–	5.50%
Risk-free interest rate	–	3.50%
Discount	–	5.20%
Company specific discount	–	5.00%

	As of June 30, 2020	As of June 30, 2019
ZolpiMist		
Relevered Beta	1.17	1.16
Market risk premium	6.00%	5.50%
Risk-free interest rate	3.00%	3.50%
Discount	5.20%	5.20%
Company specific discount	5.00%	5.00%

	As of June 30, 2020	As of June 30, 2019
Tuzistra		
Relevered Beta	0.36	1.19
Maket risk premium	6.00%	5.50%
Risk-free interest rate	3.00%	3.50%
Discount	5.20%	5.20%
Company specific discount	15.00%	15.00%

Contingent value rights

Contingent value rights ("CVRs") represent contingent additional consideration of up to $16 million payable to satisfy future performance milestones related to the Innovus Merger. Consideration can be satisfied in up to 4.7 million shares of the Company's common stock, or cash either upon the option of the Company or in the event there are insufficient shares available to satisfy such obligations. As of June 30, 2020, the Company paid out 1.2 million shares of the Company's common stock to satisfy the first $2 million milestone, which relates to the Innovus achievement of $24.0 million in revenues during the 2019 calendar year. The Company has a remaining maximum of $14.0 million of additional contingent value rights to satisfy over the remaining four years. The contingent value rights accretion expense for fiscal 2020 and 2019 was
$0.2 million and $0 million, respectively.

Non-Recurring Fair Value Measurements

The following table represents those asset and liabilities measured on a non-recurring basis for the fiscal year 2020 as a result of the (i) November 1, 2019 acquisition of the Pediatrics Portfolio and (ii) the February 14, 2020 Innovus Merger.

	Fair Value Measurements at June 30, 2020			
	Fair Value at Measurement Date	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Non-recurring				
MiOXSYS patent (Luoxis patents)	$ -	$ -	$ -	$ -
Debt	982,076	-	-	982,076
Pediatric Portfolio (November 1, 2019)				
Product technology rights	22,700,000	–	–	22,700,000
Goodwill	19,453,135	–	–	19,453,135
Fixed payment arrangements	29,837,853	–	–	29,837,853
Innovus Merger (February 14, 2020)				
Customer lists	390,000	–	–	390,000
Product distribution righs (trademarks and patents)	11,354,000	–	–	11,354,000
Goodwill	8,637,272	–	–	8,637,272
Notes payable	3,056,361	–	–	3,056,361
	$ 96,410,697	$ –	$ –	$ 96,410,697

Acquisition of the Pediatric Portfolio

Product technology rights. The Company recognized the product technology right intangible asset acquired as part of the November 1, 2019 acquisition of the Pediatric Portfolio. This intangible asset consists of the acquired product technology rights consisting of (i) Karbinal ER, (ii) Cefaclor, and (iii) Poly-Vi-Flor and Tri-Vi-Flor. The Company utilized a Multiple-Period Excess Earnings Method model.

	As of November 1, 2019 (*)
Product technology rights	
Re-levered Beta	1.60
Market risk premium	6.00%
Small stock risk premium	5.20%
Risk-free interest rate	2.00%
Company specific discount	25.00%

(*) Valuation performed as of November 1, 2019. As a non-recurring fair value measurement, there is no remeasurement at each reporting period unless indications exist that the fair value of the asset has been impaired. There were no indicators as of June 30, 2020 that the fair value of the Product technology rights was impaired.

Goodwill. Goodwill represents the fair value of consideration transferred and liabilities assumed in excess of the fair value of assets acquired. Remeasurement of the fair value of goodwill only arises upon either (i) indicators that the fair value of goodwill has been impaired, or (ii) during the annual impairment test performed at June 30 of each fiscal year. There were no indicators observed or identified during and as of the period from November 1, 2019 through June 30, 2020.

Fixed payment arrangements. The Company assumed obligations due to an investor including fixed and variable payments. The Company assumed fixed monthly payments equal to $0.1 million from November 2019 through January 2021 plus $15.0 million due in January 2021, of which $15.0 million was paid down early in June 2020. Monthly variable payments due to the same investor are equal to 15% of net revenue generated from a subset of the Pediatric Portfolio, subject to an aggregate monthly minimum of $0.1 million, except for January 2020, when a one-time payment of $0.2 million was due and paid. The variable payment obligation continues until the earlier of: (i) aggregate variable payments of approximately $9.3 million have been made, or (ii) February 12, 2026. In addition, the Company assumed fixed, product minimums royalties of approximately $2.1 million per annum through February 2023.

	As of November 1, 2019 (≠)
Fixed payment obligations	
Discount rate	1.8% to 12.4%

(≠) Valuation performed as of November 1, 2019. As a non-recurring fair value measurement, there is no remeasurement at each reporting period unless indicates that the circumstances that existed as of the November 1, 2019 measurement date indicate that the carrying value is no longer indicative of fair value.

Innovus Merger

Customer lists. The Company recognized the fair value of the customer lists that existed as of the Valuation Date to be $0.4 million. The Company utilized an income method approach.

Trademarks and patents. The Company recognized the fair value of trademarks, patents or a combination of both for 18 distinct products that the Company markets, distributes and sells. An Income Approach known as the Relief-From-Royalty Method was utilized to value the product distribution rights associated with each of the 18 products associated with trademarks and patents. A royalty rate of 15% was used based on upon a range of observable royalties between the range of 7.5% and 34.5%.

	As of February 14, 2020
Trademarks and patents	
Re-levered Beta	0.84%
Market risk premium	6.17%
Small stock risk premium	4.99%
Risk-free interest rate	1.89%
Company specific discount	20.00%

Goodwill. Goodwill represents the fair value of consideration transferred and liabilities assumed in excess of the fair value of assets acquired. Remeasurement of the fair value of goodwill only arises upon either (i) indicators that the fair value of goodwill has been impaired, or (ii) during the annual impairment test performed at June 30 of each fiscal year. There were no indicators observed or identified during and as of the period from February 14, 2020 through June 30, 2020.

Innovus Notes Payable. The Innovus Notes Payable represent twelve financial obligations assumed as part of the Innovus Merger. These notes are comprised of ten uncollateralized obligations with a face value of approximately $3.6 million and two notes secured by inventory held fulfillment centers with Amazon, Inc. and a face value of approximately $0.4 million (the “Innovus Notes”). The Innovus Notes were revalued using the estimated cost of capital at the valuation date for a total estimated fair value of approximately $3.1 million.

The ten unsecured Innovus Notes consist of ten separate loans with implied effective interest rates ranging between 14.1% and 73.4%. The weighted average interest rate for these notes was 39.5%, while the weighted average interest rate for the most recent loan (January 9, 2020) was 41.4%. All ten of the notes are unsecured, and as of the valuation date there was significant risk associated with their repayment. Accordingly, the Company has revalued the notes using an effective rate of 40% and concluded that the fair value at the February 14, 2020 Innovus Merger date was approximately $2.7 million.

The secured Innovus Notes due to Amazon had maturities of less than one year and stated rates of 17.2% and 14.7% respectively. Due to the fact that the most recent loan had a stated rate of 14.7% and that the weighted average rate for these two loans was 15.6%, the Company has estimated the current value of the loans using an effective rate of 15% and concluded that the fair value of the secured Innovus Notes totaled approximately $0.4 million.

Summary of Level 3 Input Changes

The following table sets forth a summary of changes to those fair value measures using Level 3 inputs for the year ended June 30, 2020:

	Product Technology Rights	Innovus Assets	Goodwill	Liability Classified Warrants	CVR Liability	Contingent Consideration	Fixed Payment Arrangements
Balance as of June 30, 2019	$ –	$ –	$ –	$ 13,000	$ –	$ 23,326,000	$ –
Transfers into Level 3	–	–	–	–	–	–	–
Transfer out of Level 3	–	–	–	–	–	–	–
Total gains, losses, amortization or accretion in period	–	–	–	–	–	–	–
Included in earnings	(1,513,000)	(663,000)	–	(2,000)	523,000	(9,741,000)	1,452,000
Included in other comprehensive income	–	–	–	–		–	
Purchases, issues, sales and settlements		–					
Purchases	22,700,000	11,744,000	28,090,000	–	7,049,000	183,000	–
Issues	–	–	–	–	–	–	29,838,000
Sales	–	–	–	–	–	–	–
Settlements	–	–	–	–	(2,000,000)	(180,000)	(17,778,000)
Balance as of June 30, 2020	$ 21,187,000	$ 11,081,000	$ 28,090,000	$ 11,000	$ 5,572,000	$ 13,588,000	$ 13,512,000

11. Note Receivable

On September 12, 2019, the Company announced it had entered into a definitive merger agreement with Innovus (see Note 1 and Note 4). to acquire Innovus which specializes in commercializing, licensing and developing safe and effective supplements and over-the-counter consumer health products. As part of the negotiations with Innovus, the Company agreed to provide a short-term, loan in the form of a $1.0 promissory note on August 8, 2019 (the “Innovus Note”). In addition, on October 11, 2019, the Company amended the original promissory note, providing an additional approximately $0.4 million of bridge financing under the same terms and conditions as the Innovus Note. Upon the closing of the Innovus Merger, this note receivable was used to offset a portion of the $8 million initial closing purchase price and was deducted from the consideration value used when determining the number of shares of the Company’s common stock issued upon closing of the Innovus Merger (see Note 4).

12. 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,			
	2020		2019	
Benefit at statutory rate	$ (2,934,000)	-21.00%	$ (5,698,000)	-21.00%
State income taxes, net of federal benefit	(798,000)	-5.71%	(1,077,000)	-3.97%
Stock based compensation	(35,000)	-0.25%	3,000	0.01%
Contingent consideration	54,000	0.39%	-	0.00%
Change in tax rate	-	0.00%	12,000	0.04%
Remeasurement of deferred taxes	-	0.00%	-	0.00%
Effect of phased-in tax rate	-	0.00%	-	0.00%
Loss on debt extinguishment and interest expense	167,000	1.20%	-	0.00%
Change in valuation allowance	3,496,000	25.02%	6,584,000	24.27%
Derivative income	-	0.00%	(16,000)	-0.06%
Other	50,000	0.37%	192,000	0.71%
Net income tax provision (benefit)	$ -	0.02%	$ -	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,	
	2020	2019
Deferred tax assets (liabilities):		
Accrued expenses	$ 855,000	$ 234,000
Net operating loss carry forward	37,191,000	18,085,000
Intangibles	(1,578,000)	3,377,000
Share-based compensation	1,891,000	1,210,000
Fixed assets	73,000	86,000
Capital loss carry forward	203,000	203,000
Contribution carry forward	31,000	31,000
Warrant liability	51,000	51,000
Inventory	789,000	25,000
R&D Credits	9,000	-
Lease Liability	261,000	-
ROU Asset	(224,000)	-
Total deferred income tax assets (liabilities)	39,552,000	23,302,000
Less: Valuation allowance	(39,552,000)	(23,302,000)
Total deferred income tax assets (liabilities)	$ -	$ -

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

The Company has federal net operating losses of approximately $147 million and $73.9 million as of June 30, 2020 and June 30, 2019, respectively that, subject to limitation, may be available in future tax years to offset taxable income. Of the available federal net operating losses, approximately $46.9 million can be carried forward indefinitely while the balance will begin to expire in 2031. 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, 2020, the company had various state NOL carryforwards. The determination of the state NOL carryforwards is dependent on apportionment percentages and state laws that can change from year to year and impact the amount of such carryforwards.

As of June 30, 2020, and 2019, 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. Under the general statute of limitations, the Company would not be subject to federal or Colorado income tax examinations for tax years prior to 2016 and 2015, respectively. However, given the net operating losses generated since inception, all tax years since inception are subject to examination.

13. Capital Structure

The Company has 200 million shares of common stock authorized with a par value of $0.0001 per share and 50 million shares of preferred stock authorized with a par value of $0.0001 per share.

At June 30, 2020 and June 30, 2019, Aytu had 125,837,357 and 17,538,071 common shares outstanding, respectively, and 0 and 3,594,981 preferred shares outstanding, respectively.

Included in the common stock outstanding are 4,186,056 shares of restricted stock issued to executives, directors, employees and consultants.

In September 2019, investors holding shares of Series C preferred stock exercised their right to convert 443,833 shares of Series C preferred stock into 443,833 shares of common stock. There are no remaining Series C preferred stock outstanding.

In October 2019, Armistice Capital converted 2,751,148 shares of Series E convertible preferred stock into 2,751,148 shares of common stock. There are no remaining Series E preferred stock outstanding.

In October 2019, the Company issued 10,000 shares of Series F Convertible preferred stock, with a face value of $1,000 per share, and convertible at a conversion price of $1.00 (the “Current Conversion Price”). The terms of the Series F Convertible Preferred include a conversion price reset provision in the event a future financing transaction is priced below the Current Conversion Price. The Company has determined that concurrent with the adoption of ASU 2017-11, this down-round provision feature reflects a beneficial conversion feature contingent on a future financing transaction at a price lower than the Current Conversion Price. As the Series F Convertible Preferred stock is an equity classified instrument, any accounting arising from a future event giving rise to the beneficial conversion feature would have no net impact on the Company’s financial statements, as all activity would be recognized within Additional Paid-in-Capital and offset.

In addition and concurrent with the Series F Convertible preferred stock issuance, the Company issued 10,000,000 warrants, with an exercise price of $1.25 and a term of five years. These warrants feature a contingent cashless exercise provision. During the three months ended December 31, 2019, the cashless exercise contingency was satisfied, reducing the strike price of the October 2019 Warrants to $0. During the three months ended March 31, 2020, an investor exercised 5,000,000 of the warrants using the cashless exercise provision. In April 2020, another investor exercised the remaining 5,000,000 of the October 2019 warrants using the cashless exercise provision, resulting in no remaining October 2019 warrants.

In November 2019, in connection with the Pediatric Portfolio acquisition, the Company issued 9,805,845 shares of Series G Convertible Preferred stock, of which, Pediatric Portfolio converted 9,805,845 shares of the Series G Convertible Preferred stock were converted into 9,805,845 shares of common stock in April of 2020.

In February 2014, in connection with the Innovus Merger, the Company issued (i) 3,810,293 shares of the Company’s common stock and (ii) 1,997,736 shares of Series H Convertible Preferred stock, of which, 1,997,736 shares of the Series H Convertible Preferred stock were converted into 1,997,736 shares of common stock in March 2020.

In March 2020, the Company entered into three separate offerings, on March 10, 2020, March 12, 2020 and March 19, 2020 (the “March Offerings”) in which the Company issued a combination of common stock and warrants. The following summarizes the March Offerings, including total capital raised from both the issuance of common stock and subsequent warrant exercises.

On March 19, 2020, the Company entered into a securities purchase agreement with certain institutional investors (the “the March 19, 2020 Purchasers”), pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 12,539,197 shares of the Company’s common stock (the “Common Stock”) at a purchase price per share of $1.595 and (ii) warrants to purchase up to 12,539,197 shares of Common Stock (the “March 19, 2020 Warrants”) at an exercise price of $1.47 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company. The March 19, 2020 Warrants are exercisable immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued warrants with an exercise price of $1.9938 per share to purchase up to 815,047 shares of common stock (the “March 19, 2020 Placement Agent Warrants”). The March 19, 2020 Placement Agent Warrants have a term of five years from the issuance date.

Since March 19, 2020, Aa total of 1.2 million March 19, 2020 Warrants have been exercised through May 5, 2020, for total proceeds of $1.7 million ., of which 0.7 million March 19, 2020 Warrants were exercised through March 31, 2020, for total proceeds of $1.1 million.

On March 12, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 16,000,000 shares of the Company’s common stock at a purchase price per share of $1.25 and (ii) warrants to purchase up to 16,000,000 shares of Common Stock (the “March 12, 2020 Warrants”) at an exercise price of $1.25 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the “Registered Offering”). The March 12, 2020 Warrants are exercisable immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued warrants with an exercise price of $1.5625 per share to purchase up to 1,040,000 shares of common stock (the “March 12, 2020 Placement Agent Warrants”). The March 12, 2020 Placement Agent Warrants have a term of five years from the issuance date.

Since March 12, 2020, a total of 13 million March 12, 2020 Warrants have been exercised through May 5, 2020, for total proceeds of approximately $16.3 million., of which approximately 10.5 million March 12, 2020 Warrants were exercised through March 31, 2020, for total proceeds of $13.1 million.

On March 10, 2020, Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 4,450,000 shares of the Company's common stock (the "Common Stock") at a purchase price per share of $1.15 and (ii) pre-funded warrants to purchase up to 3,376,087 shares of Common Stock (the "Pre-Funded Warrants") at an effective price of $1.15 per share ($1.1499 paid to the Company upon the closing of the offering and $0.0001 to be paid upon exercise of such Pre- Funded Warrants), for aggregate gross proceeds to the Company of approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the "Registered Offering"). The Pre-Funded Warrants were immediately exercised upon close. In addition, the Company issued warrants with an exercise price of $1.4375 per share to purchase up to 508,696 shares of common stock (the "March 10, 2020 Placement Agent Warrants"). The March 10, 2020 Placement Agent Warrants have a term of five years from the issuance date.

Since March 10, 2020 Between March 10, 2020 and March 31, 2020, a total of 6.0 million shares of the Company's October 2018 $1.50 Warrants (the "October 18 $1.50 Warrants") were exercised, resulting in proceeds of approximately $9.0 million.

In total, the Company has raised net proceeds of approximately $71. 3 million, net of fees, from the March Offerings and related warrant exercises, as well as exercises of the October 2018 Warrants. The net proceeds received by the Company from the March Offerings and related warrant exercise will be used for general corporate purposes, including working capital.

In addition, since January 1, 2020, the following Convertible Preferred Stock issuances were converted into the Company's common stock: 400,000 shares of the Series D Convertible Preferred Stock were converted into 400,000 shares of the Company's common stock. There are no remaining shares of the Series D Convertible Preferred Stock outstanding at June 30, 2020.

In June 2020, we completed an at-the-market offering program, which allows us to sell and issue shares of our common stock from time-to- time. The company issued 4,302,271 shares of common stock, with total gross proceeds of $6.8 million before deducting underwriting discounts, commissions and other offering expenses payable by the Company of $0.2 million through June 30, 2020.

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.

14. Equity Incentive Plan

2015 Stock Option and Incentive Plan. On June 1, 2015, the Company'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, 2020, we have 4,837 shares that are available for grant under the 2015 Plan.

On December 23, 2019, the Company filed Form S-4 related to the proposed Innovus merger, in which shareholders are asked to approve an increase to 5.0 million total shares of common stock in the 2015 Plan. As of the date of this report, Aytu shareholders approved the proposal to increase the total number of common shares in the 2015 Plan.

Stock Options

Employee Stock Options:

In June 2020, the Company granted 200,000 shares of stock options to executive officers pursuant to the 2015 Plan, which vest over four years. Compensation expense related to these options will be fully recognized over the four-year vesting period.

In June 2020, the Company granted 50,000 shares of stock options to board of directors pursuant to the 2015 Plan, which vest on the one employee pursuant to the 2015 Plan, which vest over four years. Compensation expense related to these options will be fully recognized over the four-year vesting period.

In June 2020, the Company granted 180,000 shares of stock options to board of directors pursuant to the 2015 Plan, which vest on the one-year anniversary of the grant date. Compensation expense related to these options will be fully recognized over the one-year vesting period.

In January 2020, the Company granted 12,500 shares of stock options to 5 employees pursuant to the 2015 Plan, which vest immediately upon grant. Compensation expense related to these options were fully recognized in the three months ended March 31, 2020.

In November 2019, the Company granted 327,000 shares of stock options to 28 employees pursuant to the 2015 Plan, which vest over four years. Compensation expense related to these options will be fully recognized over the four-year vesting period.

The fair value of the options is calculated using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. Aytu estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The fair value of all options granted during the year ended June 30, 2020 utilized the following range of assumptions:

	During the Year Ended June 30, 2020
Expected volatility	100.00-182.16%
Expected term (years)	1.-4.00
Risk-free interest rate	0.41-1.82%
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, 2018	1,798	$ 325.97	6.95
Granted	75,000	1.00	
Exercised	-	-	
Forfeited/Canceled	(75,036)	1.16	
Expired	(155)	328.00	
Outstanding June 30, 2019	1,607	325.97	6.13
Granted	769,500	1.24	
Exercised	(5,000)	0.97	
Forfeited/Canceled	-	-	
Expired	(170)	328.00	
Outstanding June 30, 2020	765,937	1.85	9.67
Exercisable at June 30, 2020	8,937	$ 53.15	8.92

The following table details the options outstanding at June 30, 2020 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
$ 0.97	7,500	$ 0.97	9.52	7,500	$ 0.97
0.98	327,000	0.98	9.37	-	0.98
1.45	430,000	1.45	9.94	-	1.45
280.00	76	280.00	6.84	76	280.00
$ 328.00	1,361	$ 328.00	5.70	1,361	$ 328.00
	765,937	$ 1.85	9.67	8,937	$ 53.15

As of June 30, 2020, there was $669,000 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 2.80 years. 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 expected to recognize this expense over a weighted-average period of 0.32 years. As of Jun 30, 2020, the aggregate intrinsic value of the stock options outstanding was approximately $0.1 million.

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, 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
Granted	1,952,912	$ 1.06	
Vested	(114,610)	$ 1.79	
Forfeited	-	-	
Unvested at June 30, 2020	4,184,516	$ 1.47	6.4

Activity during Year Ended June 30, 2020

- In January 2020, the Company issued 75,000 shares of restricted stock to an employee pursuant to the 2015 Plan, which vest in January 2030.
- In January 2020, the Company issued 10,000 shares of restricted stock to a director pursuant to the 2015 Plan, which vest in November 2027.
- In January 2020, The Company issued 200,000 shares of restricted stock to an employee pursuant to the 2015 Plan, which vest in November 2021.
- In February 2020, The Company issued 783,000 shares of restricted stock to employees pursuant to the 2015 Plan, which vest in February 2021.
- In June 2020, The Company issued 700,000 shares of restricted stock to executives pursuant to the 2015 Plan, of which 25% vests on June 7, 2021, with an additional 6.25% of the total shares vesting quarterly thereafter, subject to continued service through each vesting date until June 7, 2024.
- In June 2020, The Company issued 10,000 shares of restricted stock to a director pursuant to the 2015 Plan, which vest in June 2021.
- In June 2020, The Company issued 175,000 shares of restricted stock to employees pursuant to the 2015 Plan, of which 25% vests on June 7, 2021, with an additional 6.25% of the total shares vesting quarterly thereafter, subject to continued service through each vesting date until June 7, 2024.
- 114,610 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 $130,000.

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.

Under the 2015 Plan, there was $5,035,000 of total unrecognized stock-based compensation expense related to the non-vested restricted stock as of June 30, 2020. The Company expects to recognize this expense over a weighted-average period of 6.37 years. As of June 30, 2020, the aggregate remaining intrinsic value for the Company's restricted stock units was $5.9 million.

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 $1,197,761 as of June 30, 2020 and is expected to be recognized over the weighted average period of 6.02 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 2020 and 2019:

Selling, general and administrative:	2020	2019
Stock options	$ 80,000	$ 125,000
Restricted stock	999,000	897,000
Total stock-based compensation expense	$ 1,079,000	$ 1,022,000

15. Warrants

In connection with the October 2019 private placement financing, the Company issued warrants (the October 2019 Warrants) to the investors to purchase an aggregate of 10,000,000 shares of the Company's common stock at an exercise price of $1.25 and a term of five years. These warrants feature a contingent cashless exercise provision. During the three months ended December 31, 2019, the cashless exercise contingency was satisfied, reducing the strike price of the October 2019 Warrants to $0. During the three months ended March 31, 2020, an investor exercised 5,000,000 of the warrants using the cashless exercise provision. In April 2020, another investor exercised the remaining 5,000,000 of the October 2019 warrants using the cashless exercise provision, resulting in no remaining October 2019 warrants as of April 30, 2020.

In February 14, 2020, the Company assumed as part of the Innovus Merger 348,103 warrants to purchase 348,103 shares of the Company's common stock with exercise prices ranging from $18.00 to $47.00 with terms ending between September of 2020 through March of 2023.

In connection with the March Offerings, the following warrants were granted, and potentially subsequently exercised:

- On March 10, 2020, the Company granted 3,376,087 Pre-Funded Warrants for total proceeds of $3.9 million, which were fully exercised as of March 31, 2020. In addition, the Company issued 508,696 of Placement Agent Warrants with an exercise price of $1.4375 to purchase 508,696 shares of the Company's common stock, which expire five years after the grant date. None of the March 10, 2020 Placement Agent Warrants have been exercised as of June 30, 2020.

- On March 12, 2020, the Company granted 16,000,000 March 12, 2020 $1.25 Warrants to purchase 16,000,000 shares of the Company's common stock for an exercise price of $1.25 per share of common stock, and expire one-year after the grant date, of which 10,450,000 were exercised as of March 31, 2020 for total proceeds of approximately $13.1 million. In addition, the Company granted 1,040,000 of the March 12, 2020 Placement Agent Warrants with an exercise price of $1.5625 per share of common stock to purchase 1,040,000 shares of the Company's common stock, which expire five years after the grant date. None of the March 12, 2020 Placement Agent Warrants have been exercised as of June 30, 2020.

- On March 19, 2020, the Company granted 12,539,197 March 19, 2020 $1.47 Warrants to purchase 12,539,197 shares of the Company's common stock for an exercise price of $1.47 per share of common stock, and expire one-year after the grant date, of which 700,000 were exercised as of March 31, 2020 for total proceeds of approximately $1.0 million. In addition, the Company granted 815,047 of the March 12, 2020 Placement Agent Warrants with an exercise price of $1.9938 per share of common stock to purchase 815,047 shares of the Company's common stock, which expire five years after the grant date. None of the March 19, 2020 Placement Agent Warrants have been exercised as of June 30, 2020.

While these warrants are classified as a component of equity, in order to allocate the fair value of the March offerings between the investor warrants and the placement agent warrants, the Company was required to calculate the relative fair value of the warrants issued in March. These warrants issued had a relative fair value of $11.2 million. All warrants issued in March 2020 were valued using a Black-Scholes model. In order to calculate the fair value of the warrants, certain assumptions were made, including the selling price or fair market value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield, and contractual life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimated a volatility factor utilizing a weighted average of comparable published betas of peer companies. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity.

Significant assumptions in valuing the warrants issued during the year are as follows:

	Warrants Issued During the Year Ended June 30, 2020
Expected volatility	100 - 153%
Equivalent term (years)	1 - 5
Risk-free rate	0.20% - 1.91%
Dividend yield	0.00%

A summary of equity-based warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2018	1,641,906	$ 19.19	4.67
Warrants issued	14,827,009	$ 1.35	–
Warrants expired	–	–	–
Warrants exercised	(250,007)	–	–
Outstanding June 30, 2019	16,218,908	$ 3.15	4.36
Warrants issued	44,627,120	$ 1.21	–
Warrants expired	–	–	–
Warrants exercised (*)	(37,961,490)	–	–
Outstanding June 30, 2020	22,884,538	$ 3.06	2.00

(*) During the three months March 31, 2020, an investor exercised 5.0 million of the October 2019 private placement warrants under the cashless exercise provision. In April 2020, another investor exercised all remaining 5.0 million October 2019 private placement warrants. There are no more October 2019 private placement warrants outstanding as of June 30, 2020.

During the fiscal year 2020, warrants issued from the October 2018 registered offering and March 2020 offerings to purchase an aggregate of 20,181,994 shares of common stock were exercised for aggregate gross proceeds to our Company of approximately $27 million.

A summary of liability warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2018	240,755	$ 72.00	4.13
Warrants expired	–	–	–
Warrants exercised	–	–	–
Outstanding June 30, 2019	240,755	$ 72.00	3.16
Warrants expired	–	–	–
Warrants exercised	–	–	–
Outstanding June 30, 2020	240,755	$ 72.00	2.13

16. 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 2020, the Company's match was approximately $0.2 million.

17. Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of June 30, 2020:

	Total	2021	2022	2023	2024	2025	Thereafter
Prescription database	$ 1,635,000	$ 902,000	$ 733,000	$ –	$ –	$ –	$ –
Pediatric portfolio fixed payments and product minimums	17,996,000	3,821,000	3,300,000	3,300,000	3,300,000	3,300,000	975,000
Inventory purchase commitment	1,962,000	1,226,000	736,000	–	–	–	–
CVR liability	5,572,000	840,000	1,292,000	2,484,000	956,000	–	–
Product contingent liability	202,000	–	–	–	–	–	202,000
Product milestone payments	3,000,000	–	3,000,000	–	–	–	–
Office leases	1,193,000	389,000	403,000	362,000	36,000	3,000	–
	$31,560,000	$ 7,178,000	$ 9,464,000	$ 6,146,000	$ 4,292,000	$ 3,303,000	$ 1,177,000

Prescription Database

In May 2016, the Company entered into an agreement with a vendor that provides 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, ZolpiMist and Tuzistra. In January 2020, the Company amended the agreement and agreed to pay additional $0.6 million to add access to the database of prescriptions written for the Pediatric Portfolio. The payments have been broken down into quarterly payments.

Pediatric Portfolio Fixed Payment Obligations

Fixed Obligations. The Company assumed two fixed, periodic payment obligations to an investor (the "Fixed Obligation"). Beginning November 1, 2019 through January 2021, the Company will pay monthly payments of $86,840, with a balloon payment of $15.0 million that was to be due in January 2021 (the "Balloon Payment Obligation").

On May 29, 2020, the Company entered into an Early Payment Agreement and Escrow Instruction (the "Early Payment Agreement") pursuant to which the Company agreed to pay $15.0 million to the investor in early satisfaction of the Balloon Payment Obligation. The parties to the Early Payment Agreement acknowledged and agreed that the remaining fixed payments other than the Balloon Payment Obligation remain due and payable pursuant to the terms of the Agreement, and that nothing in the Early Payment Agreement alters, amends, or waives any provisions or obligations in the Waiver or the Investor agreement other than as expressly set forth therein.

A second fixed obligation requires the Company pay a minimum of $100,000 monthly through February 2026, except for $210,767 paid in January 2020. There is the potential for the second fixed obligation to increase an additional $1.8 million depending on product sales, which could trigger additional amounts to be paid.

The Fixed Payment Obligation is secured by some of the Company's Pediatric Portfolio and all rights thereon to those products in the event of failure to perform under the Fixed Payment Obligation consisting primarily of Cefaclor and Karbinal.

Product Make-whole.
In addition, the Company acquired a Supply and Distribution Agreement with TRIS (the "Karbinal Agreement"), under which the Company is granted the exclusive right to distribute and sell the product in the United States. The initial term of the Karbinal Agreement was 20 years. The Company will pay TRIS a royalty equal to 23.5% of net sales. A third party agreed to offset the 23.5% royalty payable by 8.5%, for a net royalty equal to 15%, in fiscal year 2018 and 2019 for net sales of Karbinal.

The Karbinal Agreement contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units through 2023, with a minimum fixed payment obligation of approximately $2.1 million per year. The Company is required to pay TRIS a royalty make whole payment of $30 for each unit under the 70,000-unit annual minimum sales commitment through 2033. The annual payment is due in August of each year.

CVR Liability

On February 14, 2020 the Company closed on the Merger with Innovus Pharmaceuticals after approval by the stockholders of both companies on February 13, 2020. Upon closing the Merger, the Company merged with and into Innovus and entered into a Contingent Value Rights Agreement (the "CVR Agreement"). Each CVR will entitle its holder to receive its pro rata share, payable in cash or stock, at the option of Aytu, of certain payment amounts if the targets are met. If any of the payment amounts is earned, they are to be paid by the end of the first quarter of the calendar year following the year in which they are earned. Multiple revenue milestones can be earned in one year.

On March 31, 2020, the Company paid out the first CVR Milestone in the form of approximately 1.2 million shares of the Company's common stock to satisfy the $2.0 million obligation as a result of Innovus achieving the $24.0 million revenue milestone for calendar year ended December 31, 2019. As a result of this, the Company recognized a gain of approximately $0.3 million.

Product Contingent Liability

In February 2015, Innovus acquired Novalere, which included the rights associated with distributing FlutiCare. As part of the Merger, Innovus is obligated to make 5 additional payments of $0.5 million when certain levels of FlutiCare sales are achieved.

Inventory Purchase Commitment

On May 1, 2020, the Company entered into a Settlement Agreement and Release (the "Settlement Agreement") with Hikma Pharmaceuticals USA Inc. ("Hikma"). Pursuant to the settlement agreement, Innovus has agreed to purchase and Hikma has agreed to manufacture a minimum amount of our branded fluticasone propionate nasal spray USP, 50 mcg per spray (FlutiCare®), under Hikma's FDA approved ANDA No. 207957 in the U.S. The commitment requires Innovus to purchase three batches of product through fiscal year 2022 each of which amount to $1.0 million.

Milestone Payments

In connection with the Company's intangible assets, the Company has certain milestone payments, totaling $3.0 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 10).

Offices Leases

In September 2015, the Company entered into a 37-month operating lease in Englewood, Colorado. In October 2017, the Company signed an amendment to extend the lease for an additional 24 months beginning October 1, 2018. In April 2019, the Company extended the lease for an additional 36 months beginning October 1, 2020. This lease has base rent of approximately $10 thousand a month, with total rent over the term of the lease of approximately $355 thousand.

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 approximately $1 thousand a month, with total rent over the term of the lease of approximately $13 thousand.

In October 2017, the Company's subsidiary, Innovus, entered into a commercial lease agreement for 16,705 square feet of office and warehouse space in San Diego, California that commenced on December 1, 2017 and continues until April 30, 2023. The initial monthly base rent was $21,000 with an approximate 3% increase in the base rent amount on an annual basis, as well as, rent abatement for rent due from January 2018 through May 2018. The Company holds an option to extend the lease an additional 5 years at the end of the initial term. On November 18, 2019 ("decision date"), Innovus determined it would no longer utilize the warehouse portion of the lease space, representing approximately 9,729 square feet, and as of December 31, 2019 ("cease use date") ceased using any such space. In accordance with ASC 842, *Leases*, the Company assessed the asset value of the separate lease component and amortized such asset from the decision date through the cease use date.

18. 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 the Company. For each of the years ended June 30, 2020 and 2019, respectively, presented, the basic and diluted loss per share were the same for the years ended June 30, 2020 and 2019, as 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, 2020 and 2019 are anti-dilutive, and therefore excluded from the calculation of diluted earnings per share.

		Year Ended June 30,	
		2020	2019
Warrants to purchase common stock - liability classified	(Note 15)	240,755	240,755
Warrant to purchase common stock - equity classified	(Note 15)	22,884,538	16,238,657
Employee stock options	(Note 14)	765,937	1,607
Employee unvested restricted stock	(Note 14)	4,186,056	2,551,024
Convertible preferred stock	(Note 13)	-	3,594,981
		28,077,286	22,627,024

19. Segment Information

The Company's chief operating decision maker (the "CODM"), who is the Company's Chief Executive Officer, allocates resources and assesses performance based on financial information of the Company. The CODM reviews financial information presented for each reportable segment for purposes of making operating decisions and assessing financial performance.

Aytu manages the Company and aggregated our operational and financial information in accordance with two reportable segments: Aytu BioScience and Aytu Consumer Health. The Aytu BioScience segment consists of the Company's prescription products. The Aytu Consumer Health segment contains the Company's consumer healthcare products, which was the result of the Innovus Merger. Select financial information for these segments is as follows:

	As of June 30,	
	2020	2019
Consolidated revenue:		
Aytu BioScience	$ 17,249,000	$ 7,320,000
Aytu Consumer Health	10,383,000	-
Consolidated revenue	$ 27,632,000	$ 7,320,000
Consolidated net loss:		
Aytu BioScience	$ (10,464,000)	$ (27,132,000)
Aytu Consumer Health	(3,157,000)	-
Consolidated net loss	$ (13,621,000)	$ (27,132,000)
Total assets:		
Aytu BioScience	$ 126,267,000	$ 34,721,000
Aytu Consumer Health	26,569,000	-
Total assets	$ 155,251,000	$ 34,721,000

	As of June 30,	
	2020	2019
Goodwill		
Aytu BioScience	$ 19,453,000	$ –
Aytu Consumer Health	8,637,000	–
Consolidated Goodwill	$ 28,090,000	$ –

20. Note Payable

The Aytu BioScience Note. On February 27, 2020, the Company issued a $0.8 million promissory note (the "Note") and received consideration of $0.6 million. The Note had an eight-month term with principal and interest payable at maturity and the recognition of approximately $0.2 million of debt discount related to the issuance of promissory notes. The discount is amortized over the life of the promissory notes through the fourth quarter of calendar 2020. During the year ended June 30, 2020, and June 30, 2019, the Company recorded approximately $0.1 million and $0, respectively, of related amortization.

The Innovus Notes. Upon completion of the Merger, the Company assumed approximately $3.1 million of debt comprised of twelve different note agreements "Innovus Notes" (see Note 1, 2 and 10).

On April 21, 2020, the Company entered into an amendment with one investor who held four different note agreements to extend the maturity date to August 1, 2020 from April 15, 2020 and to amend the conversion feature description within the note agreement. On April 27, 2020, this investor provided a notice of conversion to convert the four outstanding note agreements to shares of common stock. In connection with the notice of conversion, the Company issued 1.5 million shares of common stock in exchange for the settlement of principal and interest due totaling $1.8 million. The fair value of the shares of common stock issued was based on the market price of the Company's common stock on the date of the notice of conversion was determined to be $2.1 million. Due to the conversion of the principal and interest balance of $1.8 million into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in excess of the settled principal and interest balance totaling $0.3 million was recorded as a loss on debt extinguishment in the accompanying consolidated statement of operations.

On May 11, 2020, the Company entered into an amendment with one investor who held two different note agreements to amend the conversion feature description within the note agreement. On May 11, 2020, this investor provided a notice of conversion to convert the two outstanding note agreements to shares of common stock. In connection with the notice of conversion, the Company issued 0.3 million shares of common stock in exchange for the settlement of principal and interest due totaling $0.5 million. The fair value of the shares of common stock issued was based on the market price of the Company's common stock on the date of the notice of conversion was determined to be $0.4 million. Due to the conversion of the principal and interest balance of $0.5 million into shares of common stock, the transaction was recorded as a debt extinguishment and the fair value of the shares of common stock issued in deficit of the settled principal and interest balance totaling $0.1 million was recorded as a gain on debt extinguishment in the accompanying consolidated statement of operations.

As of June 30, 2020, there remained one outstanding note agreement with a net amount due of approximately $0.2 million which is required to be paid monthly through January 2021. The remaining note does not have any interest charge associated with it. For the period from February 14, 2020 through June 30, 2020, the Company recorded approximately $0.4 million of amortization of the debt discount initially recorded at the date of the note agreements.

21. Related Party Transactions

Tris Pharma, Inc.

On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tris License Agreement") with TRIS (See Note 8). On November 1, 2019, the Company acquired the rights to Karbinal as a result of the acquisition of the Pediatric Portfolio from Cerecor, Inc. (See Notes 4 and 17). Mr. Ketan Mehta serves as a Director on the Board of Directors of the Company, and is also the Chief Executive Officer of TRIS. During the twelve-months ended June 30, 2020, the Company paid TRIS approximately $1.3 and $1.2 million for the years ended June 30, 2020 and 2019, respectively for a combination of royalty payments, inventory purchases and other payments as contractually required. The Company's liabilities, including accrued royalties, contingent consideration and fixed payment obligations were $22.9 million and $16.0 million as of June 30, 2020 and 2019, respectively.

In March 2020, TRIS converted all the 400,0000 Series D Convertible preferred stock into 400,000 shares of the Company's common stock.

22. Subsequent Events

Innovus Pharmaceuticals, Inc.

On August 28, 2020, the Company's subsidiary Innovus signed a lease termination agreement with its lessor to terminate its lease effective September 30, 2020. The original lease termination date was April 30, 2023. As part of the agreement, Innovus agreed a make cash payment to the landlord the equivalent of two additional months' rent aggregating to $44,306 plus $125,000 less the security deposit of $20,881. The fair value of the lease liability related to this facility lease was approximately $0.7 million as of June 30, 2020.

Exhibit 21.1

Subsidiaries

- Aytu Women's Health, LLC
- Aytu Therapeutics, LLC
- Innovus Pharmaceuticals, Inc.
- Semprae Laboratories, Inc.
- Novalare, Inc.
- Supplement Hunt, Inc.
- Delta Prime Savings Club, Inc.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Aytu BioScience, Inc. and Subsidiaries' Registration Statements on Form S-8 (File No. 333-205462 and File No. 333-236598), Form S-3 (File No. 333-221735, File No. 333-235548 and File No. 333-239010), Form S-4 (File No. 333-235695 and File No. 333-239011) 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 October 6, 2020, relating to the 2020 consolidated financial statements that appear in this Annual Report on Form 10-K.

/s/ Plante & Moran, PLLC

October 6, 2020
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 report on Form 10-K for the year ended June 30, 2020 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 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 this 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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 or 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.

Date: October 6, 2020

/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 report on Form 10-K for the year ended June 30, 2020 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 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 this 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 quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

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 or 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.

Date: October 6, 2020

/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, 2020, 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.

Date: October 6, 2020

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

Date: October 6, 2020

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

AMENDMENT TO EMPLOYMENT AGREEMENT

WHEREAS, Joshua R. Disbrow ("Disbrow" or "Employee") and Aytu Bioscience, Inc. (the "Company") are parties to an Employment Agreement dated April 16, 2019 (the "Employment Agreement");

WHEREAS, on November 4, 2019, the Company's Compensation Committee approved an equity grant to Disbrow in the amount of 453,475 shares, but for various reasons, Disbrow's shares were never granted or issued;

WHEREAS, based on the lapse in time since the approval of Disbrow's shares, the Compensation Committee has approved the issuance of a cash payment of $444,406 ("Cash Payment") in lieu of the above-mentioned equity grant based on the share price of $0.98 on November 14, 2019, to be paid to Disbrow in two equal installments;

WHEREAS, the Compensation Committee approved raising Disbrow's base salary to $500,000, effective June 1, 2020, and to $590,000, effective January 1, 2021, and approved modifying his Bonus target from 100% to 60%; and

WHEREAS, the Compensation Committee approved an Equity Compensation Grant of 100,000 options with a four-year vesting schedule and 450,000 Restricted Shares with a four-year vesting schedule, as set forth below;

THEREFORE, Disbrow and the Company agree that the Employment Agreement shall be modified as specifically set forth in this Amendment, but except as specifically modified herein, shall remain in full force and effect as written:

1. All capitalized but undefined terms in this Amendment shall have the meanings ascribed to them in the Employment Agreement.

2. Section 3(a) is amended to include:
   Effective June 1, 2020, the Company shall pay Employee a Base Salary of $500,000 per annum, subject to standard deductions and withholdings, payable at least monthly on the Company's regular pay cycle for professional employees. Effective January 1, 2021, the Company shall pay Employee a Base Salary of $590,000, per annum, less applicable withholdings, payable at least monthly on the Company's regular pay cycle for professional employees.

3. Section 3(c) is amended to include:

   The Company shall grant Employee 100,000 options with the schedule set forth in the Option Agreement attached as Exhibit A to the Amendment. The Company shall grant Employee 450,000 Restricted Shares with the schedule set forth in the Restricted Stock Agreement attached as Exhibit B to the Amendment.

4. Section 3(d) is amended to include:
   Effective June 1, 2020, the Employee shall be eligible for an annual discretionary Bonus with a target amount of sixty percent (60%) of the Base Salary, subject to standard deductions and withholdings.

5. Section 3 is amended to include the following subsection:

   (e) **Cash Payment in Lieu of Equity**. The Company shall pay Employee a total of $444,406.00, subject to standard deductions and withholdings. The payment will be divided into two equal payments of $222,203.00, the first of which shall be paid by the Company on June 30, 2020, and the second of which shall be paid by the Company on July 1, 2021. The Company will enter a payment agreement that obligates the Company to pay the full amount above, irrespective of any change of control, termination, or separation from the Company, unless otherwise agreed to in writing by the Employee and the Company.

6. Section 7(e)(ii)(C) is replaced as:

   (C) All vested stock options shall remain exercisable from the date of termination until the expiration date of the applicable award. So long as the Section 8 below does not apply, 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 Employee's employment hereunder shall be deemed vested and immediately exercisable by the Employee. Any unvested options over and above the foregoing shall be cancelled and of no further force or effect, and shall not be exercisable by the Employee. Any issued restricted stock will immediately vest following the termination date.

7. Section 7(e)(ii) is amended to include the following subsection:

   (E) In the event of a termination Without Cause or Change in Control, Employee shall be paid a pro-rata amount of the target bonus determined by the percentage of time Employee was employed during the fiscal year.

IN WITNESS WHEREOF, the undersigned have caused this Amendment to Employment Agreement to be executed as of the Effective Date.

Dated:

/s/
Joshua R. Disbrow, CEO

Aytu Bioscience, Inc.

Dated:

/s/
Its:

AMENDMENT TO EMPLOYMENT AGREEMENT

WHEREAS, David A. Green ("Green" or "Employee") and Aytu Bioscience, Inc. (the "Company") are parties to an Employment Agreement dated December 18, 2017 (the "Employment Agreement");

WHEREAS, on November 4, 2019, the Company's Compensation Committee approved an equity grant to Green in the amount of 266,250 shares, but for various reasons, Green's shares were never granted or issued;

WHEREAS, based on the lapse in time since the approval of Green's shares, the Compensation Committee has approved the issuance of a cash payment of $260,925.00 ("Cash Payment") in lieu of the above-mentioned equity grant based on the share price of $0.98 on November 14, 2019, to be paid to Green in two equal installments;

WHEREAS, the Compensation Committee approved raising Green's base salary to $375,000, effective June 1, 2020, and to $400,000, effective January 1, 2021; and

WHEREAS, the Compensation Committee approved an Equity Compensation Grant of 100,000 options with a four-year vesting schedule and 250,000 Restricted Shares with a four-year vesting schedule, as set forth below;

THEREFORE, Green and the Company agree that the Employment Agreement shall be modified as specifically set forth in this Amendment, but except as specifically modified herein, shall remain in full force and effect as written:

1. All capitalized but undefined terms in this Amendment shall have the meanings ascribed to them in the Employment Agreement.

2. Section 3(a) is amended to include:
   Effective June 1, 2020, the Company shall pay Employee a Base Salary of $375,000 per annum, subject to standard deductions and withholdings, payable at least monthly on the Company's regular pay cycle for professional employees. Effective January 1, 2021, the Company shall pay Employee a Base Salary of $400,000, per annum, subject to standard deductions and withholdings, payable at least monthly on the Company's regular pay cycle for professional employees.

3. Section 3(d) is amended to include:

   The Company shall grant Employee 100,000 options with the schedule set forth in the Option Agreement attached as Exhibit A to the Amendment. The Company shall grant Employee 250,000 Restricted Shares with the schedule set forth in the Restricted Stock Agreement attached as Exhibit B to the Amendment.

4. Section 3 is amended to include the following subsection:

   (e) **Cash Payment in Lieu of Equity**. The Company shall pay Employee a total of $260,925.00, subject to standard deductions and withholdings. The payment will be divided into two equal payments of $130,462.50, the first of which shall be paid by the Company on June 30, 2020, and the second of which shall be paid by the Company on July 1, 2021. The Company will enter a payment agreement that obligates the Company to pay the full amount above, irrespective of any change of control, termination, or separation from the Company, unless otherwise agreed to in writing by the Employee and the Company.

5. Section 7(e)(ii)(C) is amended to include:

   (C) All vested stock options shall remain exercisable from the date of termination until the expiration date of the applicable award. So long as the Section 8 below does not apply, 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 Employee's employment hereunder shall be deemed vested and immediately exercisable by the Employee. Any unvested options over and above the foregoing shall be cancelled and of no further force or effect, and shall not be exercisable by the Employee. Any issued restricted stock will immediately vest following the termination date.

6. Section 7(e)(ii) is amended to include the following subsection:

   (E) In the event of a termination Without Cause or Change in Control, Employee shall be paid a pro-rata amount of the target bonus determined by the percentage of time Employee was employed during the fiscal year.

IN WITNESS WHEREOF, the undersigned have caused this Amendment to Employment Agreement to be executed as of the Effective Date.

Dated: /s/
David A. Green, CFO

Aytu Bioscience, Inc.

Dated: /s/
Its: