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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended June 30, 2022

OR

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

Commission File Number 001-38247

AYTU BIOPHARMA, 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:

Title of Each Class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**AYTU**	**The NASDAQ Capital Market**

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

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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

The aggregate market value of common stock held by non-affiliates of the Registrant as of December 31, 2021 was $38.2 million based on the closing price of $1.35 as of that date.

As of September 19, 2022, there were 62,432,727 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 BioPharma, Inc.

This Annual Report on Form 10-K refers to trademarks, such as Adzenys, Aytu, Cotempla, FlutiCare, Innovus Pharma, Neos, Poly-Vi-Flor, Tri-Vi-Flor, Tuzistra, 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.

Summary of Risk Factors

The following list summarizes what we believe to be the principal risks relevant to our company. The below summary is further elaborated on by the full text of the risk factors provided in the "Risk Factors" section of this Annual Report on Form 10-K for the year ended June 30, 2022. All capitalized terms in this section not defined herein shall have the meanings given to them elsewhere in this Annual Report. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

Risks Related to Our Business and Financial Position

- We have incurred significant losses since our inception and anticipate that we will incur continued losses in the future. We may never achieve or maintain profitability, and will likely require additional capital to fund our operations.
- Our failure to comply with the covenants or other terms of the loan and security agreement with Avenue Capital and our secured revolving loans with Eclipse could result in a default under those agreements that could materially and adversely affect the ongoing viability of our business.
- Our credit facility agreements contain restrictions that limit our flexibility in operating our business.

Risks Related to Commercialization

- If we are unable to successfully commercialize our commercial prescription products, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.
- The commercial success of our commercial prescription products will depend upon their acceptance by multiple stakeholders, including physicians, patients, and healthcare payors.
- If we are unable to differentiate our commercial prescription products from current and future products or existing methods of treatments or if the market opportunities for our commercial prescription products are smaller than we believe, our ability to successfully commercialize our commercial prescription products would be adversely affected and our revenue may be adversely affected.
- If our sole manufacturing facility for our attention deficit/hyperactivity disorder ("ADHD") products becomes damaged or inoperable or we decide to or are required to vacate our facility, our ability to continue manufacturing adequate supplies of our ADHD products could adversely affect our ability to generate revenue.
- We may encounter manufacturing problems resulting in insufficient quantities being produced or not having access to the requisite supplies.
- 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.
- If third-party payors do not reimburse patients for our commercial prescription products or if reimbursement levels are set too low for us to sell our commercial prescription products at a profit, our ability to successfully commercialize our commercial prescription products and our results of operations will be harmed.
- If we cannot implement and maintain effective patient affordability programs or improve formulary access for our commercial prescription products in the face of increasing pressure to reduce the price of medications, the adoption of our commercial prescription products by physicians and patients may decline.
- If the U.S. Food and Drug Administration ("FDA") or other applicable regulatory authorities approve generic or similar products that compete with our commercial prescription products, or if the FDA or other applicable

regulatory authorities change or create new pathways that may expedite approval of such products, it could decrease our expected sales of our commercial prescription products.

- Even though we have obtained regulatory approval for our commercial prescription products, we still face extensive FDA regulatory requirements and may face future regulatory difficulties.

- Our relationships with physicians, patients, payors, and pharmacies in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Risks Related to Product Development and Regulatory Approval

- The design and execution of clinical trials to support FDA-approval of AR101 for the treatment of Vascular Ehler-Danlos Syndrome ("VEDS"), Healight for the Treatment for SARS-CoV-2 and other viral and bacterial respiratory infections is subject to substantial risk and uncertainty.

- The clinical development and regulatory approval processes of the FDA are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates or maintain regulatory approval for our approved products, our business may be substantially harmed.

Risks Related to Our Intellectual Property

- If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our technology, our commercial prescription products or our other product candidates, our competitors could develop and commercialize technology similar to ours, and our competitive position could be harmed.

- We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Risks Related to Our Organization, Structure and Operations

- We may have difficulties integrating acquired businesses and as a result, our business, results of operations and/or financial condition may be materially adversely affected.

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

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.

- The price of our common stock may be volatile, and you may lose all or part of your investment.

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

- Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others.

General Risk Factors

- Our business may be adversely affected by the effects of the COVID-19 pandemic.
- Our business and operations would suffer in the event of system failures or security breaches.
- Our sales force and other employees, third party logistics partners, contract manufacturing organizations ("CMOs"), contract research organizations ("CROs"), principal investigators, collaborators, independent contractors, consultants and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- 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 on Form 10-K. 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.

AYTU BIOPHARMA, INC.

PART I

ITEM 1. BUSINESS

COMPANY OVERVIEW

Aytu BioPharma, Inc. (“Aytu,” the “Company”, “we”) is a pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products and developing therapeutics for rare pediatric-onset or difficult-to-treat diseases. We have two primary product candidates in development, AR101 enzastaurin for the treatment of VEDS and Healight (endotracheal light catheter) for the treatment the treatment of severe, difficult-to-treat respiratory infections. We were incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado and were re-incorporated as Aytu BioScience, Inc in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. (“Neos”) in March 2021 (“Neos Acquisition”), we changed our name to Aytu BioPharma, Inc.

RECENT BUSINESS DEVELOPMENT

Commercial Products

On March 23, 2022, our newly issued US patent No. 11,166,947 for Cotempla XR-ODT was listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." The Cotempla XR-ODT patent covers methods of use for the effective pediatric dosing of methylphenidate for the treatment ADHD. The Orange Book listing extends the exclusivity period for Cotempla XR-ODT to 2038. Teva Pharmaceuticals USA, Inc. has the right to manufacture and market its generic version of Cotempla XR-ODT under its Abbreviated New Drug Application (“ANDA”) beginning on July 1, 2026, or earlier under certain circumstances.

As part of our realization of post-Neos acquisition synergies and product prioritization, we implemented a portfolio rationalization plan whereby we discontinued or divested five non-core products: Cefaclor Oral Suspension, Flexichamber, Tussionex, Tuzistra XR, and ZolpiMist. These products, collectively, contributed $2.2 million in net revenue and $0.7 million in gross loss during the year ended June 30, 2022.

Development Products

AR101

On December 7, 2021, the FDA granted Orphan Drug designation (“ODD”) to AR101(“enzastaurin”) for the treatment of Ehlers-Danlos Syndrome, a group of rare inherited connective tissue disorders that includes the severe subtype VEDS. The FDA grants ODD status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD affords us with certain financial incentives to support clinical development and the potential for seven years of market exclusivity in the U.S. upon regulatory approval.

On December 13, 2021, the FDA cleared the Investigational New Drug (“IND”) application for AR101 in VEDS to enable the initiation of the AR101 PREVEnt Trial in VEDS. We are underway with preparation activities for our PREVEnt Trial, a randomized, double-blind, placebo-controlled clinical study evaluating once daily enzastaurin in the treatment of VEDS. The PREVEnt Trial is designed to enroll approximately 260 patients with COL3A1-positive VEDS in order to assess time to arterial events leading to intervention among patients treated with AR101 compared to patients treated with standard-of-care. The trial is expected to begin enrolling patients by early 2023.

On March 2, 2022, the European Commission granted orphan designation to AR101 for the treatment of Ehlers-Danlos Syndrome. To qualify in Europe for orphan drug designation, an investigational medicine must be intended to treat a seriously debilitating or life-threatening condition that affects fewer than five in 10,000 people in the European Union (‘EU”), and there must be sufficient non-clinical or clinical data to suggest the investigational medicine may

produce clinically relevant outcomes. The European Medicines Agency orphan designation affords us with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity.

On April 19, 2022, we were notified by the FDA that AR101 received Fast Track designation from the U.S. Food & Drug Administration ("FDA"). Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. Fast Track addresses a broad range of serious conditions, and the request can be initiated by a pharmaceutical company at any time during the development process. The FDA reviews the request and decides based on whether or not the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process.

Healight

In November 2021, we received U.S. Patent Number 11,179,575, titled "Internal Ultraviolet Therapy," which is the first issued patent protecting the Healight investigational device and covers methods of treating a patient for an infectious condition inside the patient's body through the insertion of a UV-light-emitting delivery tube inside a respiratory cavity of the patient at specific UV-A light wavelengths. The term of this patent extends to August of 2040.

In April 2022, our preclinical pilot study showed that administration of Healight delayed the time to development of ventilator-associated pneumonia ("VAP") in a novel porcine model. The proof-of-concept study was conducted at Hospital Clinic de Barcelona under the supervision of principal investigator Antonio Torres, M.D., Ph.D., FERS, FCCP, ATSF, Senior Consultant, Pulmonology Department - one of the only centers in the world with access to this well-characterized porcine model of VAP caused by oropharyngeal secretions colonized by *Pseudomonas aeruginosa*. In the study, administration of the Healight UV-A endotracheal catheter resulted in a 46% reduction in multidrug-resistant *Pseudomonas aeruginosa* (PA C1-17) versus controls following two separate 20-minute treatments. Based on these positive data, Hospital Clinic de Barcelona and we have initiated a second, larger porcine VAP study to guide the future development of Healight for patients with VAP.

Debt and Equity financing

On January 26, 2022, we entered into a Loan and Security Agreement (the "Avenue Capital Agreement") with Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund II, L.P. as lenders (the "Avenue Capital Lenders"), and Avenue Capital Management II, L.P. as administrative agent (the "Avenue Capital Agent"), collectively ("Avenue Capital"), pursuant to which the Avenue Capital Lenders provided the Company and certain of its subsidiaries with a secured $15.0 million loan. The interest rate on the loan is the greater of the prime rate and 3.25%, plus 7.4%, payable monthly in arrears. The maturity date of the loan is January 26, 2025. The proceeds from the Avenue Capital Agreement were used towards the repayment of the Deerfield Facility, which was otherwise due and payable on May 11, 2022.

In connection with the Avenue Capital Agreement, we entered into a Consent, Waiver and Second Amendment to Eclipse Loan Agreement with Eclipse Business Capital LLC (f/k/a Encina Business Credit, LLC) ("Eclipse"), dated as of January 26, 2022 (the "Eclipse Loan Agreement"). Pursuant to the Eclipse Loan Agreement, the Company, among other things, extended the maturity date of the Eclipse Loan Agreement to January 26, 2025 and reduced the maximum availability under the Eclipse Loan Agreement from $25.0 million to $12.5 million minus a $3.5 million availability block,

In March 2022, upon closing of an underwritten public offering, we raised gross proceeds of $7.6 million from the issuance of (i) 3,030,000 shares of our common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 3,030,000 shares of our common stock, and (iii) common stock purchase warrants (the "Common Warrants") to purchase up to 6,666,000 shares of our common stock (the "March 2022 Offering"). We received $6.8 million in proceeds net of underwriting fees and other expenses. In April 2022, the pre-funded warrants were exercised in full.

In August 2022, upon the closing of an underwritten public offering, we raised gross proceeds of $10.0 million from the issuance of (i) 21,505,814 shares of our common stock, and, in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 1,750,000 shares of its common stock, and (ii) accompanying warrants (the "Common Warrants") to purchase 23,255,814 shares of our common stock (the "Offering"). We received $9.1 million in proceeds net of underwriting fees and other expenses. In August, the pre-funded warrants were exercised in full.

COMMERCIAL BUSINESS OVERVIEW

We operate through two business segments (i) the BioPharma segment, consisting of various prescription pharmaceutical products sold through third parties the BioPharma segment, and (ii) the Consumer Health segment, which consists of various consumer health products sold directly to consumers. We generate revenue by selling our products through third party intermediaries in our marketing channels as well as directly to our customers. We currently manufacture our products for the treatment of ADHD at our manufacturing facilities and use third party manufacturers for our other prescription and consumer health products.

BioPharma Segment

Our BioPharma Segment consists of our ADHD Product and Pediatric Product portfolios. Our prescription products are sold solely in the United States and are distributed through multiple channels, including sales to pharmaceutical wholesalers, using third-party logistics enterprises.

We acquired our ADHD product portfolio in March 2021 with the acquisition of Neos Therapeutics. These commercial ADHD products are extended-release (“XR”) medications formulated in patient-friendly, orally disintegrating tablets (“ODT”) that utilize the Neos-developed microparticle modified-release drug delivery technology platform. Products containing amphetamine or methylphenidate are the most commonly prescribed medications in the United States for the treatment of ADHD. Adzenys XR-ODT (for patients six years of age and above) and Cotempla XR-ODT (for patients six to 17 years of age) are the first and only FDA-approved amphetamine and methylphenidate extended-release, orally disintegrating tablets, respectively, for the treatment of ADHD.

Our prescription pediatric portfolio includes Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions for patients two years and above and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based multi-vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency (Karbinal ER, Poly-Vi-Flor and Tri-Vi-Flor are collectively the “Pediatric Portfolio”). These products serve established pediatric markets and offer distinct clinical features and patient benefits.

We commercialize our Rx Portfolio through our internal commercial organization that includes approximately forty territories for our ADHD portfolio and approximately eight territories for our pediatric portfolio.

Our Aytu RxConnect™ patient support program operates through a network of approximately 1,000 pharmacies to offer affordable, predictable copays and hassle-free availability to all commercially insured patients, regardless of their individual insurance plan. In addition, RxConnect seeks to significantly reduce the challenges and frustrations that health care professionals and their office staff can face when prescribing branded medications, including our medications, for their patients.

Consumer Health Segment

Our Consumer Health segment is dedicated to being a leader in developing and commercializing safe and effective non-prescription (also known as “over-the-counter” or “OTC”) medicines, personal care products, and dietary supplements to improve health and vitality. Our core products focus in categories such as hair loss, digestive health, urological health, diabetes management (with a concentration on neuropathy), and allergy. All products are intended to be used by consumers on a regular basis, and as such, we offer a monthly subscription program to allow for ongoing use and to simplify product ordering and use by patients. We acquired our Consumer Health segment, previously known as Innovus Pharmaceuticals, Inc., in February 2020 (“Innovus Acquisition”).

The consumer health segment currently sells directly to consumers in both the United States and Canada through e-commerce platforms including branded websites and the Amazon.com platform which utilized marketing strategies focused on search engine optimization, search marketing, and affiliate marketing. Additionally, the segment sells products through its proprietary Beyond Human Sales & Marketing platform which focuses on direct mail and newspaper advertisements, allowing consumers to purchase directly through call centers with shipment directly to their homes.

The overall strategy of the consumer health division focuses on two primary objectives:

- developing a diversified product portfolio of unique OTC medicines, consumer health products and dietary supplements through: (a) the introduction of line extensions and reformulations of either our or third-parties' currently marketed products; (b) the development of new proprietary OTC products and supplements; and (c) the acquisition or exclusive licensing of products; and

- growing our e-commerce presence within the United States through the development of our own websites, continued expansion on third-party platforms and through social media marketing methodologies.

Development Portfolio

AR101

On April 12, 2021, we entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, and Rumpus Vascular, LLC (together "Rumpus") pursuant to which we acquired commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin, or AR101. AR101 is initially being studied for the treatment of VEDS.

AR101 is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways. AR101 has been studied in more than 3,300 patients across a range of solid and hematological tumor types in trials previously conducted by Eli Lilly & Company ("Hal"). Harry C. Dietz III, M.D. developed the first preclinical model that mimics the human condition and recapitulates VEDS, and this model serves as the basis for the plausible clinical benefit and rationale for conducting a clinical trial with AR101 in VEDS. This novel knock-in model has the same genetic mutation most prevalent in VEDS patients and is representative of the human condition in both the timing and location of vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that vascular structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high-throughput RNA sequencing of the aorta displayed a molecular signature for excessive PKC/ERK cell signaling that is the purported driver of disease. PKC inhibitors proved efficacious in multiple pre-clinical and murine (mice) models and indeed prevented death due to vascular rupture.

We have secured exclusive global rights to AR101 in the fields of rare genetic pediatric onset or congenital disorders outside of oncology. AR101 is protected by a suite of pending patents being pursued in major markets globally which have been licensed from The Johns Hopkins University ("Johns Hopkins") and have an earliest priority date of March 2017. In December 2021, the FDA granted ODD to AR101 for the treatment of EDS, inclusive of VEDS, allowing for seven years of marketing exclusivity in the United States. The FDA has cleared the IND application for AR101, enabling us to proceed with initiating a pivotal clinical trial for AR101. We expect to advance AR101 to a pivotal study by early-calendar year 2023.

Healight™

Our clinical-stage medical device asset, an ultraviolet-A (UV-A) light endotracheal catheter we refer to as Healight™, is being studied as a potential treatment for mechanically ventilated patients suffering from severe respiratory infections, including the infection caused by SARS-CoV-2, and VAP. In April 2020 we licensed global rights to the Healight technology platform from Cedars-Sinai Medical Center ("Cedars-Sinai"). The Healight technology employs proprietary methods of administering intermittent UV-A light via a novel endotracheal medical device that, when implemented clinically, is inserted through the patient's endotracheal tube and illuminated intermittently over a

period of multiple days. Pre-clinical findings indicate the technology's effects in eradicating a wide range of viruses and bacteria, activating a key cell signaling protein, and reducing cytokine levels responsible, in part, for the 'cytokine storm' associated with SARS-CoV-2 infections. Those data, along with recently published clinical data from a five patient study studying SARS-CoV-2, have been the basis of discussions with regulatory bodies as we consider an efficient path to enable human use for the potential treatment of coronavirus in intubated patients in the intensive care unit.

We now plan to study Healight as a prospective treatment or preventative for VAP and, as such, have completed a preclinical porcine study, demonstrating that the administration of the Healight UV-A endotracheal catheter resulted in a 46% reduction in multidrug-resistant *Pseudomonas aeruginosa* (PA C1-17) versus controls following two separate 20-minute treatments. Based on these positive data, Hospital Clinic de Barcelona and we have initiated a second, larger porcine VAP study to guide the future development of Healight for patients with VAP.

VAP has a reported mortality rate approaching 50% in some patient populations, making it one of the most difficult-to-treat and deadly infections affecting hospitalized patients. Approximately 86% of nosocomial pneumonias are associated with mechanical ventilation and result in VAP. Between 250,000 and 300,000 VAP cases per year occur in the United States alone, which is an incidence rate of 5 to 10 cases per 1,000 hospital admissions. VAP afflicts up to 15% of mechanically ventilated patients in intensive care units.

We received the first issued patent protecting Healight™ which covers methods of treating a patient for an infectious condition inside the patient's body through the insertion of a UV-light-emitting delivery tube inside a respiratory cavity of the patient at specific UV-A light wavelengths. The term of this patent extends to August of 2040.

We do not anticipate further significant development without a partner to finance further development. This could be in the shape of out-license of a portion, or all commercial rights to Healight or an asset sale.

OUR STRATEGY

Our goal is to become a leading pharmaceutical company that improves the lives of patients and healthcare consumers. We will do this by employing a focused approach of in-licensing, acquiring, developing, and commercializing novel prescription therapeutics and consumer health products. Our primary focus is on commercializing innovative prescription products that address conditions frequently developed in childhood. We also commercialize consumer healthcare products through efficient e-commerce and direct-to-patient platforms. Importantly, we are also focused on developing a late-stage pipeline of novel, promising therapeutics that address unmet medical needs, with a focus on pediatric-onset rare diseases. Our lead product candidate, AR101, is a therapeutic that, if proven safe and effective and ultimately approved, would be the first and only approved treatment for VEDS.

Our strategic priorities are to continue to increase revenues from our prescription and consumer health portfolios, enhance our financial performance through operational and manufacturing efficiencies and portfolio prioritization, and advance and expand our product pipeline focused on rare and complex disorders. Specifically, we intend to:

- continue to grow our commercial branded, revenue-generating products, by increasing product sales and improving patient access. Our primary commercial objective is to drive revenue growth of our ADHD and pediatric brands, with a focus on Adzenys XR-ODT, Cotempla XR-ODT, Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER. We expect to increase market share using our internal commercial organization and leveraging our advanced analytics platform to optimize sales force performance and increase both the breadth, or number of healthcare professionals ("HCPs") prescribing our medicines, and the depth, or the number of appropriate patients per HCP for our products;

- leverage our RxConnect patient support program, which is designed to reduce access barriers to medicines facing patients and HCPs by providing coverage for all commercially insured patients, regardless of their individual insurance plan, thus establishing an affordable and predictable monthly co-pay for patients, and

eliminating many of the hassles facing HCPs and their staffs by improving availability of Aytu products at participating pharmacies;

- grow our consumer health business by driving growth of our current consumer health brands and introducing new products into our consumer marketing channels. Through a dual approach that employs both e-commerce commercial and direct-to-consumer strategies to sell existing and future products, we expect to reach an increasing number of healthcare consumers and drive revenue growth;

- improve gross margins for our ADHD product franchise through the transfer of manufacturing of Adzenys XR-ODT and Cotempla XR-ODT to a well-established, global commercial manufacturing organization, a transition that is expected to occur in mid-calendar 2023;

- advance the development of AR101 enzastaurin to address a significant unmet need in VEDS, a rare, devastating, pediatric-onset disease with no currently approved therapies; and

- progress Healight development for VAP. We are collaborating with leading researchers at Hospital Clinic de Barcelona on a large, proof-of-concept pre-clinical study for VAP.

We believe our history of acquiring companies and in-licensing and acquiring products and pipeline assets, along with our success in building out commercial teams and executing product launch and growth strategies, is a distinct competitive advantage. Our transactional adeptness and execution orientation enable us to continue to seek growth opportunities through both organic growth and opportunistic in-licensing or strategic acquisitions. Further, our commercial infrastructure and distribution capability is scalable and lends itself to additional on-market assets and future product candidates that fit within our core therapeutic focus. As such, in the near term, we may seek to leverage our commercial model and infrastructure by expanding our commercial portfolio with external product opportunities as we have done since our inception. Near to longer term, we believe our prescription and consumer health businesses will provide resources to invest in and develop our pediatric-onset rare disease asset pipeline.

Our Products and Markets

Prescription Products

ADHD Portfolio

ADHD Market and Treatment Options

ADHD is a neurobehavioral disorder characterized by a persistent pattern of inattention and/or hyperactivity/impulsivity that interferes with functioning and/or development. ADHD can have a profound impact on an individual's life, causing disruption at school, work, home and in relationships. It is one of the most common developmental disorders in children and often persists into adulthood. In 2011, an estimated 11% of children in the United States ages 4 to 17 had previously received an ADHD diagnosis. A 2006 study estimated 4.4% of adults in the United States experience ADHD symptoms. Current ADHD treatment guidelines recommend a multi-faceted approach that uses medications in conjunction with behavioral interventions.

In 2021, approximately 84.8 million prescriptions for medications with ADHD labeling were written in the United States and generated approximately $22.6 billion in sales. Approximately 91% of these prescriptions were for stimulant medications, such as methylphenidate and amphetamine, which are and have been the standard of care for several decades. Methylphenidate and amphetamine prescriptions generated $5.6 billion and $11.3 billion in sales, respectively, in 2020 in the United States. A few non-stimulant medications are also available, but evidence of their efficacy for treating ADHD symptoms is less compelling. The market for ADHD medications outside of the United States is less developed, but we believe it will continue to grow as recognition and awareness of the disorder increase.

Extended-release, or long acting, dosage forms of stimulant medications are the standard of care for treating ADHD, making up approximately 44% of ADHD prescriptions. The most prescribed extended-release medications for ADHD, Concerta® and Adderall XR® (and each of their generic equivalents), are long-acting versions of previously short-acting methylphenidate and amphetamine medications, respectively. Most of these extended-release dosage forms allow for once-daily dosing in the morning, which eliminates the need to re-dose during the day. Our products, Adzenys XR-ODT and Cotempla XR-ODT, are extended-release orally disintegrating tablets that allow for once-daily dosing in the morning based upon an internally developed proprietary microparticle delivery technology.

There is significant competition in the ADHD market, including from well-established companies, many of whom have substantially greater financial, technical and commercial resources than we do, and entrenched existing ADHD products. For example:

- amphetamine XR is currently marketed in the United States by (i) Takeda Pharmaceutical Company Limited under the brand names Adderall XR®, Vyvanse® and Mydayis® and (ii) Tris Pharma, Inc. ("Tris"), under the brand names Dyanavel® XR, Dyanavel® XR tablets ; and

- methylphenidate XR is marketed in the United States by (i) Janssen Pharmaceuticals, Inc. under the brand name Concerta®, (ii) Tris under the brand names Quillivant XR® and QuilliChew ER®, (iii) Rhodes Pharmaceuticals LP under the brand name Aptensio XR®, (iv) Ironshore Pharmaceuticals Inc. under the brand name Jornay PM®, (v) Alora Pharmaceuticals under the name Methylphenidate HCl ER 72 mg Tablets, (vi) Novartis under the brand names Focalin XR® and Ritalin LA® and (vii) Azstarys®, a product developed by KemPharm and sold by Corium.

- a non-stimulant treatment for ADHD was approved by the FDA and commercially launched by Supernus in the U.S in 2021 is sold under the brand name Qelbree®.

Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Vallon Pharma, Cingulate Therapeutics, Sunovion, NLS Pharma and Neurovance, a subsidiary of Otsuka Pharmaceutical Co., Ltd.

Our ADHD Product Portfolio

Our modified-release drug delivery technology platform has enabled us to create XR-ODT formulations of amphetamine and methylphenidate. This was achieved by developing an extended-release profile that allows for once daily dosing and an ODT formulation that allows for easier administration and ingestion and twelve-hour duration of action.

Adzenys XR-ODT and Cotempla XR-ODT are the first and only XR-ODT products for the treatment of ADHD. These XR-ODT products offer unique attributes to ADHD patients and caregivers, including:

- ease of administration and ingestion because they disintegrate rapidly in the mouth and may be taken without water;

- taste-masking of bitter ADHD medications, with flavoring options;

- prevention of "cheeking," the practice of hiding medication in the mouth and later spitting it out rather than swallowing it; and

- convenient single-unit blister-packaging, which is both portable and discrete.

Adzenys XR-ODT: Amphetamine XR-ODT for the treatment of ADHD

Adzenys XR-ODT is approved by the FDA for the treatment of ADHD in patients six years and older. We believe Adzenys XR-ODT is the first and only amphetamine XR-ODT approved for the treatment of ADHD. The NDA for Adzenys XR-ODT relies on the efficacy and safety data that formed the basis of FDA approval for the listed drug, Adderall XR, 30 mg, together with bioequivalence, bioavailability, and aggregate safety data from the Adzenys XR-ODT clinical program. Adzenys XR-ODT contains amphetamine loaded onto a mixture of immediate-release and polymer-coated delayed-release resin particles, which are formulated and compressed into an ODT along with other typical tableting excipients using our patented rapidly disintegrating ionic masking ("RDIM") technology. The result is amphetamine with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth without the need for water. Adzenys XR-ODT is available in 30-day supply, child-resistant blister packs.

The suite of composition-of-matter patents for Adzenys XR-ODT are scheduled to expire in 2026 and 2032. These patents are listed in the FDA's publication of approved drug products with therapeutic equivalence evaluations (the "Orange Book"). In addition, we entered into a settlement agreement with Actavis Laboratories FL, Inc. ("Actavis"), which resolved all ongoing litigation involving Adzenys XR-ODT patents and Actavis' ANDA with the FDA for a generic version of Adzenys XR-ODT. Under the agreement with Actavis, Actavis (acquired by Teva Pharmaceutical Industries) has the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. No tentative approval from the FDA has been received by Teva to date.

In conjunction with the approval of the Adzenys XR-ODT NDA, the FDA has required us to conduct certain clinical studies in preschool (age four to five years) children with ADHD as a post-marketing requirement. A pharmacokinetic study in this population was completed in 2018, and we are in discussions with the FDA to further clarify the design protocols required to conduct the remaining studies.

Cotempla XR-ODT: Methylphenidate XR-ODT for the treatment of ADHD

The FDA approved Cotempla XR-ODT treatment of ADHD in patients six to seventeen years old. The Cotempla XR-ODT NDA relies on the efficacy and safety data that formed the basis of FDA approval for the listed drug, Metadate CD®, together with bioavailability/bioequivalence data and efficacy/safety data from the Cotempla XR-ODT clinical program. The results of the Cotempla XR-ODT Phase 3 clinical efficacy and safety trial showed a statistically significant improvement in ADHD symptom control compared to placebo across the classroom day. Onset of effect was observed within one hour post-dose and persisted through 12 hours. No serious adverse events were reported during the study, and the adverse event profile was consistent with the drug's mechanism of action.

Cotempla XR-ODT contains methylphenidate loaded onto a mixture of immediate-release and polymer-coated delayed-release resin particles, which are formulated and compressed into an ODT along with other typical tableting excipients using our RDIM technology. The result is methylphenidate with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth. Cotempla XR-ODT is available in 30-day supply, child-resistant blister packs. We believe Cotempla XR-ODT is the first methylphenidate XR-ODT for the treatment of ADHD, providing onset-of-effect within one hour and a 12-hour duration.

We hold composition-of-matter patents in the U.S. which we expect will provide Cotempla XR-ODT intellectual property protection until 2032, and a recent method-of-use patent was issued which will extend protection until 2038. These patents are listed in the Orange Book. In addition, Neos entered into a settlement agreement with Teva Pharmaceuticals USA, Inc. ("Teva"), which resolved all ongoing litigation involving the Cotempla XR-ODT patents and Teva's ANDA with the FDA for a generic version of Cotempla XR-ODT. Under the agreement with Teva, Neos granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

In conjunction with the approval of the Cotempla XR-ODT NDA, the FDA required us to perform additional clinical studies in preschool (age four to five years) children with ADHD as a post-marketing requirement. A pharmacokinetic study in this population was completed in 2019. In light of a new draft guidance for industry that was

published in May 2019, "Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment Guidance for Industry," and we remain in discussions with the FDA to gain concurrence on the design of the protocols required to meet the remaining post-marketing requirements.

Pediatric Portfolio

Poly-Vi-Flor and Tri-Vi-Flor: Our fluoride-based multivitamin prescription supplement product line for infants and children

Poly-Vi-Flor and Tri-Vi-Flor are two complementary prescription fluoride-based supplement product lines containing combinations of vitamins and sodium 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 also providing multi-vitamin support and folic acid supplementation. Because these products contain at least .25 mg of sodium fluoride, Poly-Vi-Flor and Tri-Vi-Flor are regulated as prescription products.

Fluoride supplementation has been proven to protect teeth from decay. Community water fluoridation prevents tooth decay by providing frequent and consistent contact with low levels of fluoride. By keeping the teeth strong and solid, fluoride stops cavities from forming and can rebuild the tooth's surface. Community water fluoridation began in the United States in 1945 and is the process of adjusting the amount of fluoride in drinking water to a level recommended for preventing tooth decay. As of 2016, more than 200 million people, or nearly 3 in 4 Americans who use public water supplies, drank water with enough fluoride to prevent tooth decay. However, American children living in municipalities that do not fluoridate the water supply or in rural areas that rely on well water supplies do not receive recommended levels of fluoride through fluoridation. Therefore, these children often require daily fluoride supplementation as part of their mineral and vitamin intake. In many instances, physicians prescribe fluoride-based multi-vitamins (Vitamins A, B, C, D and folic acid) regularly to supplement their fluoride intake and enable convenient supplementation. Infants are prescribed multi-vitamin drops while older children are prescribed tablet formulations.

In 2021, 9.5 million multi-vitamin prescriptions were written in the U.S. Of those, prescription multi-vitamins containing sodium fluoride accounted for 1.5 million total prescriptions. Common multi-vitamin combinations contain vitamins A, B, C, D and E, but no other prescription pediatric multi-vitamin products contain Metafolin, which makes the Poly-Vi-Flor and Tri-Vi-Flor product lines distinct, single-source brands. Other brands include Tri-Vite (marketed by Method Pharmaceuticals), Floriva (marketed by BonGeo Pharmaceuticals) and Quflora (marketed by Carwin Pharmaceutical Associates).

Poly-Vi-Flor is available in both chewable tablet and oral liquid suspension multivitamin formulations in six different product presentations: Poly-Vi-Flor Chewable Tablets .25 MG, .50 MG, and 1 MG tablets, Poly-Vi-Flor Chewable Tablets with Iron, Poly-Vi-Flor Oral Suspension and Poly-Vi-Flor Oral Suspension with Iron. Poly-Vi-Flor contains Vitamin A, Vitamin B1, B2, B3, and B6, Vitamin C, Sodium Fluoride in various doses and Metafolin, a proprietary, trademarked L-methylfolate form of folic acid developed by Merck & Cie ("Merck").

Tri-Vi-Flor is available as an oral liquid suspension in two different strengths (.25 MG and .50 MG fluoride) containing Vitamin A, Vitamin C, Vitamin D3, Sodium Fluoride, Sodium Benzoate and Metafolin. By virtue of its Metafolin content, Tri-Vi-Flor offers a similar clinical profile: a fluoride-based multivitamin containing body-ready Metafolin.

Metafolin® is Merck's manufactured calcium salt of L-5-methyltetrahydrofolic or L-methylfolate. It is a 'body ready' alternative to folic acid and offers good stability, solubility, and bioavailability. Folic acid supplementation is recommended in various patient groups, but a significant number of patients have difficulty metabolizing folate due to an enzymatic deficiency characterized by a genetic mutation affecting the enzyme methylenetetrahydrofolate reductase, or MTHFR. MTHFR converts ingested folate (such as supplemented folic acid) into L-methylfolate, the body's usable form. Clinical studies have demonstrated that 75% of pediatric patients may have one MTHFR genetic mutation while 40% may have two mutations. These mutations lead to impaired function of the enzyme and cause folate deficiencies.

Metafolin is unaffected by the MTHFR mutation, thereby directly delivering bioavailable L-methylfolate, and offering a distinct clinical advantage over other folic acid supplements.

The core family of patent covering Arcofolin has a priority date of March 31, 2017 and describes a crystalline sodium salt of 5-methyl-(6S)- tetrahydrofolic acid wherein the molar ratio of 5-methyl-(6S)-tetrahydrofolic acid to sodium is from 1:0.5 to 1:1.5 (in mol/mol) and/or hydrates and/or solvates thereof, as well as a process of obtaining the same. If issued, the standard 20-year exclusivity for this patent would expire in 2037.

The prescription multi-vitamin market is dominated by generic products, with brands accounting for 3.4% of the multivitamin plus fluoride market. 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.

Karbinal ER: Extended release carbinoxamine oral suspension for the treatment of seasonal and perennial allergies

Karbinal® ER (carbinoxamine maleate extended-release oral suspension) is an H1 receptor antagonist (antihistamine) indicated to treat seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and food, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled, and amelioration of the severity of allergic reactions to blood or plasma for patients two years of age and above.

Over 50 million Americans suffer from allergies in any given year, and allergies are the sixth leading cause of chronic illness in the U.S. Numerous allergy treatments exist to address allergies and allergic symptoms depending upon the symptom(s). Oral antihistamines are considered a mainstay of allergy treatment, and the prescription antihistamine market is a large category with approximately 52 million prescriptions written in 2021. The prescription antihistamine category is dominated by generic products and consists of first generation and second-generation molecules. Generally, first-generation antihistamines block both histaminic and muscarinic receptors and pass the blood-brain barrier. Second-generation antihistamines mainly block histaminic receptors, but they do not pass the blood-brain barrier. First generation antihistamines, which are generally characterized as more sedating, accounted for 6% of 2021 total prescriptions, while non-sedating, second generation antihistamines accounted for 94% of total prescriptions. The most widely prescribed oral, second-generation antihistamines are cetirizine (brand name Zyrtec®) and loratadine (brand name Claritin®). Diphenhydramine (brand name Benadryl®) is the most widely prescribed first-generation molecule.

Karbinal ER is the only FDA-approved, 12-hour carbinoxamine oral suspension and is an effective antihistamine with a broad range of indications. Karbinal ER is positioned as a second-line allergy treatment for patients who continue to suffer from allergic symptoms following initial treatment with a second-generation, non-sedating antihistamine. Further, as Karbinal ER is an oral suspension formulation, children are the primary target patient given their preference for liquid treatments and, in many cases, their inability to swallow tablets or capsules. Karbinal ER is indicated for children as young as two years of age. Karbinal has a pleasant strawberry-banana taste and is available in 480 mL bottles.

Through a supply and distribution agreement with Tris, we own exclusively rights to distribute Karbinal ER in the U.S. through August 2032, unless the agreement is terminated earlier pursuant to the termination provisions in the agreement. As part of the agreement, we pay sales-based royalties based on net revenue. Additionally, we are committed to make annual minimum payments to through 2025.

Two core patents protect Karbinal ER in the U.S., and both parents are listed in the FDA's Orange Book. The first patent describes a coated drug-ion exchange resin complex comprising a core composed of a drug complexed with a pharmaceutically acceptable ion-exchange resin. The priority date for this family is March 29, 2009, so the standard 20-year exclusivity for this patent will expire in 2029. The second patent describes an aqueous liquid suspension containing a coated drug-ion exchange resin complex comprising a core molecule complexed with a pharmaceutically acceptable ion-exchange resin and an uncoated ion exchange resin complex. The priority date for this family is June 15, 2007, so the standard 20-year exclusivity for this patent will expire in 2027.

Karbinal ER faces competition from over-the-counter ("OTC") products such as non-sedating antihistamines, sedating antihistamines as well as nasal steroids.

Consumer Health Segment

We acquired our consumer health business through the acquisition of Innovus Pharmaceuticals, Inc. in February 2020. The consumer health business is focused on OTC medicines and consumer health products designed for in-home treatment of medical conditions and ailments to help customers take care of themselves and their families in order to lead healthy lives. Now marketed under the name Aytu Consumer Health, we commercialize over 20 products in the U.S. and Canada through two distinct marketing channels: e-commerce platforms such as our website and Amazon.com and direct-to-consumer marketing channels utilizing our proprietary Beyond Human marketing and sales platform.

We classify our products into three categories:

- ANDA/Device OTC products, which compete in large consumer health categories and are marketed via e-commerce strategies;
- OTC monograph products, which compete in large categories; and
- personal care products, which are proprietary products with strong scientific and clinical support.

The following represents the core Aytu Consumer Health products:

- Regoxidine® - for Men & Women – proprietary over-the-counter aerosol foam that works to treat hair loss in both men and women.
- OmepraCareDR® - acid reducer to treat frequent heartburn.
- Urivarx® - dietary supplement to support healthy bladder function consisting of a proprietary blend of well published botanical ingredients.
- Trexar®* - supplement formulated to support healthy nerves targeting the TRPA1 pathway in both men and women which controls how we interpret both hot and cold sensations on the skin.
- Diabasens® / NeuriteRx® - scientifically formulated combination of three effective and extensively clinically tested and published ingredients to improve soft tissue pain or leg and foot discomfort.
- FlutiCare® - allergy relieving nasal spray proven to offer 24-hour relief of both nose and sinus-related allergy symptoms.

We continue to grow this business through organic growth, acquisition of new products and exclusive distribution rights and introduction of new products developed internally. In our fiscal 2022, we launched 12 new products in our product line. In addition, in June 2021, we signed an exclusive agency supply and distribution agreement with Amman Pharmaceutical Industries to exclusively market numerous sterile ophthalmic, otic, and nasal products in the U.S. that compete with large national OTC medicine brands.

We own over 180 trademarks for products in our consumer health portfolio and own or license patents covering 15 of these products.

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 products are subject to competition from alternate therapies in the form of generic products and other competitive branded products in the marketplace.

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

Some of our existing products compete with one or more products marketed by very large pharmaceutical or consumer healthcare companies that have much greater financial resources for developing and marketing their products. Many competitors 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.

MANUFACTURING

ADHD Product Portfolio

For the production of our ADHD products, we lease one manufacturing site in Grand Prairie, Texas. This facility has 77,112 square feet of manufacturing and laboratory space and contains dedicated current Good Manufacturing Practices ("cGMP") manufacturing suites for both Adzenys XR-ODT and Cotempla XR-ODT. We hold U.S. Drug Enforcement Administration ("DEA") manufacturing and analytical licenses and maintain storage and use of Schedule II through IV controlled substances. The manufacture of our products is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel and quality control.

We are in the process of a technical transfer to outsource the manufacturing of our ADHD products to a CMO. The transfer of the manufacturing of pharmaceutical products requires several steps including knowledge and method transfer, manufacturing of materials for feasibility study and confirmation batch materials, bioequivalence studies, inspections from regulatory agencies, and regulatory filings. If we are able to establish bioequivalence between the current manufactured products and the products manufactured at the prospective CMO, we believe we will be able to submit a pre-approval supplement for the transfer to the FDA by the end of calendar year 2022 or early 2023, which in turn could allow us to be able to produce these products through our CMO in mid to late-calendar 2023.

Pediatric Product Portfolio

We contract with CMOs for the manufacture and testing of our Pediatric Product portfolio. We have entered into the following key supply agreements for the commercial manufacture and supply of certain of these products:

- A supply agreement with Tris Pharma for the supply of Karbinal. This agreement terminates in August 2033, subject to earlier termination or extension in accordance with the terms of the agreement.

- Poly-Vi-Flor and Tri-Vi-Flor are not purchased under any supply agreement and only on a purchase order basis with a CMO based in the U.S.. Merck & Cie is responsible for providing either Metafolin or Arcofolin to our designated CMO. We have established relationships with U.S. CMOs for the production of both Poly-Vi-Flor and Tri-Vi-Flor.

We believe our third-party manufacturers have adequate capacity to manufacture sufficient quantities of these products to meet anticipated commercial demands. As we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record-keeping, manufacturing

processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program.

Consumer Health Segment

The Consumer Health segment maintains relationships with a number of manufacturers from which it obtains its products. With the exception of a settlement agreement with our manufacturer of FlutiCare which establishes a minimum number of batches which may be purchased, there are no manufacturing agreements in place that contain minimum requirements. Aside from those products under the ANDA classification, most products may be manufactured by a variety of manufacturers, and therefore we engage those who can produce product most cost efficiently and on a timely basis.

Research and Development

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development actives. We actively explore new treatment options for patients including novel compounds and innovative medical device technologies.

Our Development Pipeline: AR101 (enzastaurin for the treatment of Vascular Ehlers-Danlos Syndrome (VEDS))

AR101 (enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the protein kinase C (PKC) beta, PI3K and AKT pathways. AR101 has been studied in more than 3,300 patients across a range of solid and hematological tumor types. AR101 was originally developed by Eli Lilly and Company ("Lilly"), and worldwide rights were acquired by Denovo Biopharma ("Denovo") in September 2014 following Lilly's discontinuation of the enzastaurin development program. Orphan drug designation in DLBCL and GBM has been granted by the FDA and the EMA. Fast Track qualification for the first-line treatment of GBM was also granted by the FDA in July 2020. Pivotal Phase 3 studies for both newly diagnosed DLBCL and GBM patients are currently being conducted by Denovo.

VEDS is a rare genetic disorder typically diagnosed in childhood and characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. VEDS is the severe subtype of Ehlers-Danlos Syndrome, affecting 1 in 50,000 people worldwide. VEDS results from pathogenic variants in the COL3A1 gene, which encodes the chains of type III procollagen, a major protein in vessel walls and hollow organs. Twenty-five percent of VEDS patients have a first complication by the age of 20 years, and more than 80 percent have at least one complication by the age of 40. VEDS patients have a median lifespan of 51 years. There are currently no FDA approved treatments for VEDS.

The research underpinning the application of enzastaurin for the treatment of VEDS has been conducted by Dr. Harry (Hal) Dietz and his research colleagues. Dr. Dietz is the Victor A. McKusick Professor of Genetics in the departments of medicine, pediatrics, and molecular biology and genetics at The Johns Hopkins University School of Medicine and director of the William S. Smilow Center for Marfan Syndrome Research. He has also been an investigator at Howard Hughes Medical Institute since 1997. Dr. Dietz is a leading scientist in the field of genetic connective tissue disorders and developed the first preclinical model that mimics the human condition and recapitulates VEDS. His group's research findings were published in the Journal of Clinical Investigation in February 2020. The VEDS knock-in murine (mouse) preclinical model from Dr. Dietz has the same genetic mutation most prevalent in VEDS patients and is representative of the human condition in both the timing and location of vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high-throughput RNA sequencing of the aorta displayed a consistent molecular signature for excessive PKC/ERK cell signaling that is now known to be the driver of disease. Based on the scientific rationale for intervention along the PKC/ERK pathway, PKC inhibition and treatment with PKCβ inhibitors proved efficacious in multiple pre-clinical and murine studies and indeed prevented death due to vascular rupture.

Taken together, the pre-clinical efficacy model along with extensive previous pharmacokinetic, safety, and tolerability findings from Lilly's IND and NDA provide significant support for once daily dosing of 500mg of enzastaurin in the potential treatment of patients with VEDS. Given the nature of this rare disease, the high unmet medical need, the well-characterized nature of AR101, and guidance from the FDA, we expect to advance AR101 to a pivotal safety and efficacy study in VEDS patients which we refer to as the PREVEnt Trial. The development plan includes a well-controlled global clinical trial designed to demonstrate that AR101 delays time to intervention related to arterial rupture, dissection or pseudoaneurysm patients in VEDS patients whose VEDS diagnoses have been confirmed with COL3A1 gene mutations. Additional data will also be collected to evaluate the effectiveness of AR101 in preventing intestinal rupture, uterine rupture, pneumothorax, and any of the severe clinical events related to VEDS confirmed with COL3A1 gene mutations, as adjudicated by an independent event committee. In fiscal 2022 we received Orphan Drug Designation for AR101 in Ehlers-Danlos Syndrome including VEDS and in Europe, allowing for seven years' marketing exclusivity in the United States and ten years in Europe. We also received Fast Track designation for AR101 in VEDS by the FDA, allowing for an accelerated review timeline upon submission of the New Drug Application (NDA) and more frequent interaction with the FDA during the development process.

AR101 is protected by a suite of pending patents being pursued in major markets globally which have been licensed from Johns Hopkins and have an earliest priority date of March 2017. The cornerstone of the intellectual property family surrounds enzastaurin initially targeting the treatment of VEDS focused on the U.S. and certain foreign jurisdictions which include Europe, Japan, China, Brazil, Mexico, Canada, Israel, Australia, New Zealand, and South Korea. This pending patent provides compositions and methods for treating VEDS and associated connective tissue disorders and has a priority date of October 16, 2018. Additional molecule intellectual property is afforded through the license with Denovo whose pending patent provides methods and compositions for the prediction of the activity of enzastaurin and has a priority date of September 1, 2016. The third pending patent provides methods and compositions for the diagnosis, treatment, and prevention of Marfan syndrome and related diseases, disorders and conditions and has a priority date of March 2, 2017, in select geographies. The fourth patent, titled "Pathway Targets for the Treatment of Vascular Ehlers-Danlos Syndrome," deepens the scientific evidence of the pathophysiology of Vascular Ehlers-Danlos Syndrome and is highly confirmatory of the therapeutic approach for AR101/Enzastaurin.

Healight Medical Device Platform Technology

In April 2020, we signed an exclusive worldwide license with Cedars-Sinai in Los Angeles, California, to develop and commercialize the Healight Platform Technology ("Healight" or the "Healight Platform") in respiratory fields of use. This medical device technology platform is currently envisioned as an endotracheal, UV-A light catheter, developed by scientists at Cedars-Sinai, is being studied as a potential first-in-class treatment for viral and bacterial respiratory infections. The Healight Platform has been in development since 2016 by the Medically Associated Science and Technology (MAST) team at Cedars-Sinai. We and our research collaborators engaged in clinical and scientific research to establish the clinical utility of Healight as an intervention for critically ill, mechanically ventilated patients with an initial focus on SARS-CoV-2 infections, and we are now pivoting research efforts to assess the clinical benefits of Healight in VAP.

The agreement with Cedars-Sinai grants us a license to all patent and development related technology rights for the intra-corporeal therapeutic use of ultraviolet light in the field of endotracheal and nasopharyngeal applications. The term of the agreement is on a country-by-country basis and will expire on the latest of the date upon which the last to expire valid claim shall expire, ten years after the first bona fide commercial sale of such licensed product in a country, or the expiration of any market exclusivity period granted by a regulatory agency.

As part of the Healight development plan we entered into an agreement with Sterling Medical Devices ("Sterling") to support our product development efforts. This agreement with Sterling is a fee-for-service development agreement for which we pay Sterling on a project-by-project basis.

Given the significant reduction in cases and severity of SARS-CoV-2 and the potential for broader, longer-term clinical applications for Healight, we are now evaluating the Healight platform as a potential treatment for VAP, a severe respiratory infection caused by the infiltration of pathogens through a hospitalized, mechanically ventilated patient's

endotracheal tube. VAP has a reported mortality rate approaching 50% in some patient populations, making it one of the most difficult-to-treat and deadly infections affecting hospitalized patients. Approximately 86% of nosocomial pneumonias are associated with mechanical ventilation and result in VAP. Between 250,000 and 300,000 VAP cases per year occur in the United States alone, which is an incidence rate of 5 to 10 cases per 1,000 hospital admissions. VAP afflicts up to 15% of mechanically ventilated patients in intensive care units.

We conducted a proof-of-concept study with Healight at Hospital Clinic de Barcelona under the supervision of principal investigator Antonio Torres, M.D., Ph.D., FERS, FCCP, ATSF, Senior Consultant, Pulmonology Department - one of the only centers in the world with access to a specific, well-characterized porcine model of VAP caused by oropharyngeal secretions colonized by Pseudomonas aeruginosa. In the study, administration of the Healight UVA endotracheal catheter resulted in a 46% reduction in multidrug-resistant Pseudomonas aeruginosa (PA C1-17) versus controls following two separate 20-minute treatments. Based on these positive data, Hospital Clinic de Barcelona and the company have initiated a second, larger porcine VAP study to guide the future development of Healight for patients with VAP and expect results from this study by the end of the calendar 2022 or early calendar 2023.

Given our focus on growing our commercial Rx and Consumer Health businesses and advancing AR101/enzastaurin, we are considering various strategic options to maximize the value of Healight including out-licensing regional or global rights to a third-party or divesting the asset.

Other intellectual property rights

We seek trademark protection in the United States when appropriate. We currently have registered trademarks for Aytu, Neos Therapeutics, Innovus Pharma, Beyond Human, Supplement Hunt, Healight, Poly-Vi-Flor, Adzenys, Adzenys XR-ODT, Adzenys ER and Cotempla XR-ODT in the United States, as well as for a number of our consumer health products and two for our DTRS technology.

From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders.

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The FDCA and the FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, sale, advertising and promotion of our products and product candidates. We may seek approval for, and market, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences.

Development and Approval

Under the FDCA, FDA approval of an NDA is required before any new drug can be marketed in the U.S. NDAs in the case of new drugs, or PMAs or 510(k)s in the case of medical devices, may require extensive studies and submission of a large amount of data by the applicant, including the following:

Preclinical Testing. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator.

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and

pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential AEs.

- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug's overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, multi-site, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. Phase 3 data often form the core basis on which the FDA evaluates a drug's safety and effectiveness when considering the product application.

Medical Device Regulations

The FDA requires that a manufacturer introducing a new medical device or a new indication for use of an existing medical device obtain either a Section 510(k) premarket notification clearance or a premarket approval ("PMA") before introducing it into the U.S. market. The process of obtaining a Section 510(k) clearance generally requires the submission of performance data and clinical data, which in some cases can be extensive, to demonstrate that the device is "substantially equivalent" to another legally U.S. marketed device. Substantial equivalence means that the new device is as safe and effective as the predicate. A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; and

- has the same technological characteristics as the predicate; or

- has the same intended use as the predicate; and

- has different technological characteristics and does not raise different questions of safety and effectiveness; and

- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

We must also comply with post-market surveillance regulations, including medical device reporting ("MDR") requirements which require that we review and report to the FDA any incident in which our products may have caused or contributed to a death or serious injury. We must also report any incident in which our product has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur.

Post-Approval Regulation

Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post-marketing studies or clinical trials, changes to a product's approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution-related restrictions, if there are new safety information developments.

DEA Regulation

Several of our approved products are each a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, because Adzenys XR-ODT and Adzenys ER contain amphetamine, Cotempla XR-ODT contains methylphenidate, ZolpiMist contains zolpidem tartrate, Tuzistra XR contains codeine and our Tussionex generic contains hydrocodone. Because amphetamine, methylphenidate and hydrocodone are all Schedule II controlled substances, The DEA has Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT and our Tussionex generic listed and regulated as Schedule II controlled substances. Tuzistra XR is listed and regulated as a Schedule III controlled substance, while ZolpiMist is listed and regulated as a Schedule IV controlled substance. None of our pediatric products (Poly-Vi-Flor, Tri-Vi-Flor and Karbinal ER) 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.

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

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, we use third-party logistics firms to inventory and fill sales orders for our commercial portfolio.

We contract with third parties for the manufacture and testing of Karbinal, Poly-Vi-Flor and Tri-Vi-Flor. Poly-Vi-Flor and Tri-Vi-Flor and ZolpiMist are not supplied under any contract. We have entered into the following key supply agreements for the commercial manufacture and supply of certain of these products:

- A supply agreement with Tris for the supply of Karbinal. This agreement terminates in August 2033, subject to earlier termination or extension in accordance with the terms of the agreement.

- Poly-Vi-Flor and Tri-Vi-Flor are not purchased under any supply agreement and only on a purchase order basis with a CMO based in the U.S. Merck & Cie is responsible for providing either Metafolin or Arcofolin to our designated CMO.

We believe our third-party manufacturers have adequate capacity to manufacture sufficient quantities of these products to meet anticipated commercial demands. Because we rely on CMOs, we employ personnel with extensive technical, manufacturing, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record-keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program.

For the production of our ADHD products, we lease one manufacturing site in Grand Prairie, Texas. This facility has 77,112 square feet of manufacturing and laboratory space, and contains dedicated cGMP manufacturing suites for both Adzenys XR-ODT and Cotempla XR-ODT. We hold DEA manufacturing and analytical licenses, and maintain storage and use of Schedule II through IV controlled substances. The manufacture of our products is subject to extensive cGMP regulations, which impose various procedural and documentation requirements and govern all areas of record keeping, production processes and controls, personnel, and quality control.

We are in the process of a tech transfer to outsource the manufacturing of our ADHD products to a CMO. The transfer of the manufacturing of pharmaceutical products requires several steps including knowledge and method transfer, manufacturing of materials for feasibility study and confirmation batch materials, bioequivalence studies and regulatory filings. We believe we will be able to submit a pre-approval supplement for the transfer to the FDA by the end of calendar year 2022, which in turn could allow us to be able to produce these products through our CMO in mid-calendar 2023

HUMAN CAPITAL

As of June 30, 2022, we employed 164 full-time employees, including 56 who are involved in operations, 8 who are directly involved in research and development, 51 who are involved in commercialization and 49 who are involved in general and administrative activities. All of our colleagues are located in the U.S. Of these colleagues, 37% are female and 63% are male. Our colleagues are not represented by a labor union. We do not have written employment contracts with most of our colleagues.

Our values – team-oriented, hard-working, relentlessly determined, integrity, visionary, entrepreneurial, and service-oriented - are built on the foundation that the colleagues we hire and the way we treat one another promote creativity, innovation, and productivity, which spur our success. This culture depends in large part on our ability to attract, retain and develop a diverse population of talents and high-performing employees at all levels of our organization. Providing market competitive pay and benefit programs, opportunities to participate in the success they help create, while engaging colleagues in important dialogue regarding organization performance, we create a culture of inclusion in which all colleagues have the opportunity to thrive.

The success of our business is fundamentally connected to the well-being of our employees. In response to the COVID-19 pandemic, we implemented modifications to our normal operations, including a work-from-home policy in accordance with guidance issued by the CDC, the WHO and state and local authorities. In addition, employees were provided multiple communications related to COVID safety through their managers, on the employee portal website, and in posters located around the facilities which indicate workplace safety guidelines for those employees who continue to work from our offices and manufacturing facilities. Following COVID, we have maintained a flexible work policy for our non-production employees that has enabled a high level of productivity and communication across the organization.

AVAILABLE INFORMATION

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

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

CODE OF ETHICS

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

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 on Form 10-K. 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 BUSINESS AND FINANCIAL POSITION

We have incurred losses to date and can give no assurance of profitability.

We have incurred losses in each year since our inception. As of the filing of this Annual Report on Form 10-K, there is a substantial doubt regarding our ability to continue as a going concern. Our net loss for the years ended June 30, 2022 and 2021 was $110.2 million and $58.3 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. Potential investors should evaluate us in light of the expenses, delays, uncertainties, and complications typically encountered by healthcare businesses, many of which will be beyond our control. These risks include the following:

- uncertain market acceptance of our products and product candidates;
- difficulties in maintaining coverage and reimbursement for our products;
- lack of sufficient capital;
- U.S. and 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 our historical strategy of product and/or business acquisition to 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, as applicable, may never succeed in these activities and, even if we or our collaborators do, we may never generate revenues that are sufficient to achieve profitability.

We have not established sources of ongoing revenue to cover operating costs and allow us to continue as a going concern.

We have not yet established an ongoing source of revenue sufficient to cover operating costs and allow us to continue as a going concern. Our ability to continue as a going concern is dependent on obtaining adequate capital to fund operating losses until we become profitable. If we are unable to obtain adequate capital, we may be unable to develop and commercialize our product offerings and we could be forced to cease operations.

We will need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our product expansion and development efforts or other operations. Further, future sales and issuances of our common stock or rights to purchase common stock will result in dilution of the percentage ownership of our existing stockholders and could cause our stock price to fall.

We are expending resources to continue the expansion of commercialization efforts for our prescription and consumer health products, and to obtain regulatory approval for, and to commercialize, our product candidates. We will require additional funding 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. As of June 30, 2022, our cash, cash equivalents and restricted cash totaled $19.4 million. During the year ended June 30, 2022, we raised approximately $11.7 million, 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 could need significant additional capital in the future to continue our operations and may need to seek additional funds sooner than planned. Raising funds in the current economic environment 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.

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 our existing common stockholders. 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 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 also have an adverse effect on the market price of our common stock.

In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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 products, and/or be required to significantly curtail, delay or discontinue one or more of our research or development programs for our current or any future product candidates 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 may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

We have a $15.0 million term loan with Avenue Capital and up to $12.5 million of secured revolving loans with Eclipse. As of June 30, 2022, $3.8 million was outstanding under the secured revolving loan. All obligations under our loans are secured by substantially all of our existing property and assets subject to certain exceptions. These debt financings and any future debt financings may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. Since our inception, we have had significant operating losses. As of June 30, 2022, we had accumulated deficit of $288.5 million. As we fund our product candidate pipeline, we expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future.

As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our debt agreements. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, finance our operations, our research and development efforts and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail or eliminate one or more of our programs.

Failure to satisfy our current and future debt obligations under our loan agreements with Avenue Capital or Eclipse could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under one or both of our debt agreements as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness.

The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

The loan agreements with Avenue Capital and Eclipse subject us to financial covenants and restrictions on our ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of the lender. Failure to comply with such covenants could permit the lenders to declare our obligations under the loan agreements, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination.

These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

As of June 30, 2022, we had federal net operating loss carryforwards of approximately $503.2 million. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2024 and, except for certain indefinite-lived net operating loss carryforwards, will completely expire in 2037. Under the Internal Revenue Code of 1986, as amended (the “Code”) and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes could limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income.

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 June 2021 acquisition of Neos caused an ownership change of Neos, resulting in a limitation in our ability to use their pre-acquisition net operating loss carryovers. We also believe that the financing transactions in fiscal 2022 may have caused, together with equity ownership changes in the past five years, an ownership change resulting in a limitation of our ability to use our pre-acquisition net operating loss carryovers. The ownership change scenario could result in increased future tax liability to us.

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, 2021, and concluded that a certain control was not effective. We concluded that we had a material weakness in internal control over financial reporting related to our analysis for the accounting of goodwill and other intangible assets and accounting for the impairment of long-lived assets. As a result, we sought and received technical guidance from a third-party provider. In response, we have taken a number of steps, including incorporating the third-party provider review and expertise in our analysis, and we believe that the issue has been remediated. For the year ended June 30, 2022, we have concluded that our internal controls over financial reporting were effective.

However, if in the future we were to conclude that our internal controls 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 controls 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 controls 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 COMMERCIALIZATION

We are heavily dependent on the commercial success of our commercial products. To date, we have not generated sufficient revenues from the sales of these products to achieve profitability and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate increased revenues from sales of our prescription and consumer health product portfolios. While we have been selling pharmaceutical products for several years, we have limited commercial experience selling our current lineup of pharmaceutical products, having only generated revenues from the sale of our pediatric products since acquiring that portfolio in November 2019 and from our ADHD products since acquiring that portfolio in March 2021. None of our marketed prescription or consumer health products have thus far generated product sales revenues at levels sufficient for us to attain profitability. We have not generated any revenues from product sales of any other product candidates and, to date, have incurred significant operating losses.

We have incurred, and anticipate continuing to incur, significant costs associated with commercialization of our approved products and, if approved, any other product candidates that we may develop. It is possible that we will never attain sufficient product sales revenues to achieve profitability.

If we are unable to differentiate our products or product candidates from branded drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, our ability to successfully commercialize such products or product candidates would be adversely affected.

We expect to compete against branded drugs with distinct clinical attributes and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our Rx Portfolio and product candidates are or will be differentiated from branded drugs and their generic counterparts, if any, including through clinical efficacy or through improved patient compliance and ease of administration, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products and product candidates against other drugs, the opportunity for our products and, if approved, product candidates to achieve premium pricing and be commercialized successfully would be adversely affected.

After an New Drug Application ("NDA"), including a 505(b)(2) application, is approved, the covered product becomes a "listed drug" that, in turn, can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices.

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as our Rx Portfolio products, can be lost to the generic version. Accordingly, competition from generic equivalents to our product candidates would materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our product candidates. [For example, on July 25, 2016, Neos received a paragraph IV certification from Actavis advising them that Actavis filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement with Actavis, pursuant to which Neos granted Actavis the right to manufacture and market its generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. On October 31, 2017, Neos received a paragraph IV certification from Teva advising them that Teva filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. On December 21, 2018, Neos entered into a Settlement Agreement and a Licensing Agreement with Teva, pursuant to which we have granted Teva the right to manufacture and market its generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

Our consumer health division relies heavily on obtaining products that change from a prescription to over the counter through an FDA approval process. Any delays in this process might impact the financial performance of our consumer health division.

Our consumer health division actively pursues opportunities where existing prescription drugs have recently, or are expected to, change from a prescription to over-the-counter. Historically the FDA has highly scrutinized any product application submitted to switch a product from physician prescribed prescription to unsupervised over-the-counter use by the general public. The expansion of Rx-to-OTC switches is critical to our future growth. Reluctance of FDA to approve Rx-to-OTC switches in new product categories could impact that growth and could impact the financial performance of our consumer health division.

Our pharmaceutical, device and consumer health products may prove to be difficult to effectively commercialize as planned or on the timeframes we announce and expect.

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. Moreover, we have limited experience selling our current products given their acquisition from other companies or their recent approval. We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory, and other product development objectives and, from time to time, we may publicly announce the expected timing of some of these milestones. The achievement of many of these milestones may be outside of our control and 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. Specifically, we may encounter difficulty by virtue of the following, each of which could be negatively impacted if expected timeframe goals are not achieved:

- our available capital resources;
- our inability to receive regulatory clearances required to market them as drugs;
- our inability to have clear proprietary rights to the products;
- our inability to manufacture or cost-effectively manufacture the products;
- our inability to adequately market and increase sales of any of these products;
- existence of adverse side effects that make using the products less desirable;
- our inability to adequately market and increase sales of any of these products;
- our inability to attract and retain a 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;
- 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 rely on limited sources of supply for our products, and any disruption in the chain of supply may impact production and sales of our products, and cause delays in developing and commercializing our product candidates and currently manufactured and commercialized products.

Many of our products are produced in single annual production lots by single-source suppliers. Due to the limited production quantities, production of these lots may not be prioritized by the third-party manufacturer, and may not be scheduled and produced at all. Our ADHD products are currently manufactured in our own production facility in Grand Prairie, Texas. We are reliant on a limited number of suppliers for resin, drug compounds, coating and other component substances of our final product candidates and products. If any of these single source suppliers were to

breach or terminate its supply agreement, if any, with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our product candidates and products. If we fail to procure supply of our products, we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our product candidates or products could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our approved products or product candidates or a decrease in sales of our approved products, which could harm our financial position and commercial potential for our product candidates and products. Any alternative vendor would also need to be qualified through an NDA supplement which could result in further delay, including delays related to additional clinical trials. The FDA, DEA, or other regulatory agencies outside of the United States may also require additional studies if we enter into agreements with new suppliers for the manufacture of our ADHD products that differ from the suppliers used for clinical development of such product candidates.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products and product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our ADHD products may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

Third-party 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 in the near future. For any future product, we expect to use third-party manufacturers because we will 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 to a third-party CMO for our ADHD products. 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.

If we fail to manufacture our ADHD products in sufficient quantities and at acceptable quality and pricing levels, or fail to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of these products or our product candidates, if approved, or be unable to meet market demand, and may be unable to generate potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state, and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our raw material manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products and product candidates would be jeopardized. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial. We purchase raw materials and components from various suppliers in order to manufacture our ADHD products. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing our ADHD products, and may not be able to meet customer demand for our products.

In addition, we must comply with federal, state, and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products or product candidates is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such products or product candidates or successfully commercialize such products or product candidates, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in clinical development, regulatory submissions, approvals or commercialization of our products or product candidates, entail higher costs or adversely impact our commercialization of our products or product candidates. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If our sole manufacturing facility becomes damaged or inoperable or we decide to or are required to vacate our facility, our ability to manufacture our ADHD products may be jeopardized. Our inability to continue manufacturing adequate supplies of our products could adversely affect our ability to generate revenues.

All of our ADHD products manufacturing capabilities are currently housed in our sole manufacturing facility located in Grand Prairie, Texas. Our facility and equipment could be harmed or rendered inoperable by natural or manmade disasters, including war, fire, tornado, power loss, communications failure or terrorism, any of which may render it difficult or impossible for us to operate our drug delivery technology platform and manufacture our product candidates or products for some period of time. While we seek to maintain finished goods inventory of our products outside of this facility, it is unlikely that the level of such inventory would be sufficient if we were to sustain anything other than a short-term disruption in our ability to manufacture our products and product candidates at our Grand Prairie, Texas facility. The inability to manufacture our products and product candidates if our facility or our equipment is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to manufacture our products and product candidates could become damaged and time consuming to repair or replace. It would be difficult, time consuming and expensive to rebuild our facility or repair or replace our equipment or to

complete the transfer of our proprietary technology to a third party, particularly in light of the requirements for a DEA registered manufacturing and storage facility like ours and FDA site change requirements.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. An inability to continue manufacturing adequate supplies of our ADHD products at our Grand Prairie, Texas facility could result in a disruption in the supply of our products to physicians and pharmacies, which would adversely affect our ability to generate revenues.

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.

Collaboration agreements typically provide for the ownership of intellectual property. 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 and we may be limited in our ability to use, make or sell these 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.

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 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.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete with companies that design, manufacture and market already-existing and new 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. Our competitors may be more successful in acquiring new products than we are. If we fail to acquire new products, implementation of our business plan would be delayed, which could have a negative adverse effect on our business and prospects. 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.
For our approved products, we compete with companies that design, manufacture and market treatments that compete with our products. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an

exclusive basis drug products or drug delivery technologies that are more effective or less costly than that of our products or any product candidate that we are currently developing or that we may develop.

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

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

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

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

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

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

In addition, in some foreign countries, the proposed pricing for a drug or medical device must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the EU 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 EU 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 clinicians, hospitals, third-party payors and the medical community of our products and product candidates.

Physicians may not choose to prescribe our products 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 existing medicines or treatments. 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. We cannot predict the degree of market acceptance of any of our approved products. 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, safety and economic value our products and product candidates over existing technologies and products;
- the approved labeling for the product and any required warnings;
- the prevalence and severity of adverse events or publicity;
- potential product liability claims
- the relative convenience and ease of our products and product candidates over existing technologies and products;
- the introduction of new technologies and competing products that may make our products and product candidates less attractive for our target customers;
- our success in training medical personnel on the proper use of our products and product candidates;
- the willingness of third-party payors to reimburse our target customers that adopt our products and product candidates;
- increases in rebate payments with payors;
- the acceptance in the medical community of our products and product candidates;
- the extent and success of our manufacturing, marketing, and sales efforts; and
- general economic conditions.

If our future therapeutic candidates fail to gain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some therapies achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue.

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.

Reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial

condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company's financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to the Centers for Medicare & Medicaid Services ("CMS"), it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs.

Additionally, if a pharmaceutical company overcharges the government in connection with the FSS program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against a company under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our collaborators are also subject to similar requirements outside of the U.S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

Our future growth may depend, 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 may 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 U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to coordinate our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We have adopted a Code of Business Conduct and Ethics that mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. We cannot ensure, however, that our employees and third party intermediaries will comply with this code or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any such action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

RISKS RELATED TO PRODUCT DEVELOPMENT AND REGULATORY APPROVAL

Our pre-commercial product candidates undergo clinical trials that are time-consuming and expensive, with uncertain timelines and the outcomes of which are unpredictable, and for which there is a high risk of failure. 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.

We may not be able to develop our current or future product candidates. 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 future therapeutic candidates, we must demonstrate through lengthy, complex, and expensive nonclinical studies, preclinical studies and clinical trials that the applicable therapeutic candidate is both safe and effective for use in each target

indication. A therapeutic candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval.

Pre-clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays for reasons such as product safety and efficacy, agreeing on acceptable terms with prospective CROs and clinical trial sites, validating testing, obtaining or manufacturing sufficient quantities of the product being tested, obtaining approval of an IND from the FDA, obtaining appropriate board approvals, and determining dosing and design. Further, identifying, qualifying, and retaining patients to participate in our clinical trials will be critical to our success. Patient enrollment depends on many factors, including the available patient population size, identifying and enrolling willing and eligible patients, the safety profile of product candidate and its perceived risks, our ability to recruit qualified clinical trial investigators, the existence of competing clinical trials, the availability of approved products for the indication that is the subject of the clinical trial, and our ability to obtain and maintain patient informed consents.

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. Delays, suspensions or terminations of trials can occur for various reasons, including product ineffectiveness; adverse events, safety issues or side effects; inability to fund the trial; trial design may be costly or lengthy; an inability to collaborate regarding development or commercialization; failing to follow regulatory requirements or to adjust to changes in regulations while the trial is in process; failure to obtain needed patient information due to patients ceasing contact after treatment; and interpretations of trial results that differ from ours. These factors may also lead to denial of an NDA for a product candidate.

Sometimes our product candidates are developed for other indications by another sponsor. Undesirable adverse events that occur in relation to the activities by another sponsor related to our product candidate could cause us or regulatory authorities to interrupt, delay or halt development or could result in the delay or denial of regulatory approval by the FDA or other comparable regulatory authorities. Drug-related adverse events involving our product candidate by another sponsor could also harm our reputation, business, financial condition and business prospects.

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. 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, the issues identified in the list of risks above and others, including these:

- 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 CRO 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.

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.

In order to market and sell our products in the EU 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. 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.

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 Healight Platforms for clinical use.

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 of 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.

We expect the Healight Platform will be subject to 510k (or, potentially 510k De Novo) clearance 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 510k clearance, pre-market approval, or foreign regulatory approvals. The 510k clearance and pre-market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510k De Novo clearance, and from one to three years from submission to obtain pre-market approval; however, it may take longer, and 510k, 510k De Novo clearance or pre-market approval may never be obtained. We have limited experience in filing FDA applications for 510k, 510k De Novo clearance and pre-market approval. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements even after obtaining clearance or approval. There can be no assurance that we will obtain or maintain any required clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations.

Even if we, or our collaborators, obtain marketing approvals for our product candidates, we may be subject to additional marketing limitations, be subject to continual requirements and review by regulatory authorities or be subject to a withdraw of our product's marketing for various reasons.

Any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to post-approval marketing limitations that could limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the therapy may be marketed or to the conditions of approval. For this type of limitation, the FDA or other regulatory authorities may (1) require a product to carry a warning in its labeling and on its packaging, where products with black box warnings are subject to more restrictive advertising regulations than products without such warnings, or (2) require the Company to carry out additional and costly post-marketing testing and monitoring, such as Phase IV clinical trials or a monitoring program to measure the safety and efficacy of such product candidates. 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.

Furthermore, any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to continual requirements of and review by the FDA and other regulatory authorities. We would be required to extensively record, monitor, and report on our products, including their underlying

therapeutic substances; the manufacturing and distributing processes for our products, any adverse events to our products, and any advertising and promotional efforts of our products. All of which is to ensure safety and continued compliance with cGMP and with good clinical practice ("GCP") for any clinical trials that we conduct post-approval. These record and monitoring processes may result in significant expense and limit our ability to commercialize such therapies.

Moreover, 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.

Finally, any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to a withdrawal of our product's marketing approval for various reasons. Later discovery of previously unknown problems with any approved product candidate, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in (1) restrictions on the labeling, distribution, marketing or manufacturing of our future product candidates; (2) withdrawal of the product from the market or product recalls; (3) interruption, delay or halt of clinical trials or requirements to conduct post-marketing studies or clinical trials; (4) refusal by the FDA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals; (5) restrictions on coverage by third-party payors; (6) fines, restitution or disgorgement of profits or revenue; (7) suspension or withdrawal of marketing approvals; (8) product seizure or detention, or refusal to permit the import or export of the product; and (9) injunctions or the imposition of civil or criminal penalties.

We are subject to various health care fraud and abuse and reimbursement laws 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.

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, Adzenys XR-ODT and Cotempla XR-ODT, (collectively, our "Controlled Substance Products") which are approved by the FDA, are regulated by the DEA as Schedule II 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. Our Controlled Substance Products are, and our other product candidates may, if approved, be regulated as "controlled substances" as defined in the Controlled Substances Act of 1970, or CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our third-party manufacturers and to distributors, prescribers, and dispensers of our product candidates. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. 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. State-controlled substance laws and regulations may have more extensive requirements than those determined by the DEA and FDA. Though state-controlled substances laws often mirror federal law because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, other states require additional state rulemaking or legislative action, which could delay commercialization. Some state and local governments also require manufacturers to operate a drug stewardship program that collects, secures, transports, and safely disposes of unwanted drugs. 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.

Amphetamine and methylphenidate, which are the active ingredients in our Adzenys XR-ODT and Cotempla XR-ODT products, are listed by the DEA as a Schedule II controlled substance under the CSA. Scheduled controlled substances are subject to DEA regulations relating to supply, procurement, manufacturing, storage, distribution, and physician prescription procedures. We currently manufacture these products in our own facilities, which are registered with and inspected by the DEA.

Registered entities are subject to DEA inspection and also must follow specific labeling and packaging requirements, and provide appropriate security measures to control against diversion of controlled substances. Security requirements vary by controlled substance schedule with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Failure to follow these requirements can lead to significant civil and/or criminal penalties and possibly even lead to a revocation of a DEA registration. The DEA also has a production and procurement quota system that controls and limits the availability and production of Schedule I or II controlled substances. If we or any of our suppliers of raw materials that are DEA classified as Schedule I or II controlled substances are unable to receive any quota or a sufficient quota to meet demand for our products, if any, our business would be negatively impacted.

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.

The design, development, manufacture, supply and distribution of our products and product candidates are highly regulated processes and technically complex.

We are subject to extensive regulation of the preparation and manufacture of our products for commercial sale. Components of a finished therapeutic product approved for commercial sale or used in late stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing

processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products and product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our approved products as well as any of our future potential product candidates, are highly regulated processes and technically complex. We, along with our third party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of our ADHD products is a regulated drug product and subject to the DEA and state-level regulations, we have had to, and will continue to, need to secure state licenses from each state in which we intend to sell such product allowing us to distribute a regulated drug product in such state.

Regulatory authorities also may audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we may be required to take remedial measures that may be costly and/or time consuming for us to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of our facility. Any such remedial measures imposed upon us could materially harm our business. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or revocation of a pre-existing approval, or civil or criminal penalties. As a result, our business, financial condition and results of operations may be materially harmed.

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 tracking and monitoring of the sale and distribution of prescription drugs. We are required to provide product identification information, or serialization, at the manufacturing batch, or lot level. In addition, we are required to track and verify wholesaler and pharmacy authentication and verification. By the end of 2023 we will be required to conduct unit level tracking throughout the entire supply chain. 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.

Failure to comply with health and data protection laws and regulations could lead to U.S. federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to U.S. federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health ("HITECH"). To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers, the federal government, and media outlets with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with U.S. and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal, and administrative penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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.

We rely on third parties to conduct our clinical trials, perform data collection and analysis, develop certain technologies, and manufacture certain products, 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, CRO's, contract laboratories, and collaborators to perform data collection and analysis and others to carry out our clinical trials. We are contractually obligated to rely on research collaborators to conduct testing and clinical trials of the Healight Technology, which makes us dependent on a third party to conduct the ongoing 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;
- the third party has relationships with our competitors that interfere with their work on our project; 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.

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 plan to outsource the manufacturing of our ADHD products to a third-party manufacturer to produce commercial quantities of our ADHD products. This may require us to fund the third party's capital improvements to manufacture our products. If the third party is not successful or does not meet our expectations (for example, timeliness of production, quantity of production, maintenance of needed documentation or regulatory compliance), we may have to find a different manufacturer and incur expenses and delays in the process. Manufacturers of our ADHD products must comply with good manufacturing practice ("GMP") requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our FDA regulated products may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to a manufacturer's failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our drugs, which would seriously harm our business.

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.

We have and may continue to seek Orphan Drug Designation or other designations for our product candidates, but even if designated we may not ultimately realize the potential benefits of such designations.

We have and may continue to seek Orphan Drug Designation or other designations for our product candidates from the FDA. Under the Orphan Drug Act, the FDA may designate a drug product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States but where there is no reasonable expectation to recover the costs of developing and marketing a treatment drug in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and application fee waivers. After the FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. However, Orphan Drug Designation nor any other designation shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a demonstration of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity for the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. Even if we obtain Orphan Drug Designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective, or makes a major contribution to patient care.

We may seek certain designations for our product candidates, including Fast Track and Breakthrough Therapy, designations, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. For example, if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation. Drugs that have received Fast Track designation from the FDA are eligible for expedited development and priority review, and the opportunity for a rolling review, under certain circumstances.

A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA has broad discretion whether or not to grant such designations, so even if we believe a particular product candidate is eligible for the designation, we cannot assure that the FDA would decide to grant it. Moreover, even if we do receive Fast Track or breakthrough therapy designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. We or the FDA may withdraw these designations if either party believes that the designation is no longer supported by data from our clinical development program.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

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

A number of our patent and trademark rights are derived from our license agreements with third parties. Pursuant to these license agreements, we have licensed rights to various patents, patent applications, trademarks and trademark applications within and outside of the United States. We may lose our rights to this intellectual property 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 may 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 or trademark or trademark application, and our business, results of operations, financial condition and prospects would be materially adversely affected. In addition, the licensor may not be able to obtain valid and enforceable patents that protect the licensed products or product candidates and may not be able to prevent third parties from infringing on those rights.

From time to time we may renegotiate the terms of our existing licensing agreements or other material contracts. There can be no guarantee that the terms of the renegotiated license agreement will be viewed favorably by the market although the renegotiated terms might be advantageous to our business or that the other party would agree to material changes to benefit the Company. For example, in May 2022, we negotiated to terminate the License, Development, Manufacturing and Supply agreement with Tris. The negotiations resulted in reducing the future minimum payments we owed to Tris by approximately $8 million. If we were unable to renegotiate the terms of the agreement, it would have had a material negative impact on our cash flows and financial position.

Our ability to compete may decline if we do not adequately protect or enforce our intellectual property rights.

Our success depends in part on our ability to manufacture, use, sell and offer to sell our product candidates and proposed product candidates and in obtaining and maintaining intellectual property rights in our products, product candidates, proprietary know-how and technology advances. We rely on patent protection, as well as a combination of trademark and trade secret laws to protect and prevent others from making, using and/or selling our compounds, processes, apparatuses and technology. While a presumption of validity exists with respect to patents issued to us in the U.S., there can be no assurance that any of our patents will not be challenged, invalidated, circumvented or rendered unenforceable. Such means may afford only limited protection of our intellectual property and may not (i) prevent our competitors from duplicating our inventions; (ii) prevent our competitors from gaining access to our proprietary information and technology; or (iii) permit us to gain or maintain a competitive advantage. In addition, our competitors or other third parties may obtain patents that restrict or preclude our ability to lawfully practice, produce or sell our products in a competitive manner,

Obtaining and maintaining a patent portfolio entails significant expense and resources. 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. In addition, the patent scope can be limited in prosecution or by the courts after issuance.

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. 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.

Legal actions to enforce our patent rights and administrative challenges at the U.S. Patent and Trademark Office can be expensive and may involve the diversion of significant management time. In addition, these 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.

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. In addition, some countries allow patents to be challenged by third parties in administrative proceedings, which may result in a reduction in scope or cancelation of some or all of the claims. 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.

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 that relate to our prescription and consumer health business. 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 or universities 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, wrongful disclosure of confidential information, 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 intellectual property 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 reasonable or 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 efforts to expand and transform our businesses may require significant investments; if our strategies are unsuccessful, our business, results of operations and/or financial condition may be materially adversely affected.

We continuously evaluate opportunities for expansion and change. These initiatives may involve making acquisitions, entering into partnerships and joint ventures, divesting assets, restructuring our existing operations and assets, creating new financial structures and building new facilities—any of which could require a significant investment and subject us to new kinds of risks. We may incur additional indebtedness to finance these opportunities. If our strategies for growth and change are not successful, we could face increased financial pressure, such as increased cash flow demands, reduced liquidity and diminished access to financial markets, and the equity value of our businesses could be diluted.

The implementation of strategies for growth and change may create additional risks, including:

- diversion of management time and attention away from existing operations;
- requiring capital investment that could otherwise be used for the operation and growth of our existing businesses;
- disruptions to important business relationships;

- increased operating costs;
- limitations imposed by various governmental entities; and
- difficulties due to lack of or limited prior experience in any new markets we may enter.

Our inability to mitigate these risks or other problems encountered in connection with our strategies for growth and change could have a material adverse effect on our business, results of operations and financial condition. In addition, we may fail to fully achieve the savings or growth projected for current or future initiatives notwithstanding the expenditure of substantial resources in pursuit thereof.

We may have difficulties integrating acquired products and businesses and as a result, our business, results of operations and/or financial condition may be materially adversely affected.

We have completed a number of acquisitions, and we intend to continue to acquire additional products and businesses through mergers, asset purchases or in-licensing, businesses or products, or form strategic alliances as part of our business strategy. Such growth strategies involve risks, including:

- inability to efficiently operate new businesses or to integrate acquired products and businesses;
- inability to accurately predict delays in realizing the costs and benefits of acquisitions, partnerships, or joint ventures;
- unexpected losses of customers or suppliers of an acquired or existing business;
- difficulties in retaining key employees of acquired businesses;
- difficulties in realizing projected synergies;
- failure of the acquired business to produce the expected value;
- exposure to unanticipated liabilities, including unexpected environmental exposures, litigation challenging a merger, product liability or illegal activities conducted by an acquired company or a joint venture partner.

Our inability to address these risks in a timely manner or at all could cause us to fail to realize the anticipated benefits of such acquisitions or joint ventures and could have a material adverse effect on our business, results of operations and financial condition.

In fiscal 2022, 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 our gross revenue during the years ended June 30, 2022 and 2021. During the years ended June 30, 2022 and 2021, three customers accounted for 78% and 54% of gross revenue, respectively. The loss of one or more of our significant partners or collaborators could have a material adverse effect on our business, operating results or financial condition. Any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline. If we are unable to diversify our customer base, we will continue to be susceptible to risks associated with customer concentration.

Our accounts receivable subjects us to credit risk.

We are also subject to credit risk from our accounts receivable related to our product sales. As of June 30, 2022, three customers accounted for 94% of gross accounts receivable. As of June 30, 2021, three customers accounted for 86% of gross accounts receivable. Our profitability and cash flow are dependent on receipt of timely payments from

customers. Any delay in payment by our customers may have an adverse effect on our profitability, working capital and cash flow. There is no assurance that we will be able to collect all or any of its trade receivables in a timely matter. If any of our customers face unexpected situations such as financial difficulties, we may not be able to receive full or any payment of the uncollected sums or enforce any judgment debts against such clients, and our business, results of operations and financial condition could be materially and adversely affected.

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 and Mark Oki 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 and one year, respectively, of salary if we terminate him without cause, as defined in the agreement, which could hurt our liquidity. The loss of the services of either 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.

We will be exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of therapeutic candidates. Any failure of future therapeutic candidates by us and our corporate collaborators in clinical trials may expose us to liability claims as may the potential sale of any therapies approved in the future. These claims might be made by patients who use our therapies, healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that research or sell our therapies. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our future therapeutic candidates or any prospects for commercialization of our future therapeutic candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our future therapeutic candidates causes adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities.

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. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. 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, insurance coverage is increasingly expensive and difficult to obtain. For example, we have experienced increasing difficulty in procuring insurance coverage for our products, in particular, our opioid based products, due to their status as controlled substances. 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. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Public concern over the abuse of medications that are controlled substances, including increased legislative, legal and regulatory action, could negatively affect our business.

Products containing controlled substances may generate public controversy. Certain governmental and regulatory agencies, as well as state and local jurisdictions, are focused on the abuse of controlled substances such as opioids in the United States. State and local governmental agencies have commenced investigations into pharmaceutical companies and others in the supply chain in connection with the distribution of opioid medications. For example, on March 7, 2018 and April 18, 2019, we received citations advising us that the County of Harris Texas and the County of Walker Texas filed lawsuits on December 13, 2017 and January 11, 2019, respectively, against us and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees. In addition, multiple lawsuits have been filed against pharmaceutical companies alleging, among other claims, failures to provide effective controls and procedures to guard against the diversion of controlled substances, negligence by distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, and failures to report suspicious orders of controlled substances in accordance with regulations. Certain of these cases have recently been settled, some for hundreds of millions of dollars. In the future, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of our product or product candidates, the withdrawal of currently approved products from the market, or result in other legal action.

In addition, we are aware of other legislative, regulatory or industry measures to address the misuse of prescription opioid medications which could affect our business in ways that we may not be able to predict. For example, the State of New York has undertaken efforts to create an annual surcharge on all manufacturers and distributors licensed to sell or distribute opioids in New York, as well as a tax on sales of opioids in the state. Other states have implemented and are also considering legislation that could require us to pay taxes, licensing fees, or assessments on the distribution of opioid medications in those states. These laws and proposed bills vary in the amounts and the means of calculation. Liabilities for taxes or assessments under any such laws will likely have an adverse impact on our results of operations, unless we are able to mitigate them through operational changes or commercial arrangements where permitted and may result in us ceasing to continue to sell our products in these jurisdictions.

RISK 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 notification, we anticipate that we would take actions to restore our compliance with applicable exchange requirements, such as stabilize our market price, improve the liquidity of our common stock, prevent our common stock from dropping below such

exchange's minimum bid price requirement, or prevent future non-compliance with such exchange's listing requirements.

On May 24, 2022, we received a letter from the Nasdaq Stock Market, LLC ("Nasdaq") indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share required for continued inclusion on the Nasdaq Capital Market under the Nasdaq Listing Rules (the "Notice"). The Notice has no effect at this time on the listing of our common stock, which will continue to trade on the Nasdaq Capital Market under the symbol "AYTU."

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Notice the closing bid price of our common stock is at or above $1.00 for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and its common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing.

If, by November 21, 2022, we cannot demonstrate compliance with Nasdaq Listing Rules, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirements for the Nasdaq Capital Market, with the exception of the minimum bid price requirement, and would need to provide written notice of its intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If we are not eligible for the second compliance period, then Nasdaq will provide notice that our securities will be subject to delisting. At such time, we may appeal the delisting determination to a Nasdaq Hearings Panel ("Panel"). We would remain listed pending the Panel's decision. There can be no assurance that, if we appeal a subsequent delisting determination by the Panel, that such appeal would be successful.

We intend to monitor the closing bid price of our common stock and consider our available options if the closing bid price of our common stock remains below $1.00 per share. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement for the additional 180-day compliance period with respect to the minimum bid price requirement, or maintain compliance with the other listing requirements.

Effecting a reverse stock split, if determined by the Board in its discretion, may not achieve one or more of our objectives.

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.

On May 24, 2022, we received notification from Nasdaq that we were not in compliance with the Nasdaq Listing Rules because we did not meet the minimum bid price of $1 per share requirement. We have 180 calendar days from May 24, 2022 to regain compliance and may be eligible for additional time to regain compliance.

We have scheduled a special meeting of the Stockholders on October 5, 2022, for stockholders to approve a reverse stock split of our common stock of a ratio up to 1-for-20. The approval of a reverse stock split will provide us with another means to regain compliance with the Nasdaq listing requirements. There are no certainties that we will

receive stockholder approval for the reverse stock split. If approved by our stockholders, the Board may determine in its discretion to effect a reverse stock split.

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 success of products or product candidates we acquire for development or commercialization relative to the success of our competitors;
- clinical trial outcomes;
- product safety;
- conditions or trends in the healthcare, biotechnology and pharmaceutical industries, including healthcare payment systems;
- our ability to effectively manage operations, financial decisions, internal controls over financial reporting or disclosure controls, performance relative to projections, and attract and retain employees;
- our dependence on third parties, including CROs and scientific and medical advisors;
- adverse regulatory decisions or changes in laws or regulations;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- general political and economic conditions and effects of natural or man-made catastrophic events; and
- other events or factors, many of which are beyond our control.

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. You might not be able to resell your shares at or above the price you paid for them.

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. We cannot control the number of securities and industry analysts who publish research on us, the extent of their coverage or the content of their reports. Downgrades of our stock or publishing inaccurate or unfavorable research about our business, would likely lead to a decline in our stock price. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we would lose market visibility and demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

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.

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 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.

GENERAL RISK FACTORS

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

Our business could be adversely affected by health epidemics in regions where we have business activities and could cause significant disruption to our operations or in the operations of CMOs and CROs upon whom we rely. For example, beginning in late 2019, the outbreak of a novel strain of virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID-19, has evolved into a global pandemic. The coronavirus has spread to most regions of the world.

As a result of the coronavirus pandemic, we may experience disruptions that could severely impact our business and clinical trials, including:

- We believe that the COVID-19 pandemic has had, and may continue to have, an adverse impact on demand for our products due to government-imposed quarantines, stay-at-home orders, travel restrictions, mandated business closings and other public health safety measures which may result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled. Initially, we suspended in-person interactions by our sales and marketing personnel in healthcare settings. We engaged with these customers remotely, via webinar programs and virtual meetings, as we sought to continue to support healthcare professionals and patient care. As parts of the country reopened, our sales and marketing personnel reengaged with healthcare professionals, sometimes in limited number of in-person interactions. Remote interactions may be less effective than in-person interactions.

- We currently rely on third-party suppliers, CMOs, and third-party logistics providers. If any such third party in our supply chain for materials is adversely impacted by restrictions resulting from the COVID-19 pandemic, including staffing shortages and retention, production shutdowns and disruptions in delivery systems, our supply chain may be disrupted, limiting our ability to manufacture commercial quantities of our products.

- In March 2020, we closed some of our offices and manufacturing facilities, and requested that most of our personnel, including our administrative employees, work remotely, restricted on-site staff to only those personnel who must perform essential activities that must be completed on-site and limited the number of staff in any given location. We reopened our manufacturing in 2020 and our offices reopened on a voluntary basis for those personnel who prefer to work from the office. Our increased reliance on personnel working remotely may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

- We may in the future conduct clinical trials for product candidates in geographies which are affected by the coronavirus pandemic. Potential impacts of the coronavirus pandemic on our potential clinical trials may include disruptions or delays in site initiations, patient enrollment and recruitment, standard study monitoring practices, shipment of samples and availability of clinical trial materials, data analysis and reporting of results due to changes in policies at various clinical sites or in federal, state, local or foreign laws, rules and regulations. Other impacts could include quarantines or other travel restrictions. Interruption or delays in the operations of the FDA could also impair our ability to discuss clinical programs. It is unknown how long these pauses or disruptions could continue.

- Health regulatory agencies globally may experience disruptions in their operations as a result of the coronavirus pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under-resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur.

- The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising further capital through sales of our common shares or convertible debt or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares.

The coronavirus pandemic continues to rapidly evolve. The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID-19 and

the actions taken to contain coronavirus or address its impact in the short and long term. We do not yet know the full extent of potential delays or impact on our business, our clinical trials, healthcare systems or the global economy.

Our business and operations would suffer in the event of system failures or security breaches.

We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in preventing cyber attacks or successfully mitigating their effects.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from such cyber attacks, including computer viruses, unauthorized access, ransomware attacks, phishing expeditions, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. For example, the loss of data from completed clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could suffer reputational harm or face litigation or adverse regulatory action and the development of our product candidates could be delayed.

Our sales force and other employees, third party logistics partners, CMOs, CROs, principal investigators, collaborators, independent contractors, consultants and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We lease various properties, including office buildings, manufacturing, research and development facilities and sales offices within the U.S. We continuously review and evaluate our facilities as a part of our strategy to optimize our business operations. The following table sets forth a list of our properties as of June 30, 2022.

Location	Leased/Owned	Purpose
Englewood, CO	Leased	Corporate headquarters
Grand Prairie, TX	Leased	Administrative offices, Laboratory and Manufacturing facilities
Berwyn, PA	Leased	Office
Oceanside, CA	Leased	Warehouse
Carlsbad, CA	Leased	Warehouse

ITEM 3. LEGAL PROCEEDINGS

Harris and Walker County. On March 7, 2018 and April 18, 2019, we received citations advising us that the County of Harris Texas ("Harris County") and the County of Walker Texas ("Walker County") filed lawsuits on December 13, 2017 and January 11, 2019, respectively, against our Neos subsidiary and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees. While we believe that these lawsuits are without merit and we intend to vigorously defend

against them, we are not able to predict at this time whether these proceedings will have a material impact on our financial condition or results of operations.

Aponowicz and Paguia Class-Action Securities Litigations. A putative class action was filed on February 9, 2022 in the Delaware Chancery Court by Rafal Aponowicz derivatively and on behalf of all Aytu stockholders, challenging the grant in 2021 of certain stock option awards to directors and officers. The stockholder contends those awards were in amounts exceeding the shares available under the Company's 2015 equity incentive plan and that the directors therefore breached their fiduciary duties and breached a purported contract between them and stockholders. The Complaint seeks rescission of the awards, unspecified damages to stockholders as a result of the awards, and attorneys' fees. A second such action was filed by Paul John M. Paguia on March 7, 2022; Mr. Paguia asserts the same claims and seeks the same relief. The two actions have been assigned to the Vice Chancellor McCormick, who will hear a partial motion to dismiss in December 2022. The Company does not believe there are any damages attributable to the awards.

Witmer Class-Action Securities Litigation. A shareholder derivative suit was filed on September 12, 2022 in the Delaware Chancery Court by Paul Witmer derivatively and on behalf of all Aytu stockholders against Armistice Capital, LLC, Armistice Capital Master Fund, Ltd., Steve Boyd (Armistice's Chief Investment Officer and Managing Partner, and a former director of Aytu), and certain other current and former directors of Aytu, Joshua Disbrow, Gary Cantrell, John Donofrio, Jr., Michael Macaluso, Carl Dockery and Ketan B. Mehta. The complaint alleges that (i) Armistice facilitated the sale of assets of Cerecor in 2019 and Innovus in 2020 to Aytu in exchange for convertible securities which it subsequently converted and sold at a profit on the open market; (ii) the Armistice defendants breached their fiduciary duties, were unjustly enrichment and wasted corporate assets in connection with these acquisitions; (iii) the Armistice defendants breached their fiduciary duties by engaging in as insider trading; and (iv) the other directors breached their fiduciary duties, aided and abetted the Armistice defendants breaches of fiduciary duties, and wasted corporate assets in connection with these acquisitions. The Complaint seeks unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees. While we believe that this lawsuit is without merit and we intend to vigorously defend against it, we are not able to predict at this time whether this proceeding will have a material impact on our financial condition or results of operations.

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

Our common stock has been listed on the NASDAQ Capital Market under the symbol "AYTU" since October 20, 2017.

On September 19, 2022, the closing price as reported on the NASDAQ of our common stock was $0.20, and there were 1,094 holders of record of our common stock.

Equity Compensation Plan Information

In June 2015, our stockholders approved the adoption of a stock and option award plan (the "Aytu 2015 Plan"). At the special meeting of stockholders on July 26, 2017, our stockholders voted to increase the plan to 3.0 million shares. The Aytu 2015 Plan permits grants of equity awards to employees, directors, and consultants. At the Special meeting of the stockholders on January 24, 2020, our Stockholders voted to increase the plan to 5.0 million shares.

The following table displays equity compensation plan information as of June 30, 2022 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)[1]	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	1,819,701	$ 25.90	2,383,061
Equity compensation plans not approved by security holders[2]	138,406	$ 6.38	45,294
Total	1,958,107	$ 16.61	2,428,355

(1) It reflects the weighted-average exercise prices of options outstanding. Restricted stocks and restricted stock units (RSUs) do not have exercise prices (see Note 16 - Equity Incentive Plan).

(2) It reflects the equity plan we assumed pursuant to the Neos Acquisition and restricted stock previously issued outside of the Aytu 2015 Plan (see Note 16 - Equity Incentive Plan).

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors. Our ability to pay dividends on our common stock is limited by restrictions under the terms of our credit facility with Avenue Capital. In addition, any future indebtedness that we may incur could preclude us from paying dividends. Investors should not purchase our common stock with the expectation of receiving cash dividends.

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.

OBJECTIVE

The purpose of the Management Discussion and Analysis (the "MD&A") is to present information that management believes is relevant to an assessment and understanding of our results of operations and cash flows for the fiscal year ended June 30, 2022 and our financial condition as of June 30, 2022. The MD&A is provided as a supplement to, and should be read in conjunction with, our financial statements and notes.

OVERVIEW

We are a commercial-stage pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products and developing therapeutics for rare pediatric-onset or difficult-to-treat diseases. We operate through two business segments (i) the BioPharma segment, consisting of various prescription pharmaceutical products sold through third party wholesalers (the Rx Portfolio"), and (ii) the Consumer Health segment, which consists of various consumer health products sold directly to consumers. We generate revenue by selling our products through third party intermediaries in our marketing channels as well as directly to our customers. We currently manufacture our products for the treatment of ADHD at our manufacturing facilities and use third party manufacturers for our other prescription and consumer health products. We also have two product candidates in development, AR101 (enzastaurin) for the treatment of VEDS and Healight (endotracheal light catheter) for the treatment the treatment of severe, difficult-to-treat respiratory infections.

We have incurred significant losses in each year since inception. Our net losses were $110.2 million and $58.3 million for the years ended June 30, 2022 and 2021, respectively. As of June 30, 2022 and 2021, we had an accumulated deficit of approximately $288.5 million and $178.3 million, respectively. We expect to continue to incur significant expenses in connection with our ongoing activities, including the integration of our acquisitions and development of our product pipeline.

SIGNIFICANT DEVELOPMENTS

Business Environment

The ongoing COVID-19 pandemic continues to impact the global economy and create economic uncertainties. We believe COVID-19 has negatively impacted the market for prescription products, disrupted the reliability of the supply chain, and impacted the ability and efficiency of conducting clinical trials. The extent to which COVID-19 continues to negatively impact our business in the future will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that may emerge concerning the severity of the new variants of coronavirus, the actions taken to contain the coronavirus or treat its impact, and the continued impact of each of these items on the economies and financial markets in the United States and abroad. While states and jurisdictions have rolled back stay-at-home and quarantine orders and reopened in phases, it is difficult to predict what the lasting impact of the pandemic will be, and if we or any of the third parties with whom we engage were to experience additional shutdowns or other prolonged business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could have a material adverse impact on our business, results of operation and financial condition. In addition, a recurrence or impact from new strains of COVID-19 cases

could cause other widespread or more severe impacts depending on where infection rates are highest. We will continue to monitor developments as we deal with the disruptions and uncertainties relating to the COVID-19 pandemic.

We have continued to experience significant inflationary pressure and supply chain disruptions related to the sourcing of raw materials, energy, logistics and labor during fiscal 2022. While we do not have sales or operations in Russia or Ukraine, it is possible that the conflict or actions taken in response, could adversely affect some of our markets and suppliers, economic and financial markets, costs and availability of energy and materials, or cause further supply chain disruptions. We expect that inflationary pressures and supply chain disruptions could continue to be significant across the business throughout the year.

Commercial Products

On March 23, 2022, our newly issued US patent No. 11,166,947 for Cotempla XR-ODT was listed in the U.S. FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations", commonly known as the "Orange Book." The Cotempla XR-ODT patent covers methods of use for the effective pediatric dosing of methylphenidate for the treatment of attention deficit hyperactivity disorder. The Orange Book listing extends the exclusivity period for Cotempla XR-ODT to 2038. Teva Pharmaceuticals USA, Inc. has the right to manufacture and market its generic version of Cotempla XR-ODT under its ANDA beginning on July 1, 2026, or earlier under certain circumstances.

Development Products

AR101

On December 7, 2021, the FDA granted ODD to AR101 for the treatment of Ehlers-Danlos Syndrome, a group of rare inherited connective tissue disorders that includes the severe subtype VEDS. The FDA grants ODD status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. ODD affords us with certain financial incentives to support clinical development and the potential for up to seven years of market exclusivity in the U.S. upon regulatory approval.

On December 13, 2021, the FDA cleared the IND application for AR101 in VEDS to enable the initiation of the AR101 PREVEnt Trial in VEDS. We are underway with preparation activities for our PREVEnt Trial, a randomized, double-blind, placebo-controlled clinical study evaluating once daily enzastaurin in the treatment of VEDS. The trial is expected to begin enrolling patients by early 2023.

On March 2, 2022, the European Commission granted orphan designation to AR101 (enzastaurin) for the treatment of Ehlers-Danlos Syndrome. The European Medicines Agency orphan designation affords us with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity.

On April 19, 2022, we were notified by the FDA that AR101 received Fast Track designation. Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. Fast Track addresses a broad range of serious conditions, and the request can be initiated by a pharmaceutical company at any time during the development process. FDA reviews the request and decides based on whether or not the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process.

Healight

In November 2021, we received U.S. Patent Number 11,179,575, titled "Internal Ultraviolet Therapy," which is the first issued patent protecting the Healight investigational device and covers methods of treating a patient for an

infectious condition inside the patient's body through the insertion of a UV-light-emitting delivery tube inside a respiratory cavity of the patient at specific UV-A light wavelengths. The term of this patent extends to August of 2040.

In April 2022, our preclinical pilot study showed that administration of Healight delayed the time to development of VAP in a novel porcine model. The proof-of-concept study was conducted at Hospital Clinic de Barcelona under the supervision of principal investigator Antonio Torres, M.D., Ph.D., FERS, FCCP, ATSF, Senior Consultant, Pulmonology Department - one of the only centers in the world with access to this well-characterized porcine model of VAP caused by oropharyngeal secretions colonized by Pseudomonas aeruginosa. In the study, administration of the Healight UV-A endotracheal catheter resulted in a 46% reduction in multidrug-resistant Pseudomonas aeruginosa (PA C1-17) versus controls following two separate 20-minute treatments. Based on these positive data, Hospital Clinic de Barcelona and we have initiated a second, larger porcine VAP study to guide the future development of Healight for patients with VAP.

Debt and Equity Financings

On January 26, 2022, we entered into the Avenue Capital Agreement with the Avenue Capital, pursuant to which Avenue Capital provided the Company and certain of its subsidiaries with a secured $15.0 million loan. The interest rate on the loan is the greater of the prime rate and 3.25%, plus 7.4%, payable monthly in arrears. The maturity date of the loan is January 26, 2025. The proceeds from the Avenue Capital Agreement were used towards the repayment of the Deerfield Facility, which was otherwise due and payable on May 11, 2022.

In connection with the Avenue Capital Agreement, we entered into an amendment to the Eclipse Loan Agreement. Pursuant to the amendment, the Company, among other things, extended the maturity date of the Eclipse Loan Agreement to January 26, 2025 and reduced the maximum availability under the Eclipse Loan Agreement from $25.0 million to $12.5 million minus a $3.5 million availability block.

On March 7, 2022, upon closing of an underwritten public offering, we raised gross proceeds of $7.6 million from the issuance of (i) 3,030,000 shares of our common stock, (ii) pre-funded warrants (the “Pre-Funded Warrants”) to purchase up to 3,030,000 shares of common stock, and (iii) common stock purchase warrants (the “Common Warrants”) to purchase up to 6,666,000 shares of common stock (the “March 2022 Offering”). We received $6.8 million in proceeds net of underwriting fees and other expenses. In April 2022, the pre-funded warrants were exercised in full.

In August 2022, upon the closing of an underwritten public offering, we raised proceeds of $10.0 million from the issuance of (i) 21,505,814 shares of our common stock, and, in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 1,750,000 shares of our common stock, and (ii) accompanying warrants (the "Common Warrants") to purchase 23,255,814 shares of our common stock (the "Offering") We received $9.1 million in proceeds net of underwriting fees and other expenses. In August 2022, the pre-funded warrants were exercised in full.

Discontinued Products

As part of our realization of post-acquisition synergies and product prioritization, we have implemented a portfolio rationalization plan whereby we will discontinue or divest five non-core products in our BioPharma segment: Cefaclor Oral Suspension, Flexichamber, Tussionex, Tuzistra XR, and ZolpiMist. These products, collectively, contributed $2.2 million in net revenue and $0.7 million in gross loss during the year ended June 30, 2022.

RESULTS OF OPERATIONS

Comparison of the years ended June 30, 2022 and 2021.

	Year Ended June 30,		
	2022	2021	Change
		(In thousands)	
Product revenue, net	$ 96,669	$ 65,632	$ 31,037
Cost of sales	44,386	36,432	7,954
Gross profit	52,283	29,200	23,083
Operating expenses			
Research and development	14,439	5,623	8,816
Advertising and direct marketing	19,589	20,568	(979)
Other selling and marketing	19,124	9,740	9,384
General and administrative	31,167	25,500	5,667
Acquisition related costs	—	2,919	(2,919)
Restructuring costs	—	4,886	(4,886)
Impairment expense	75,458	12,825	62,633
Amortization of intangible assets	4,067	6,009	(1,942)
Total operating expenses	163,844	88,070	75,774
Loss from operations	(111,561)	(58,870)	(52,691)
Other income (expense)			
Other (expense), net	(862)	(2,050)	1,188
Gain (loss) from contingent consideration	1,760	4,459	(2,699)
Gain (loss) on extinguishment of debt	169	(1,569)	1,738
Gain on derivative warrant liability	211	—	211
Total other income	1,278	840	438
Loss before income tax	(110,283)	(58,030)	(52,253)
Income tax (benefit) expense	(110)	259	(369)
Net loss	$ (110,173)	$ (58,289)	$ (51,884)

Product revenue.

	Year Ended June 30,		
	2022	2021	Change
		(In thousands)	
Net Revenue by product portfolio:			
ADHD Product Line	$ 42,855	$ 10,883	$ 31,972
Pediatric Product Line	16,084	12,437	3,647
Consumer Health Division	35,548	32,954	2,594
Others	2,182	9,358	(7,176)
Total net revenue	$ 96,669	$ 65,632	$ 31,037

During the year ended June 30, 2022, net product revenue increased by $31.0 million, or 47%, compared to the year ended June 30, 2021. The increase was primarily driven by net revenue generated from the ADHD product portfolio, which we acquired in March 2021. The increase in revenue from our consumer health products was attributable to the continued growth of the e-commerce portion of the business. These increases were partially offset by decreases in other revenues related to discontinued products.

Gross margin by product portfolio

	Year Ended June 30,		
	2022	2021	Change
		(In thousands)	
Gross margin by product line:			
ADHD Product Line	$ 21,927	$ 5,389	$ 16,538
Pediatric Product Line	12,970	9,812	3,158
Consumer Health Division	18,080	19,727	(1,647)
Others	(694)	(5,728)	5,034
Total gross margin	$ 52,283	$ 29,200	$ 23,083

Gross margins. During the year ended June 30, 2022, gross margins increased by $23.1 million, or 79%, compared to the year ended June 30, 2021. The increase was primarily driven by net revenue increases in revenue as described above. Gross margin percentage increased to 54% for the year ended June 30, 2022 compared to 44% for the same period in 2021. The improvement was primarily due improvements in gross margins in the ADHD and Pediatric product lines, a result of cost reduction efforts and greater volume, and the impairment of inventory during the year ended June 30, 2021. The reduction of gross margins in the Consumer Health Division was due to the growth of the e-commerce business, which generates lower gross margins than the direct to customer business. Others includes discontinued products described above and covid test kits for the year ended June 30, 2021.

Research and development

	Year Ended June 30,		
	2022	2021	Change
		(In thousands)	
Research and development:			
AR101	$ 10,673	$ 3,128	$ 7,545
ADHD	2,478	1,176	1,302
Healight	926	883	43
Others	362	436	(74)
Total Research and development	$ 14,439	$ 5,623	$ 8,816

During the year ended June 30, 2022, research and development expense increased by $8.8 million, or 157%, compared to the year ended June 30, 2021. AR101 spending primarily consists of costs associated with preparing for the PREVEnt registrational clinical trial and the $2.5 million and $1.5 million milestone payments due upon receiving ODD and Fast Track designations during fiscal 2022. Spending on the ADHD product portfolio primarily consists of medical monitoring costs and costs associated with post-marketing requirements. We expect spending will be subject to material fluctuations between periods based on the timing of activities, including clinical and pre-clinical trials, of each program.

Advertising and direct marketing

During the year ended June 30, 2022, advertising and direct marketing expenses decreased by $1.0 million, or 5%, compared to the year ended June 30, 2021. Advertising and direct marketing expenses include direct-to-consumer marketing, advertising, sales and customer support and processing fees related to our Consumer Health segment. The reduction was primarily due to our emphasis on the e-commerce business from the direct-to-consumer business. In general, the e-commerce business generates lower gross margin percentages, but incurs lower customer acquisition costs such as advertising and direct marketing.

Other selling and marketing

During the year ended June 30, 2022, other selling and marketing expense increased $9.4 million, or 96%, compared to the year ended June 30, 2021. The increases were primarily driven by the addition of the ADHD product portfolio and associated sales and marketing efforts in March 2021.

General and administrative

During the year ended June 30, 2022, general and administrative expense increased by $5.7 million or 22%, compared to the year ended June 30, 2021, respectively. The increases were primarily driven by the additional infrastructure and spending from the acquisition of Neos ("Neos Acquisition") in March 2021, partially offset by reduced spending by our Consumer Health segment.

Impairment expense

During the year ended June 30, 2022, we recognized total impairment expense of $75.5 million, consisting of (i) $65.8 million in goodwill, (ii) $7.1 million intangible assets, (iii) $2.0 million inventory, (iv) $0.4 million other assets and (v) $0.2 million property and equipment. The impairment expense related to write-down of assets was due to the discontinuation of commercializing certain products and products not marketed. See Note 8 – Goodwill and Other Intangible Assets in the accompanying consolidated financial statements for further information.

During the year ended June 30, 2021, we recognized impairment expense of $12.8 million related to impairment of the Tuzistra and Natesto licensed intangible asset, which were divested on March 31, 2021.

Amortization of intangible assets

During the year ended June 30, 2022, amortization expense of intangible assets, excluding amounts included in cost of sales, decreased by $1.9 million, or 32%, compared to the year ended June 30, 2021. The decrease was primarily related to licensed intangible assets that were being amortized during the year ended June 30, 2021 but have subsequently been divested or discontinued.

Other income/(expense), net

During the year ended June 30, 2022, other expense, net decreased by $1.2 million, or 58%, compared to the year ended June 30, 2021. The decreases were primarily due to proceeds from the Natesto divestiture for the year ended June 30, 2021, partially offset by increases in interest expense from our debt for the period ended June 30, 2022.

Gain (loss) from contingent consideration

During the year ended June 30, 2022, net gain from contingent consideration decreased by $2.7 million, or 61%, compared to the year ended June 30, 2021. The gain from contingent consideration included a $1.4 million gain from the reversal of contingent consideration liability related to Tuzistra and ZolpiMist. See Note 13 – Fair Value Considerations in the accompanying consolidated financial statements for further information.

Gain (Loss) on debt extinguishment

During the year ended June 30, 2022, we recognized $0.2 million gain from repayment of the Deerfield Facility. In the year ended June 30, 2021, we recognized $0.3 million loss from conversion of outstanding debt to our shares of common stock.

Gain on derivative warrant liability

During the year ended June 30, 2022, we recognized $0.2 million gain from change in fair value of warrants upon the reclassification from a liability to equity warrant. See Note 13 – Fair Value Considerations in the accompanying consolidated financial statements for further information.

Income tax benefit

The impairment of the BioPharma segment book goodwill decreased the net deferred tax liability by $0.1 million resulting in an income tax benefit of $0.1 million during the year ended June 30, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Cash Flows

The following table sets forth the primary sources and uses of cash for the periods indicated:

	Year Ended June 30,		Increase (Decrease)
	2022	2021	
		(In thousands)	
Net cash used in operating activities	$ (28,823)	$ (25,964)	$ (2,859)
Net cash used in investing activities	$ (3,248)	$ (2,782)	$ (466)
Net cash provided by financing activities	$ 1,530	$ 30,314	$ (28,784)

Net Cash Used in Operating Activities

Net cash used in operating activities during these periods primarily reflected our net losses, partially offset by changes in working capital and non-cash charges including goodwill and intangible asset write-down, inventory, changes in fair values of various liabilities, stock-based compensation expense, depreciation, amortization and accretion and other charges.

During fiscal 2022, net cash used in operating activities totaled $28.8 million. The use of cash was approximately $81.4 million less than the net loss primarily due to non-cash charges of depreciation, amortization and accretion, impairment of goodwill and intangible assets, stock-based compensation, inventory and other assets write-downs and loss on debt extinguishment. These charges were offset by gains from change in fair values of contingent consideration and contingent value rights. In addition, our use of cash decreased due to changes in working capital including decreases in accounts receivable, inventory and prepaids, offset by a decrease in accrued liabilities and accounts payable.

During fiscal 2021, net cash used in operating activities totaled $26.0 million. The use of cash was approximately $32.3 million less than the net loss due primarily to non-cash charges of depreciation, amortization and accretion, impairment of intangible assets, stock-based compensation, inventory write-down and loss on debt extinguishment. These charges were offset by gains from change in fair values of contingent consideration and contingent value rights. In addition, our use of cash decreased due to changes in working capital including decreases in accounts receivable and inventory, offset by a decrease in accounts payable.

Net Cash Used in Investing Activities

Net cash used in investing activities is generally related to our merger and acquisitions as well as purchase of assets to support our operations.

Net cash used in investing activities of $3.2 million during the year ended June 30, 2022, was primarily due to $3.2 million payment of contingent consideration.

Net cash used in investing activities of $2.8 million during the year ended June 30, 2021, was primarily due to $15.5 million principally for the pay down of debt of Neos as part of the Neos Acquisition, $2.3 million for the Rumpus asset acquisition and $0.7 million payment of contingent considerations, partially offset by $15.7 million cash acquired due to the Neos Acquisition.

Net Cash from Financing Activities

Net cash provided by financing activities of $1.5 million during the year ended June 30, 2022, was primarily from $15.0 million proceeds from long-term debt and $11.7 million net proceeds from issuance of our common stock, partially offset by $16.1 million full repayment of long-term debt, $4.1 million net reduction in our revolving loan, $4.4 million in payments of fixed payment arrangements and $0.5 million payment of debt issuance costs.

Net cash provided by financing activities of $30.3 million during the year ended June 30, 2021, was primarily from $28.8 million gross proceeds from public offering of our shares in December 2021, offset by $2.6 million in related offering costs and $16.3 million gross proceeds from issuance of our common stock under the ATM, offset by $2.3 million in related offering costs. These increases were partially offset by $6.1 million in payments of fixed payment arrangements, $2.7 million paydown on the revolving loan and $1.0 million repayment of term loans.

Capital Resources

Sources of Liquidity

We have obligations related to our loan agreements, contingent considerations related to our acquisitions, milestone payments for licensed products and manufacturing purchase commitments.

We finance our operations through a combination of sales of our common stock and warrants, borrowings under our line of credit facility and cash generated from operations.

Shelf Registrations

On September 28, 2021, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 7, 2021. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the “2021 Shelf”). As of June 30, 2022, approximately $92.4 million remains available under the 2021 Shelf.

On June 8, 2020, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on June 17, 2020. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the “2020 Shelf”). As of June 30, 2022, approximately $43.0 million remains available under the 2020 Shelf.

In June 2020, we initiated an at-the-market offering program ("ATM"), which allow us to sell and issue shares of our common stock from time-to-time. On June 2, 2021, we terminated our “at-the-market” sales agreement with a sales agent, and on June 4, 2021, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the “ATM Sales Agreement”) with a sales agent, pursuant to which we agreed to sell up to $30.0 million of our common stock from time to time in “at-the-market” offerings.

Since initiated in June 2020 through June 30, 2022, we issued a total of 5,524,326 shares of common stock for aggregate proceeds of $28.3 million before estimated offering costs of $2.8 million.

As of June 30, 2022, approximately $12.2 million of our common stock remained available to be sold pursuant to the ATM Sales Agreement.

Underwriting Agreements

On August 11, 2022, we closed on underwritten public offering, pursuant to which we sold an aggregate of (i) 21,505,814 shares of its common stock, (ii), pre-funded warrants to purchase 1,750,000 shares of its common stock, and (ii) accompanying warrants to purchase 23,255,814 shares of our common stock. The shares of common stock (or Pre-Funded Warrants) and the accompanying Common Warrants were issued separately but could only be purchased together in this Offering. The combined public offering price for each share of common stock and accompanying Common Warrant was $0.43, and the combined offering price for each Pre-Funded Warrant and accompanying Common Warrant is $0.429, which equals the public offering price per share of the common stock and accompanying Common Warrant, less the $0.001 per share exercise price of each Pre-Funded Warrant. The Pre-Funded Warrants were exercised in full in August 2022. The Common Warrants are exercisable at any time after the date of issuance for a period of five years from the date such Common Warrants are first exercisable. The number of shares of common stock issuable upon exercise of the Common Warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. The received gross proceeds of $10.0 million and net proceeds of approximately $9.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

On March 7, 2022, we closed on the March 2022 Offering, pursuant to which, we sold (i) 3,030,000 shares of our common stock, (ii) Pre-Funded Warrants to purchase up to 3,030,000 shares of common stock, and (iii) Common Warrants to purchase up to 6,666,000 shares of common stock. The shares of common stock and the Pre-Funded Warrants were each sold in combination with corresponding Common Warrants, with one Common Warrant to purchase 1.1 shares of common stock for each share of common stock or each Pre-Funded Warrant sold. The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and were exercised in full in April 2022. The Common Warrants have an exercise price of $1.30 per share of common stock and are exercisable six months after the date of issuance and have a term of five years from the date of exercisability. We raised gross proceeds of $7.6 million through the March 2022 Offering before commission and other costs of $0.8 million. The Pre-Funded Warrants and Common Warrants have a combined fair value of approximately $5.6 million and are classified as additional paid in capital in the stockholders' equity.

On December 10, 2020, we entered into an underwriting agreement, pursuant to which, we agreed to sell, in an upsized firm commitment offering, 4,166,667 shares of our common stock, to the underwriter at an offering price to the public of $6.00 per share, less underwriting discounts and commissions. In addition, pursuant to the underwriting agreement, we granted the underwriter a 30-day option to purchase up to an additional 625,000 shares of common stock at the same offering price to the public, less underwriting discounts and commissions. The underwriter exercised their over-allotment option in full, purchasing a total of 4,791,667 shares of common stock. We raised gross proceeds of $28.8 million through this offering. Offering costs totaled $2.6 million resulting in net cash proceeds of $26.2 million. In connection with the offering, we issued 311,458 underwriter warrants to purchase up to 311,458 shares of common stock. The exercise price per share of the underwriter warrants is $7.50 (equal to 125% of the public offering price per share for the shares of common stock sold in the offering) and the underwriter warrants have a term of five years from the date of effectiveness of the offering. The underwriter warrants are exercisable immediately. These warrants have a fair value of approximately $1.3 million and are classified as additional paid in capital in the stockholders' equity. Effective June 2, 2021, we terminated the underwriting agreement; pursuant to such termination, there will be no future sales of our common stock under this underwriting agreement.

Avenue Capital Agreement

On January 26, 2022, we entered into the Avenue Capital Agreement, pursuant to which the Company received $15.0 million loan. The interest rate on the loan is the greater of the prime rate and 3.25%, plus 7.4%, payable monthly in arrears. The maturity date of the loan is January 26, 2025. The proceeds from the Avenue Capital Agreement were used towards the repayment of outstanding debt.

In the event we prepay the outstanding principal prior to the maturity date, we will pay Avenue Capital a fee equal to (i) 3.0% of the loan if such event occurs on or before January 26 2023, (ii) 2.0% of the loan if such event occurs after January 26, 2023 but on or before January 26, 2024, and (iii) 1.0% of the loan if such event occurs after January 26,

2024 but before January 26, 2025. In addition, upon the payment in full of the obligations, we shall pay to Avenue Capital a non-refundable fee in the amount of $0.6 million ("Final Payment"). See Note 12 – Long-term Debt in the accompanying unaudited consolidated financial statements for further information.

Eclipse Loan Agreement

The Eclipse Loan Agreement, as amended, provides us with up to $12.5 million in Revolving Loans, of which up to $2.5 million may be available for short-term swingline loans, against 85% of eligible accounts receivable. The Revolving Loans bore interest at Secure Overnight Financing Rate ("SOFR"), plus 4.50% through April 2022. Beginning in May 2022 through maturity, the Revolving Loans bear interest at the Secured Overnight Financing Rate plus 4.50%. In addition, we are required to pay an unused line fee of 0.50% of the average unused portion of the maximum Revolving Loans amount during the immediately preceding month. Interest is payable monthly in arrears. The maturity date under the Eclipse Loan Agreement, as amended, is January 26, 2025.

In the event that, for any reason, all or any portion of the Eclipse Loan Agreement is terminated prior to the scheduled maturity date, in addition to the payment of all outstanding principal and unpaid accrued interest, we are required to pay a fee equal to (i) 2.0% of the Revolving Loans commitment if such event occurs on or before January 26, 2023, (ii) 1.0% of the Revolving Loans commitment if such event occurs after January 26, 2023 but on or before January 26, 2024, and (iii) 0.5% of the Revolving Loans commitment if such event occurs after January 26, 2024 but on or before January 26, 2025. We may permanently terminate the Eclipse Loan Agreement with at least five business days prior notice. See Note 11 – Line of Credit in the accompanying unaudited consolidated financial statements for further information.

Contractual Obligations, Commitments and Contingencies

As a result of our acquisitions and licensing agreements, we are contractually and contingently obliged to pay, when due, various fixed and contingent milestone payments. See Note 19 – Commitments and Contingencies in the accompanying unaudited consolidated financial statements for further information.

On May 12, 2022, the Company entered into an agreement with Tris to terminate the License, Development, Manufacturing and Supply Agreement dated November 2, 2018 (the "License Agreement"). Pursuant to such termination, the Company agreed to pay Tris a total of approximately $6 million to $9 million, which reduced our total liability for minimum payments by approximately $8.0 million from the original License Agreement. The settlement payment will be paid in three installments from December 2022 through July 2024.

Upon closing of the acquisition of a line of prescription pediatric products from Cerecor, Inc. in October 2019, we assumed payment obligations that require us to make fixed and product milestone payments. As of June 30, 2022, up to $6.3 million of fixed and product milestone payments remain.

In connection with the February 2020 acquisition of Innovus Pharmaceuticals, Inc. (the "Innovus Acquisition"), all of Innovus's shares were converted to our common stock and CVRs, which represents contingent additional consideration of up to $16.0 million payable to satisfy future performance milestones. As of June 30, 2022, up to $5.0 million of potential CVR milestone payments remain.

In connection with our Innovus Acquisition, we assumed a contingent obligation which required us to make milestone payment of $0.5 million, between fiscal year 2026 through fiscal year 2033 to Novalere, if and when certain levels of FlutiCare sales are achieved.

In connection with our acquisition of the Rumpus assets, upon satisfaction of milestones, we may be required to pay up to $67.5 million in regulatory and commercial-based earn-out payments to Rumpus. Under the licensing agreement with Denovo Biopharma LLC ("Denovo"), we are required to make a payment of $0.6 for a license fee in April 2022 and upon achievement of regulatory and commercial milestones, up to $101.7 million. Under the licensing agreement with Johns Hopkins University ("JHU"), upon achievement of regulatory and commercial milestone, we may

be required to pay up to $1.6 million to JHU. In fiscal 2022, two milestones payable to Rumpus were achieved totaling $4.0 million, which were paid in 2,188,940 shares of common stock and $2.6 million in cash.

CRITICAL ACCOUNTING ESTIMATES

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The preparation of our financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of any contingent assets and liabilities at the date of the financial statements, as well as reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on our historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 Summary of Significant Accounting policies to the notes to our audited financial statements included elsewhere in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

We generate revenue from product sales through our BioPharma segment and Consumer Health segment. We evaluate our contracts with customers to determine revenue recognition using the following five-step model: (1) identify the contract with the customer; (2) identify the performance obligations and if they are distinct; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) a performance obligation is satisfied.

Net product sales in the BioPharma segment consist of sales of prescription pharmaceutical products under the Rx Portfolio, principally to a limited number of wholesale distributors and pharmacies in the United States. Rx product revenue is recognized at the point in time that control of the product transfers to the customer in accordance with shipping terms (i.e., upon delivery), which is generally "free-on-board" destination when shipped domestically within the United States and "free-on-board" shipping point when shipped internationally consistent with the contractual terms.

The Company makes estimates of the net sales price, including estimates of variable consideration to be incurred on the respective product sales (known as "Gross to Net" adjustments). Estimating gross to net adjustments and applying the constraint on variable consideration requires the use of significant management judgment and other market data.

The Gross to Net adjustments include:

- *Savings offers* The Company offers savings programs for its patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted.
- *Prompt payment discounts* Prompt payment discounts are based on standard programs with wholesalers.
- *Wholesale distribution fees* Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers.
- *Rebates* The Rx Portfolio products are subject to commercial managed care and government managed Medicare and Medicaid programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals are estimated based on historical information from third-party providers.

- *Wholesaler chargeback* The Rx Portfolio products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to the Company.

- *Returns* Wholesalers' contractual return rights are limited to defective product, product that was shipped in error, product ordered by customer in error, product returned due to overstock, product returned due to dating or product returned due to recall or other changes in regulatory guidelines. The return policy for expired product allows the wholesaler to return such product starting six months prior to expiry date to twelve months post expiry date. The Company analyzes return data available from sales since inception date to determine a reliable return rate.

Savings offers, rebates and wholesaler chargebacks reflect the terms of underlying agreements, which may vary. Accordingly, actual amounts will depend on the mix of sales by product and contracting entity. Future returns may not follow historical trends. Our periodic adjustments of our estimates are subject to time delays between the initial product sale and ultimate reporting and settlement of deductions. We continually monitor these provisions and do not believe variances between actual and estimated amounts have been material.

A 10% increase or decrease in these estimates impacts net sales by a corresponding increase or decrease of approximately $17.0 million.

We generate Consumer Health Segment product revenue from sales of various consumer health products through e-commerce platforms and direct-to-consumer marketing channels utilizing our proprietary Beyond Human marketing and sales platform. Revenue is 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

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. Until objective and persuasive evidence exists that regulatory approval has been received and future economic benefit is probable, pre-launch inventories are expensed into research and development. Post-FDA approval, manufacturing costs for the production of our products are being capitalized into inventory. We periodically review the composition of our inventories in order to identify obsolete, slow-moving, excess or otherwise unsaleable items. Inventory items are written down to net realizable value in the period an impairment is identified. Net realizable value estimates are subject to projections of future plans, sales and price levels, which may vary from actual results.

We incurred charges of $1.7 million and $7.3 million to reduce the carrying value of inventory to net realizable value during the years ended June 30, 2022 and 2021, respectively, primarily as a result of the discontinuance of non-core products.

Stock-based compensation expense

Stock-based compensation awards, including stock options, restricted stock and restricted stock units are recognized in the statement of operations based on their fair values on the date of grant. We calculate the fair value of options using the Black-Scholes option pricing model. Restricted stock and restricted stock unit grants are valued based on the estimated grant date fair value of our common stock. The Black-Scholes option pricing model requires the input of subjective assumptions, including stock price volatility and the expected life of stock options. The application of this valuation model involves assumptions that are highly subjective, judgmental, and sensitive in the determination of compensation cost. The expected term of stock options is determined according to the "simplified method," which is the

midpoint between the vesting date and the end of the contractual term. The expected stock price volatility for stock option awards is based on our historical stock price volatility over the expected term. The risk-free rate is based on the U.S. Treasury yield curve in effect commensurate with the expected life assumption. We have not paid and do not anticipate paying cash dividends. Forfeitures are adjusted for as they occur.

There is a high degree of subjectivity involved when using option pricing models to estimate stock-based compensation. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models. Such estimates may not be indicative of the fair value that would be observed in a market transaction between a willing buyer and willing seller. Estimated option values increase and decrease as assumed volatility and estimated lives increase and decrease. If factors change and we employ different assumptions when valuing our options, the compensation expense that we record in the future may differ significantly from what we have historically reported. If significant forfeitures occur in the future, compensation expense may be significantly reduced in future reporting periods.

Impairment of Long-lived Assets

We assess impairment of long-lived assets annually and when events or changes in circumstances indicates that their carrying value amount may not be recoverable. Long-lived assets consist of property and equipment, net and goodwill and other intangible assets, net. 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) changes in business plans or (iv) expectations that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. If the estimated future undiscounted cash flows, excluding interest charges, from the use of an asset are less than the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value. Such estimates involve projections of future sales and costs, which may vary from actual results. Declines in the outlook for the related products, particularly soon after fair-value measurement upon acquisition or prior impairment, can negatively impact our ability to recover the carrying value and can result in an impairment charge.

During the year ended June 30, 2022, in connection with the decision to discontinue commercializing or divesting certain products within the BioPharma segment that have minimal revenue and gross margin contribution, the Company recorded $4.9 million impairment expense for the write-down of intangible assets consisting of (i) $2.6 million for AcipHex, (ii) $1.4 million for ZolpiMist, (iii) $0.5 million for Tussionex, (iv) $0.2 million for Cefaclor and (v) $0.2 million for the Neos tradename. Additionally, our Consumer Health segment recorded an impairment of $2.2 million related to products no longer being marketed and products that have been underperforming.

During the year ended June 31, 2021, the Company recorded $12.8 impairment expense in the BioPharma segment consisting of (1) $4.3 million in connection with the divestiture of Natesto and (2) $8.5 million for write-down of Tuzistra licensed asset. These products generated $0.4 million and $1.0 million of revenue during the years ended June 30, 2022 and 2021, respectively.

Goodwill

Goodwill is recorded as the difference between the fair value of the purchase consideration and the fair value of the net identifiable tangible and intangible assets acquired. As described in footnote 2 Summary of Significant Accounting Policies to our financial statements, Goodwill is reviewed for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount of an intangible asset may not be recoverable. If, after assessing events or circumstances, we determine it is more likely than not that the fair value of a reporting unit is less than its carrying amount, we perform a quantitative impairment test by comparing the fair value of the reporting unit with the carrying value. If the fair value of a reporting unit is less than the carrying amount, an impairment charge is recorded in the amount of the difference. The fair value of a reporting unit is estimated using a combination of a market multiple and a discounted cash flow approach. Determining the fair value of a reporting unit requires the use of estimates, assumptions and judgment. The principal estimates and assumptions that we use include prospective financial information (revenue growth, operating margins, and capital expenditures), future market conditions, weighted average costs of capital, a terminal growth rate, comparable multiples of publicly traded companies in our industry, and the

earnings metrics and multiples utilized. We believe that the estimates and assumptions used in impairment assessments are reasonable. We have determined that we have two reporting units that require periodic review for goodwill impairment, the BioPharma segment, and the Consumer Health segment.

During fiscal 2022, the Company's market capitalization significantly declined. The decline was considered a qualitative factor that led management to assess whether an impairment had occurred. Management's evaluation indicated that the goodwill related to one of its reporting units within the BioPharma segment and Consumer Health segment was potentially impaired and performed a quantitative impairment test. As a result, we recorded an impairment charge of $65.8 million for the year ended June 30, 2022.

Contingent Consideration

We estimate the fair value of contingent consideration liabilities related to business acquisitions 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.

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 re-measured for future expected payout as well as the increase in fair value due to the time value of money. These gains or losses, if any, are included as a component of operating cash flows.

These contingent liabilities are remeasured each period with changes in fair value recognized in income. Discounts associated with estimated probabilities of milestone achievements and projected revenues are subject to significant judgment.

Warrants

Equity classified warrants are valued using a Black-Scholes model at issuance and are not remeasured. Liability classified warrants are carried at fair value using lattice valuation model. Changes in the fair value of liability classified warrants in subsequent periods are recorded as a gain or loss on remeasurement and reported as a component of cash flows from operations. All of our liability-classified warrants expired in August 2022.

Research and Development

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. At each period end, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- vendors in connection with discovery and preclinical development activities;
- CROs in connection with preclinical studies and testing; and
- CMOs in connection with the process development and scale up activities and the production of materials.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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 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. Based on the evaluation of our disclosure controls and procedures as of June 30, 2022, our principal executive officer and principal financial officer concluded that our controls were operating effectively and present fairly, in all material respects, our financial position, results of operations, changes in stockholders' equity (deficit) and cash flows in conformity with GAAP.

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, 2022. 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, 2022, 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

No changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTION THAT PREVENT INSPECTIONS

Not applicable

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. Our Board of Directors is currently comprised of five members, who are elected annually to serve for one year or until their successor is duly elected and qualified, or until their earlier resignation or removal. We have two executive officers that serve at the discretion of the Board of Directors and are appointed by the Board of Directors.

Name	Age	Position
Joshua R. Disbrow	47	Chairman and Chief Executive Officer
Mark Oki	53	Chief Financial Officer, Secretary, and Treasurer
Gary V. Cantrell	67	Director
Carl C. Dockery	59	Director
John A. Donofrio, Jr.	54	Director
Vivian H. Liu	61	Director
Michael E. Macaluso	71	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 directors in other companies subject to the reporting requirements under the federal securities law.

Joshua R. Disbrow – Chairman and Chief Executive Officer

Mr. Disbrow has been employed by us since April 16, 2015 and a member of our Board of Directors since January 2016. Prior to the closing of the merger between Luoxis Diagnostics, Inc. and Vyrix Pharmaceuticals, Inc. that formed Aytu BioPharma, Mr. Disbrow was the Chief Executive Officer of Luoxis since January 2013. Mr. Disbrow jointly served as the Chief Operating Officer of Ampio Pharmaceuticals, Inc. ("Ampio") from December 2012 until April 2015. Prior to joining Ampio, he served as the Vice President of Commercial Operations at Arbor Pharmaceuticals, LLC ("Arbor"), 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 and to over $250 million in net sales in 2012. By the time Mr. Disbrow departed Arbor in late 2012, he handled 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 25 years in the pharmaceutical, diagnostic, and medical device industries and has held positions of increasing responsibility in sales, commercialization, 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 Inc., 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 member of our Board of Directors.

Mark K. Oki – Chief Financial Officer, Secretary, and Treasurer

Mr. Oki has served as our Chief Financial Officer since January 2022 and as our Secretary and Treasurer since May 5, 2022. From October 2015 through January 2022, Mr. Oki served as Chief Financial Officer of Vivus LLC, (formerly Vivus Inc.) a commercial-stage pharmaceutical company. Vivus was a Nasdaq listed company up to December 2020. From April 2006 to October 2015, Mr. Oki held several positions at Alexza Pharmaceuticals, Inc., a publicly listed specialty pharmaceutical company, most recently as Senior Vice President, Finance, Chief Financial Officer and Secretary. Before Alexza, Mr. Oki held roles of increasing responsibility at life science companies, Pharmacyclics, Inc. and Incyte Genomics, Inc. (now Incyte Corporation). Mr. Oki began his career in public accounting at Deloitte & Touche, LLP (now Deloitte). Mr. Oki received his degree in Business Administration – Accounting and graduated with honors from San Jose State University and is a Certified Public Accountant (inactive).

Gary V. Cantrell – Director

Mr. Cantrell joined our Board of Directors 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 executive consulting business as Principal of Averaden, LLC, where he has served since July 2015. Prior to his service at Averaden, LLC, Mr. Cantrell consulted exclusively with Mayne Pharma Group Limited ("Mayne") (ASX: MYX) as Business Development Executive focused on acquiring branded prescription assets for Mayne's U.S. Specialty Brands Division, a position he held from July 2015 to October 2017. Mr. Cantrell served as CEO of Yasoo Health Inc. ("Yasoo"), a global specialty nutritional company from 2007 through June 2015, highlighted by the sale of its majority asset AquADEKs to Actavis Generics 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 Inc., 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, 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 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 member of our Board of Directors.

Carl C. Dockery – Director

Mr. Dockery joined our Board of Directors 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 since 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. From September 2014 through September 2019, Mr. Dockery served as a director of CytoDyn Inc. (OTCQB: CYDY), and a publicly-traded biotechnology company focused on the development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV and cancers. 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 member of our Board of Directors.

John A. Donofrio, Jr.

Mr. Donofrio joined our Board of Directors in July 2016. He is a senior pharmaceutical executive with over 30 years of experience in the industry across a broad range of areas, including President, Chief Financial Officer, and Chief Operating Officer positions. Mr. Donofrio has significant finance experience in consolidated financial reporting, international accounting and internal controls, financial systems development and implementation, cost accounting, inventory management, supply chain, transfer pricing, budget and forecast planning, integration of mergers and acquisitions and business development. Since March 2022 Mr. Donofrio has served as Executive Vice President, Chief Operating Officer of Novan Inc., a publicly held specialty dermatology company, and as President of Novan Inc.'s wholly owned subsidiary EPI Health, a specialty pharmaceutical company commercializing products in the dermatology market. From March 2019 until its acquisition by Novan, Inc in March 2022, Mr. Donofrio served as EPI Health's President. Mr. Donofrio previously served as Chief Financial Officer and Head of Business Development at TrialCard from March of 2018 to March 2019. TrialCard is a technology-driven pharmaceutical services company providing patient access and support programs to the pharmaceutical and biotechnology industries. Prior to joining TrialCard, Mr. Donofrio was the Chief Financial Officer and Head of North American Business Development for Merz North America, or Merz, from August 2013 to March 2018. Merz is a specialty healthcare company that develops and commercializes innovative treatment solutions in aesthetics, dermatology and neurosciences in the United States and Canada. At Merz, Mr. Donofrio was accountable for financial performance, cost management, business development and strategic business

planning and analysis for the finance organization in North America. Prior to joining Merz, Mr. Donofrio served as Vice President, Stiefel Global Finance, U.S. Specialty Business and Puerto Rico for Stiefel, a GlaxoSmithKline plc company from July 2009 to July 2013. In that role, Mr. Donofrio was responsible for the financial strategy, management reporting, and overall control framework for the Global Dermatology Business Unit. Mr. Donofrio served as a director of Vyrix from February 2014 to April 2015. Mr. Donofrio holds a degree in Accounting from North Carolina State University. Mr. Donofrio's broad executive leadership experience and financial expertise along with experience in the pharmaceutical industry led to the conclusion that he should serve as a member of our Board of Directors.

Vivian H. Liu

Ms. Liu joined our Board of Directors in July 2022. Ms. Liu currently serves as Head of Corporate Affairs for PREMIA Holdings (HK) Limited, a developer of clinical-genomic oncology databases and service provider to pharmaceutical companies seeking to operate clinical trials throughout Asia. Prior to joining PREMIA, Ms. Liu served in various roles, including as a member of Board of Directors and President, Chief Executive Officer and Chief Financial Officer for Innovus Pharmaceuticals, Inc., a publicly listed consumer healthcare company acquired by Aytu BioPharma in February 2020. Prior to Innovus, she served as the President and Chief Executive Officer of FasTrack Pharmaceuticals, Inc. Ms. Liu is an independent board member and Chair of the Audit Committee for ThermoGenesis Holdings Inc., a publicly listed cell therapy company. From 2017-2018, she served as the Chief Operating Officer and a member of the Board of Directors of ThermoGenesis' predecessor company, Cesca Therapeutics, Inc. Previously, Vivian served as Managing Director of OxOnc Services Company, an oncology development company, and prior to that, Ms. Liu co-founded and served as President, Chief Executive Officer, and board director of NexMed, Inc., a drug development company which was later renamed Apricus BioSciences. Prior to her appointment as President of NexMed, Ms. Liu served in several executive capacities, including as Executive Vice President, Chief Operating Officer, Chief Financial Officer and Vice President of Corporate Affairs. Ms. Liu has an M.P.A. from the University of Southern California and a B.A. from the University of California, Berkeley. Ms. Liu's experience in executive management within the pharmaceutical industry, as a director of a publicly traded biotech company and in corporate finance led to the conclusion that he should serve as a member of our Board of Directors.

Michael E. Macaluso – Director

Mr. Macaluso joined our Board of Directors in April 2015. Mr. Macaluso was a member of Ampio's board of directors from March 2010 through 2022 and Ampio's Chief Executive Officer from January 2012 through November 2021. 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 within the pharmaceutical industry, monetizing company opportunities, and corporate finance led to the conclusion that he should serve as a member of our Board of Directors.

Family Relationships

Jarrett T. Disbrow, our Executive Vice President, Corporate Operations, is the brother of Joshua R. Disbrow, our Chairman and Chief Executive Officer. There are no other family relationships among or between any of our current or former executive officers and directors.

Involvement in Certain Legal Proceedings

Mr. Oki was the Chief Financial Officer of Vivus, Inc.at the time a Chapter 11 petition was filed under the Federal bankruptcy laws in July 2020.

Our directors or executive officers have not 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. Dockery and Mr. Macaluso. Our Compensation Committee consists of Mr. Macaluso (Chair), Mr. Cantrell, Mr. Dockery, and Mr. Donofrio. Our Nominating and Governance Committee consists of Mr. Dockery (Chair), Mr. Cantrell and Mr. Donofrio. The independence of our directors is discussed in Part III, Item 13 under the caption "Director Independence."

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

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

Stockholder Proposals

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

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

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

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

In accordance with Item 402 of Regulation S-K promulgated by the SEC, we are required to disclose certain information regarding the makeup of and compensation of our Company's 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 for work required for a company of our size and scope;
- compensation should align the executive officers' 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, 2020, consists of: an annual cash retainer of $70,000 for the non-executive Board chair, $40,000 for each other director, $20,000 for each audit committee and compensation committee chair, $10,000 for nominating and governance committee chair, and $10,000 for each other committee member of the audit and compensation committees and $5,000 for each other committee member of the nominating and governance committee; a grant of 6,500 restricted shares of stock or restricted stock units upon appointment to the Board; and an annual stock option grant of 1,500 shares thereafter.

The following table provides information regarding all compensation paid to non-employee directors of Aytu during the fiscal year ended June 30, 2022.

Name	Fees Earned or Paid in Cash	All Other Compensation	Total
Gary V. Cantrell (1)(2)	$ 55,000	$ —	$ 55,000
Carl C. Dockery (1)(2)	$ 70,000	$ —	$ 70,000
John A. Donofrio Jr. (1)(2)	$ 75,000	$ —	$ 75,000
Michael E. Macaluso (1)(2)	$ 70,000	$ —	$ 70,000

(1) As of June 30, 2022, the number of restricted shares held by each non-employee director was as follows: 203,071 restricted shares for Mr. Cantrell; 203,071 restricted shares for Mr. Dockery; 203,071 restricted shares for Mr. Donofrio; 208,071 restricted shares for Mr. Macaluso.

(2) As of June 30, 2022, the number of stock options held by each non-employee director was as follows: (i) 4,005 shares for Mr. Dockery; (ii) 4,004 shares for Mr. Donofrio; (iii) 4,012 shares for Mr. Macaluso; and (iv) 2,004 shares for Mr. Cantrell.

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, 2022 and 2021 to each of the following named executive officers.

Name and Principal Position (a)	Year (b)	Salary ($) (c)	Bonus ($) (d)	Stock Award ($) (e)	Option Award ($)(1) (f)	Non-Equity Incentive Plan Compensation ($) (g)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($) (h)	All Other Compensation ($) (i)	Total ($) (j)
Named Executive Officers:									
Joshua R. Disbrow									
Chief Executive Officer	2022	$ 567,308	$ —	$ —	$ —	—	—	—	$ 567,308
since December 2012	2021	$ 545,000	$ 462,203	$ 5,192,000	$ —	—	—	—	$ 6,199,203
Mark Oki (2)									
Chief Financial Officer, Secretary and Treasurer since January 2022	2022	$ 167,596	$ 50,000	$ 135,000	$ —	$ —	$ —	$ —	$ 352,596
Richard Eisenstadt (3)									
Former Chief Financial Officer, Secretary and Treasurer, resigned in December 2021	2022	$ 269,231	$ 61,660	$ —	$ —	$ —	$ —	$ —	$ 330,891
	2021	$ 151,934	$ 175,000	$ 455,947	$ —	$ —	$ —	$ —	$ 782,881

(1) Option awards are reported at fair value at the date of grant.

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 our 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 the Company and our stockholders. No interest is paid on amounts reimbursed to the executives.

Outstanding Equity Awards at Fiscal Year-End 2022

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2022.

	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	5,000	5,000	—	$ 14.50	6/8/2030	—	$ —	—	$ —
Chief Executive Officer	13	—	—	3,280.00	11/11/2025	—	—	—	—
	15	—	—	3,280.00	7/7/2026	—	—	—	—
	—	—	—	—	—	750	518	—	—
	—	—	—	—	—	44,550	30,740	—	—
	—	—	—	—	—	533,360	368,018	—	—
	—	—	—	—	—	22,500	15,525	—	—
	—	—	—	—	—	48	33	—	—
Total	**5,028**	**5,000**	**—**	**$**		**601,208**	**$ 414,834**	**—**	**$ —**
Mark Oki	—	—	—	$ —	—	100,000	$ 69,000	—	$ —
Chief Financial Officer									
Total	**—**	**—**	**—**	**$**		**100,000**	**$ 69,000**	**—**	**$ —**

(1) Based on $0.69 per share which was the closing price of our common stock on NASDAQ on June 30, 2022, the last trading day of that fiscal year.

Employment Agreements

Joshua R. Disbrow Agreement

We entered into an employment agreement with Joshua R. Disbrow in connection with his employment as our Chief Executive Officer. The agreement was 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 was entitled to receive $330,000 in annual salary, plus a discretionary performance bonus with a target of 125% of his base salary. Mr. Disbrow was and continues to be 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 the compensation committee of the Board of Directors amended the employment agreements with Mr. Disbrow with the following material terms:

- 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;

- Granted 800,000 shares of restricted stock on the terms set forth in a separate restricted stock agreement.

On April 12, 2021, we entered into a second amendment to the employment agreement with Mr. Disbrow (the "CEO Second Amendment"). The CEO Second Amendment was approved by the compensation committee of our Board of Directors on March 14, 2021. The material terms of the CEO Second Amendment are as follows:

- Extend term of the CEO Employment Agreement to a term expiring 24 months from the date of the CEO Second Amendment.
- Grant of restricted stock equal to 3% of our issued and outstanding stock as of March 19, 2021 and an additional future grant of 2% if certain performance standards are satisfied, as determined by the compensation committee of the Board.
- Increase severance payment upon termination without cause or for good reason, as those terms are defined in the CEO Employment Agreement, to 2.5 times base salary; and
- Update the Change in Control definition to be consistent with the "Sale Event" definition in the restricted stock agreement.

Mark K. Oki Agreement

On January 17, 2022, Mark K. Oki was appointed as our Chief Financial Officer pursuant to an employment agreement with an effective date of January 17, 2022 (the "Oki Employment Agreement"). Under the Oki Employment Agreement Mr. Oki will receive:

- An annual base salary of $415,000, plus a target bonus of 40% of the base salary if certain performance milestones are met;
- A signing bonus of $50,000;
- Reimbursements of reasonable expenses associated with relocating to the Denver, Colorado area;
- A restricted stock grant of 100,000 shares of our common stock, subject to certain vesting provisions set forth therein;
- Eligibility to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans;
- Upon a termination without cause by the Company or for good reason, as those terms are defined in the Oki Employment Agreement, by Mr. Oki, a severance payment equal to his base salary plus any earned incentive compensation, as well as a continuation of our portion of COBRA payments for a period of 12 months and vesting of any issued restricted stock; and
- Upon a change in control, as defined in the Oki Employment Agreement, a payment equal to one time the base salary and the target annual incentive bonus compensation for the then-current year, plus 12 months of COBRA payments and accelerated vesting of all stock-based awards.

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 Mark Oki had a Change in Control occurred as of June 30, 2022, would be the acceleration of the vesting of all equity securities held by them at that date. On June 30, 2022, 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 August 31, 2022 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 August 31, 2022. The percentage ownership information shown in the table is based upon 62,432,727 shares of common stock outstanding as of August 31, 2022.

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, 2022. 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 BioPharma, Inc., 373 Inverness Parkway, Suite 206, Englewood, Colorado 80112.

	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or more Beneficial Owners		
Heights Capital Management, Inc. (1)	3,400,000	5.45 %
Non-employee Directors		
Cantrell, Gary(2)	206,093	*
Dockery, Carl(3)	208,077	*
Donofrio, John(4)	208,076	*
Liu, Vivian(5)	6,500	*
Macaluso, Michael(6)	212,091	*
Named Officers		
Disbrow, Joshua(7)	905,415	1.45 %
Mark Oki(8)	100,000	*
All directors and executive officers as a group, including those named above (seven persons)	1,846,252	2.96 %

* Represents beneficial ownership of less than 1%.

(1) The number of shares is from a schedule 13G filed by Height's Capital Management Inc. ("Heights Capital") and CVI Investments, Inc. ("CVI") filed with the SEC on August 15, 2022. Based on such filing, Heights Capital and CVI are deemed to have the voting and dispositive power with respect to 3,400,000 shares of common stock. Heights Capital have their principal business office at 101 California Street, Suite 3250, San Francisco, California 94111. CVI have their principal business office at P.O. Box 309GT, Ugland House, South Church Street, George Town, Grand Cayman, KY1-1104, Cayman Islands.
(2) Consists of (i) 79,264 shares of common stock, (ii) 124,825 unvested restricted shares, and (iii) 2,004 shares of common stock issuable upon the exercise of vested options.
(3) Consists of (i) 78,247 shares of common stock, (ii) 124,825 unvested restricted shares, and (iii) 4,005 shares of common stock issuable upon the exercise of vested options, (iv) 1,001 shares of common stock 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.
(4) Consists of (i) 78,246 shares of common stock, (ii) 124,825 unvested restricted shares, (iii) 4,004 shares if common stock issuable upon the exercised of vested options.
(5) Consists of 6,500 unvested restricted shares.
(6) Consists of (i) 78,254 shares of common stock, (ii) 129,825 unvested restricted shares, and (iii) 4,012 shares of common stock issuable upon the exercise of vested options.
(7) Consists of (i) 362,968 shares of common stock, (ii) 534,538 unvested restricted shares, (iii) 5,653 shares of common stock issuable upon the exercise of vested options, and (iv) 2,256 shares of common stock issuable upon the exercise of warrants. Does not include 116 shares of common stock 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.
(8) Consists of 100,000 shares of unvested restricted shares.

ITEM 13. CERTAIN RELATIONSHIPS, RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Party Transactions

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

- the amounts involved exceeded or will exceed $120,000; and

- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Jarret T. Disbrow, the brother of Joshua R. Disbrow, our Chief Executive Officer, is employed by us as Executive Vice President, Corporate Operations. His total annual salary and other cash compensation was approximately $448,400, which consists of $350,000 base salary plus $98,400 cash bonus during the year ended June 30, 2022, and he receives benefits consistent with other employees serving in the same capacity.

Review, Approval or Ratification of Transactions with Related Persons

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

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

Director Independence

Our common stock is listed on the NASDAQ Capital Market. Therefore, we must comply with the exchange rules regarding director independence. Audit Committee members must satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, for listed companies. In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries; or (2) be an affiliated person of the listed company or any of its subsidiaries.

Five of our six 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, 2022.

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,	
	2022	2021
	(In thousands)	
Audit fees	$ 547	$ 216
Audit related fees*	32	63
Total fees	$ 579	$ 279

* Audit-related fees for both fiscal year 2022 and 2021 were comprised of fees related to registration statements, including S-3, S-4 and S-8 filings, our registered offerings, and at-the-market (ATM) offerings.

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 the Consolidated Financial Statements found on page F-1.

- Reports of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets as of June 30, 2022 and 2021
- Consolidated Statements of Operations for the years ended June 30, 2022 and 2021
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2022 and 2021
- Consolidated Statements of Cash Flows for the years ended June 30, 2022 and 2021
- Notes to Consolidated 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	09/18/19	2.1	
2.2	Asset Purchase Agreement, dated October 10, 2019, by and between Aytu Bioscience, Inc. and Cerecor Inc.	8-K	10/15/19	2.1	
2.3	Agreement and Plan of Merger, dated as of December 10, 2020, by and among Aytu BioScience, Inc., Neutron Acquisition Sub, Inc. and Neos Therapeutics, Inc.	8-K	12/10/20	2.1	
2.4	Asset Purchase Agreement, dated April 12, 2021, by and among Aytu BioPharma, Inc., Rumpus VEDS LLC, Rumpus Therapeutics LLC, Rumpus Vascular LLC, Christopher Brooke and Nathaniel Massari.	10-Q	05/17/21	2.4	
3.1	Certificate of Incorporation effective, June 3, 2015.	8-K	06/09/15	3.1	
3.2	Certificate of Amendment of Certificate of Incorporation, effective June 1, 2016.	8-K	06/02/16	3.1	
3.3	Certificate of Amendment of Certificate of Incorporation, effective June 30, 2016.	8-K	07/01/16	3.1	
3.4	Certificate of Amendment of Certificate of Incorporation, effective August 25, 2017.	8-K	08/29/17	3.1	
3.5	Certificate of Amendment to the Restated of Certificate of Incorporation, effective August 10, 2018.	8-K	08/10/18	3.1	
3.6	Certificate of Amendment to the Restated Certificate of Incorporation, effective December 8, 2020.	8-K	12/08/20	3.1	
3.7	Certificate of Amendment of Certificate of Incorporation, effective March 22, 2021.	8-K	03/22/21	3.1	
3.8	Amended and Restated Bylaws.	8-K	05/09/22	3.1	
4.1	Form of Common Stock Purchase Warrant.	S-1	02/27/18	4.8	
4.2	Form of Placement Agent Common Stock Purchase Warrant.	8-K	03/13/20	4.2	
4.3	Form of Common Stock Purchase Warrant.	8-K	03/13/20	4.1	
4.4	Form of Common Stock Purchase Warrant.	8-K	03/20/20	4.1	
4.5	Form of Placement Agent Common Stock Purchase Warrant.	8-K	03/20/20	4.2	
4.6	Form of Wainwright Warrant.	8-K	07/02/20	4.1	
4.7	Form of Prefunded Common Stock Purchase Warrant.	8-K	03/04/22	4.1	
4.8	Form of Common Stock Purchase Warrant.	8-K	03/04/22	4.2	
4.9	Description of Securities				X
10.1	Registration Rights Agreement dated July 27, 2016, by and between Aytu BioScience, Inc. and Lincoln Park Capital Fund, LLC.	8-K	07/28/16	10.2	
10.2	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	07/27/17	10.1	

10.3	Registration Rights Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	08/16/17	10.2
10.4	Warrant Exercise Agreement dated March 23, 2018.	8-K	03/28/18	10.1
10.5	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
10.6	Common Stock Purchase Warrant.	10-Q	02/07/19	10.5
10.7	License, Development, Manufacturing and Supply Agreement, dated November 2, 2018.	10-Q	02/07/19	10.2
10.8	Second Amendment to Lease Agreement, dated April 4, 2019.	10-Q	05/14/19	10.3
10.9	Employment Agreement with Joshua R. Disbrow, dated April 16, 2019.	10-Q	05/14/19	10.1
10.10	Amended and restated License and Supply Agreement with Acerus Pharmaceuticals, dated July 29, 2019.	8-K	08/02/19	10.1
10.11	Form of Contingent Value Rights Agreement.	8-K	09/18/19	10.1
10.12	Loan and Security Agreement, by and between Neos Therapeutics, Inc., Neos Therapeutics Brands, LLC, and Neos Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, LLC, and Encina Business Credit, LLC, dated October 2, 2019.	8-K	10/3/2019	10.1
10.13	Registration Rights Agreement, dated October 11, 2019.	8-K	10/15/19	10.3
10.14	First Amendment to Asset Purchase Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.1
10.15	Registration Rights Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.2
10.16	Transition Services Agreement, dated November 1, 2019.	8-K	11/04/19	10.7
10.17	Consent and Limited Waiver Agreement, dated November 1, 2019.	8-K/A	11/04/19	10.6
10.18	Consent and Limited Waiver Agreement, dated November 1, 2019.	8-K/A	11/07/19	10.6
10.19	Waiver and Amendment to the July 29, 2019 Amended and Restated License and Supply Agreement, dated November 29, 2019.	8-K	12/02/19	10.1
10.20	Form of Restricted Stock Cancelation and Exchange Agreement.	8-K	07/02/20	10.1
10.21	First Amendment to Amended Employment Agreement with Joshua R. Disbrow dated July 1, 2020.	10-K	10/06/20	10.62
10.22	Commitment Letter, dated as of December 10, 2020, by and among Aytu BioScience, Inc., Neos Therapeutics, Inc. and Encina Business Credit, LLC	8-K	12/10/20	10.3
10.23	Consent, Waiver and Amendment No. 1 to Loan and Security Agreement, by and among Aytu BioScience, Inc., Neos Therapeutics, Inc., Neos Therapeutics Brands, LLC, Neos	8-K	03/22/21	10.2

	Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, LLC, and Encina Business Credit, LLC, dated March 19, 2021.				
10.24	Termination and Transition Agreement between Aytu BioPharma, Inc. and Acerus Pharmaceuticals Corporation, dated March 31, 2021.	10-Q	05/17/21	10.9	
10.25	Second Amendment to Employment Agreement with Joshua R. Disbrow dated April 7, 2021.	10-Q	05/17/21	10.11	
10.26	Employment Agreement between Aytu BioPharma, Inc. and Christopher Brooke, dated April 12, 2021.	10-Q	05/17/21	10.13	
10.27	Option Agreement between Rumpus VEDS, LLC and Denovo Biopharma LLC, dated December 21, 2019.	10-Q	05/17/21	10.14	
10.28	Exclusive License Agreement between Rumpus VEDS, LLC and Johns Hopkins University, dated December 20, 2019.	10-Q	05/17/21	10.15	
10.29	Controlled Equity Offering℠ Sales Agreement, dated June 4, 2021, by and between the registrant and Cantor Fitzgerald & Co.	8-K	06/04/21	1.1	
10.30	Asset Purchase Agreement, dated July 1, 2021 by and between Aytu BioPharma, Inc. and UAB "Caerus Biotechnologies."	10-K	9/28/2021	10.79	
10.31	Termination Agreement, dated June 29, 2021 by and between Aytu BioPharma, Inc. and Avrio Genetics, LLC.	10-K	9/28/2021	10.80	
10.32†	Employment Agreement between Aytu BioPharma, Inc. and Mark Oki, effective January 17, 2022.	10-Q	02/14/22	10.1	
10.33†	Restricted Stock Award Agreement between Aytu BioPharma, Inc. and Mark Oki, effective January 17, 2022.	10-Q	02/14/22	10.2	
10.34&	Loan and Security Agreement dated January 26, 2022 between the registrant and the Avenue Capital Lenders and Avenue Capital Agent.	10-Q	02/14/22	10.3	
10.35&	Consent, Joinder and Second Amendment to Loan and Security Agreement dated January 26, 2022 between the registrant and Eclipse Business Capital LLC.	10-Q	02/14/22	10.4	
10.36	Registration Rights Agreement dated January 26, 2022 between Aytu and each of the warrant holders.	10-Q	02/14/22	10.5	
10.37&	Form of Warrant.	10-Q	02/14/22	10.6	
10.38#&	Settlement and Termination of License Agreement between the Registrant and TRIS Pharma, Inc., dated May 12, 2022.	10-Q	05/16/22	10.1	
21.1	List of Subsidiaries				X
23.1	Consent of Plante and Moran, Independent Registered Public Accounting Firm				X
24.1	Power of Attorney (contained on signature page hereto)				X
31.1	Certificate of the Chief Executive Officer of Aytu BioScience, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certificate of the Chief Financial Officer of Aytu BioScience, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X

32.1	Certificate of the Chief Executive Officer and the Chief Financial Officer of Aytu BioScience, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101 INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.	X
101 SCH	Inline XBRL Taxonomy Schema Linkbase Document	X
101 CAL	Inline XBRL Taxonomy Calculation Linkbase Document	X
101 DEF	Inline XBRL Taxonomy Definition Linkbase Document	X
101 LAB	Inline XBRL Taxonomy Labels Linkbase Document	X
101 PRE	Inline XBRL Taxonomy Presentation Linkbase Document	X
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	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.

& Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit (indicated by asterisks) have been omitted as the registrant has determined that (1) the omitted information is not material and (2) the omitted information would likely cause competitive harm to the registrant if publicly disclosed.

ITEM 16. FORM 10-K SUMMARY

None

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 BIOPHARMA, INC.

Date: September 27, 2022

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

POWER OF ATTORNEY

We the undersigned directors and officers of Aytu BioPharma, Inc. (the "Company"), hereby severally constitute and appoint Joshua R. Disbrow and Mark Oki, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, to file any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities indicated, on September 27, 2022.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chairman and Chief Executive Officer *(Principal Executive Officer)*
/s/ Mark K. Oki Mark K. Oki	Chief Financial Officer *(Principal Financial and Accounting Officer)*
/s/ Gary V. Cantrell Gary V. Cantrell	Director
/s/ Carl C. Dockery Carl C. Dockery	Director
/s/ John A. Donofrio, Jr. John A. Donofrio, Jr.	Director
/s/ Vivian H. Liu Vivian H. Liu	Director
/s/ Michael E. Macaluso Michael E. Macaluso	Director

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS
AYTU BIOPHARMA, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors
Aytu BioPharma, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Aytu BioPharma, Inc. (the "Company") as of June 30, 2022 and 2021; the related consolidated statements of operations, stockholders' equity, and cash flows for each of 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, 2022 and 2021, 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.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the accompanying consolidated financial statements, the Company's operations have historically consumed cash and are expected to continue to consume cash, which raises substantial doubt about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans in regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Goodwill and Intangibles – Refer to Notes 2 and 8 to the consolidated financial statements

Critical Audit Matter Description

The Company's evaluation of goodwill for impairment involves comparing the carrying value of each reporting unit to the estimated fair value of the reporting unit. The Company's determination of estimated fair value of the reporting unit is determined by the income approach and market approach. The determination of the estimated fair value requires management to make significant estimates and assumptions related to the valuation of the reporting unit. Management evaluates the recoverability of indefinite-lived intangible assets by comparing the fair value of the assets to their carrying values. Recoverability of definite-lived intangible assets is determined by comparing their carrying value to the forecasted undiscounted cash flows associated with the assets. If the evaluation of the forecasted cash flows indicates that the carrying value of the assets is not recoverable, the assets are written down to their fair value using the income approach. The Company's consolidated goodwill and intangible assets balance was zero and $70.6M, respectively, as of June 30, 2022. During the year ended June 30, 2022, the company recorded a $65.8 million impairment related to goodwill and $9.7 million impairment related to intangible assets.

We identified the valuation of goodwill and intangible assets as a critical audit matter because of the significant estimates and assumptions management makes to estimate their fair value. These assumptions included revenue growth rates, forecasted EBITDA margins, and the selection of a discount rate. These assumptions are affected by expectations about future market or economic conditions. Changes in these assumptions could have a significant impact the either the goodwill or intangible impairment charge, or both. Our performance of audit procedures to evaluate the assumptions required a high degree of auditor judgment and an increased extent of audit effort, including the need to involve our fair value specialists.

How the Critical Audit Matter was Addressed in the Audit

Our audit procedures related to the estimated recoverability of Goodwill and intangible assets focused on revenue growth rates, gross margin, and the selection of the discount rate and included the following procedures, among others:

- We obtained an understanding of management's process to determine recoverability of goodwill and intangible assets and ensure the accuracy of key data used in their estimation process. We also evaluated the design of key controls used by management to develop their fair value estimates.
- We evaluated management's knowledge and skill to accurately forecast net sales and earnings.
- We assessed the reasonableness of management's forecast by comparing the forecasted revenue growth rates and gross margins used to Aytu BioPharma's historical results and internal communications to management and the board of directors.
- With the assistance of our internal valuation specialists, we assessed the sensitivity of the Company's impairment conclusions to changes in the forecasts, discount rates, and forecasted EBITDA margins. We evaluated the assumptions used by management, including testing the underlying source information and the mathematical accuracy of the calculations by developing a range of independent estimates and comparing those to the rates, including weighted average cost of capital and discount rates, selected by management.

/s/ Plante & Moran, PLLC

Denver, Colorado

September 27, 2022

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

AYTU BIOPHARMA, INC.
Consolidated Balance Sheets
(In thousands, except shares and per-share)

	June 30, 2022	June 30, 2021
Assets		
Current assets		
Cash and cash equivalents	$ 19,360	$ 49,649
Restricted cash	—	252
Accounts receivable, net	21,712	28,176
Inventory, net	10,849	16,339
Prepaid expenses	7,375	9,780
Other current assets	633	1,038
Total current assets	59,929	105,234
Property and equipment, net	3,025	5,140
Operating lease right-of-use asset	3,271	3,563
Intangible assets, net	70,632	85,464
Goodwill	—	65,802
Other non-current assets	766	465
Total non-current assets	77,694	160,434
Total assets	$ 137,623	$ 265,668
Liabilities		
Current liabilities		
Accounts payable and other	$ 10,987	$ 19,255
Accrued liabilities	44,187	57,234
Short-term line of credit	3,813	7,934
Current portion of debt	96	16,668
Other current liabilities	5,359	8,347
Total current liabilities	64,442	109,438
Debt, net of current portion	14,279	180
Other non-current liabilities	12,810	18,482
Total liabilities	91,531	128,100
Commitments and contingencies (Note 19)		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of June 30, 2022 and June 30, 2021	—	—
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 38,578,825 and 27,490,412, respectively, as of June 30, 2022 and June 30, 2021	4	3
Additional paid-in capital	334,560	315,864
Accumulated deficit	(288,472)	(178,299)
Total stockholders' equity	46,092	137,568
Total liabilities and stockholders' equity	$ 137,623	$ 265,668

See the accompanying Notes to the Consolidated Financial Statements.

AYTU BIOPHARMA, INC.
Consolidated Statements of Operations
(In thousands, except share and per-share)

	Year Ended June 30,	
	2022	2021
Product revenue, net	$ 96,669	$ 65,632
Cost of sales	44,386	36,432
Gross profit	52,283	29,200
Operating expenses		
Research and development	14,439	5,623
Selling and marketing	38,713	30,308
General and administrative	31,167	25,500
Acquisition related costs	—	2,919
Restructuring costs	—	4,886
Impairment expense	75,458	12,825
Amortization of intangible assets	4,067	6,009
Total operating expenses	163,844	88,070
Loss from operations	(111,561)	(58,870)
Other income (expense)		
Other (expense), net	(862)	(2,050)
Gain (loss) from contingent consideration	1,760	4,459
Gain (loss) on extinguishment of debt	169	(1,569)
Gain on derivative warrant liability	211	—
Total other income	1,278	840
Loss before income tax	(110,283)	(58,030)
Income tax (benefit) expense	(110)	259
Net loss	$ (110,173)	$ (58,289)
Weighted average number of common shares outstanding	29,397,504	16,746,679
Basic and diluted net loss per common share	$ (3.75)	$ (3.48)

See the accompanying Notes to the Consolidated Financial Statements.

AYTU BIOPHARMA, INC.
Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except shares)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance, June 30, 2021	—	$ —	27,490,412	$ 3	$ 315,864	$ (178,299)	$ 137,568
Stock-based compensation	—	—	408,689	—	5,248	—	5,248
Issuance of common stock, net of $1,048 issuance cost	—	—	8,490,784	1	11,652	—	11,653
Tax withholding for stock-based compensation	—	—	—	—	(8)	—	(8)
Issuance of common stock related to milestone payment	—	—	2,188,940	—	1,425	—	1,425
Warrants issued with debt refinance	—	—	—	—	379	—	379
Net loss	—	—	—	—	—	(110,173)	(110,173)
Balance, June 30, 2022	—	$ —	38,578,825	$ 4	$ 334,560	$ (288,472)	$ 46,092

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance, June 30, 2020	—	$ —	12,583,736	$ 1	$ 215,024	$ (120,010)	$ 95,015
Stock-based compensation	—	—	1,722,125	—	3,574	—	3,574
Issuance of common stock, net of $3,371 issuance costs	—	—	7,479,476	1	41,679	—	41,680
Issuance of common stock for business acquisition, net of $130 issuance costs	—	—	5,471,804	1	53,102	—	53,103
Issuance of common stock related to debt conversion	—	—	130,081	—	1,058	—	1,058
Estimated fair value of replacement equity awards	—	—	—	—	432	—	432
Contingent Value Rights payouts	—	—	103,190	—	1,000	—	1,000
Tax withholding for stock-based compensation	—	—	—	—	(5)	—	(5)
Net loss	—	—	—	—	—	(58,289)	(58,289)
Balance, June 30, 2021	—	$ —	27,490,412	$ 3	$ 315,864	$ (178,299)	$ 137,568

See the accompanying Notes to the Consolidated Financial Statements

AYTU BIOPHARMA, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended June 30,	
	2022	**2021**
Operating Activities		
Net loss	$ (110,173)	$ (58,289)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	10,251	9,201
Impairment expense	75,458	12,825
Shares issuance related to milestone payment	1,425	—
Stock-based compensation expense	5,248	3,574
(Gain) loss from contingent considerations	(1,760)	(4,459)
Amortization of senior debt (premium) discount	(126)	(44)
(Gain) loss on debt extinguishment	(193)	1,569
Changes in allowance for bad debt	(69)	608
Inventory write-down	2,186	7,332
Gain on derivative warrant liability	(211)	—
Other noncash adjustments	4	38
Changes in operating assets and liabilities:		
Accounts receivable	6,533	1,544
Inventory	1,299	2,786
Prepaid expenses and other current assets	2,228	157
Accounts payable and other	(7,681)	(3,245)
Accrued liabilities	(13,292)	771
Other operating assets and liabilities, net	50	(332)
Net cash used in operating activities	(28,823)	(25,964)
Investing Activities		
Contingent consideration payment	(3,178)	(683)
Cash received from acquisition	—	15,722
Cash payment for business acquisition	—	(15,520)
Cash payment for asset acquisition	—	(2,341)
Other investing activities	(70)	40
Net cash used in investing activities	(3,248)	(2,782)
Financing Activities		
Net proceeds from issuance of stock	11,694	40,148
Payment made to fixed payment arrangement	(4,409)	(6,088)
Proceeds from short-term line of credit	152,236	51,206
Payments made on short-term line of credit	(156,357)	(53,979)
Payments made to borrowings	(16,101)	(968)
Proceeds from borrowings	15,000	—
Payment for debt issuance costs	(526)	—
Other financing activities	(7)	(5)
Net cash provided by financing activities	1,530	30,314
Net change in cash, cash equivalents, and restricted cash	(30,541)	1,568
Cash, cash equivalents and restricted cash at beginning of period	49,901	48,333
Cash, cash equivalents and restricted cash at end of period	$ 19,360	$ 49,901
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 19,360	$ 49,649
Restricted cash	—	252
Total cash, cash equivalents and restricted cash	$ 19,360	$ 49,901

See accompanying Notes to Consolidated Financial Statements

AYTU BIOPHARMA, INC.
Consolidated Statements of Cash Flows, Cont'd
(In thousands)

	Year Ended June 30,	
	2022	2021
Supplemental cash flow data		
Cash paid for interest	$ 3,148	$ 1,249
Non-cash investing and financing activities:		
Warrants issued	$ 3,177	$ 1,628
Other noncash investing and financing activities	$ 54	$ —
Issuance of common stock for note conversion	$ —	$ 1,058
Contingent value rights payout	$ —	$ 1,000
Issuance related to acquisition of Neos	$ —	$ 53,103
Fair value of non-cash assets acquired	$ —	$ 104,322
Fair value of liabilities assumed	$ —	$ 88,700
Estimated fair value of replacement equity awards	$ —	$ 432

See accompanying Notes to Consolidated Financial Statements

AYTU BIOPHARMA, INC.
Notes to the Financial Statements

1. Nature of Business and Financial Condition

Aytu BioPharma, Inc. ("Aytu," the "Company" or "we"), is a pharmaceutical company focused on commercializing novel therapeutics and consumer health products and developing therapeutics for rare pediatric-onset or difficult-to-treat diseases. The Company operates through two business segments (i) the BioPharma segment, consisting of prescription pharmaceutical products (the "Rx Portfolio") and (ii) the Consumer Health segment, which consists of various consumer healthcare products (the "Consumer Health Portfolio"). The Company also has two product candidates in development, AR101 (enzastaurin) for the treatment of vascular Ehlers-Danlos Syndrome ("VEDS") and Healight (endotracheal ultraviolet light catheter) for the treatment of severe, difficult-to-treat respiratory infections. The Company was incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado and was re-incorporated as Aytu BioScience, Inc in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. ("Neos") in March 2021, the Company changed its name to Aytu BioPharma, Inc.

The BioPharma portfolio primarily consists of (i) Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets for the treatment of attention deficit hyperactivity disorder ("ADHD"), (ii) 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, and (iii) Karbinal ER, an extended-release antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions.

The Consumer Health Portfolio consists of over twenty consumer health products competing in large healthcare categories, including diabetes management, pain management, digestive health, sexual and urological health, and general wellness, commercialized through direct-to-consumer and e-commerce marketing channels.

The Company's strategy is to continue building its portfolio of revenue-generating products, leveraging its commercial team's expertise to build leading brands within large therapeutic markets, while also developing a therapeutic pipeline focused on rare pediatric-onset conditions and difficult-to-treat diseases.

As of June 30, 2022, the Company had approximately $19.4 million of cash and cash equivalents. The Company's operations have historically consumed cash and are expected to continue to consume cash. The Company incurred a net loss of approximately $110.2 million and $58.3 million during the years ended June 30, 2022 and 2021, respectively. The Company had an accumulated deficit of $288.5 million and $178.3 million as of June 30, 2022 and 2021, respectively. Cash used in operations was $28.8 million and $26.0 million during the years ended June 30, 2022 and 2021, respectively.

In August 2022, the Company completed an underwritten public offering of (i) 21,505,814 shares of its common stock, and, in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 1,750,000 shares of its common stock, and (ii) accompanying warrants (the "Common Warrants") to purchase 23,255,814 shares of its common stock (the "Offering") resulting in gross and net proceeds of $10.0 million and $9.1 million, respectively, assuming none of the accompanying Common Warrants issued in the Offering are exercised. The pre-funded warrants were exercised in full in August 2022. The Company intends to use the net proceeds from the Offering for advancing the development of its pipeline assets, including for advancing the PREVEnt Trial evaluating AR101 for the treatment of vascular Ehlers-Danlos Syndrome ("VEDS"), for growth of the company's commercial business, and for working capital and general corporate purposes.

As the Company does not have sufficient cash and cash equivalents as of June 30, 2022 to cover its cash needs for the twelve months following the filing date of this Annual Report on Form 10-K, there exists substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include adjustments that might be necessary if the Company is unable to continue as a going concern.

Management plans to mitigate the conditions that raise substantial doubt about its ability to continue as a going concern are primarily focused on raising additional capital through public or private equity or debt offerings or monetizing assets in order to meet its obligations. Management believes that the Company has access to capital resources, however, the Company cannot provide any assurance that it will be able to raise additional capital, monetize assets or obtain new financing on commercially acceptable terms. If the Company is unable to secure additional capital, it may be required to curtail its operations or delay the execution of its business plan. Alternatively, any efforts by the Company to reduce its expenses may adversely impact its ability to sustain revenue-generating activities and delay the progress of its developmental product candidates or otherwise operate its business. As a result, there can be no assurance that the Company will be successful in implementing its plans to alleviate this substantial doubt about its ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Principals of Consolidation. The Company's consolidated financial statements include the accounts of: Aytu Therapeutics, LLC, Innovus Pharmaceuticals, Inc. and Neos Therapeutics, Inc. and their respective wholly owned subsidiaries. All significant inter-company balances and transactions have been eliminated in consolidation.

Basis of Presentation. The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP").

Use of estimates. The preparation of financial statements and footnotes requires the use of management estimates, judgments and assumptions. Actual results may differ from estimates. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation; revenue recognition, determination of variable consideration for accruals of chargebacks, administrative fees and rebates, government rebates, returns and other allowances; allowance for doubtful accounts; inventory impairment; determination of right-of-use assets and lease liabilities; valuation of financial instruments, intangible assets, long-lived assets, and goodwill; purchase price allocations, and the depreciable lives of long-lived assets; accruals for contingent liabilities; and determination of the income tax provision, deferred taxes and valuation allowance.

Prior Period Reclassification. Certain prior year amounts in the consolidated balance sheets, statements of earnings and statements of cash flows have been reclassified to conform to the current year presentation, including a reclassification made in the presentation of the U.S. Food and Drug Administration (the "FDA") fees for commercialized products. This was previously included in general and administrative expenses and is currently recorded as a component of cost of sales on the condensed consolidated statements of operations. These reclassifications did not impact operating results or cash flows for the year ended June 30, 2022 and 2021 or the Company's financial position as of June 30, 2022 or June 30, 2021.

Cash, Cash Equivalents and Restricted Cash. The Company's primary objectives for investment of available cash are the preservation of capital and the maintenance of liquidity. The Company invests its available cash balances in bank deposits and money market funds. The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents. Restricted cash consists of amounts held in a certificate of deposit to maintain certain business credit cards. As of June 30, 2022 and 2021, cash, cash equivalents and restricted cash was $19.4 million and $49.9 million, respectively.

Accounts Receivable. Accounts receivable represent amounts due from customers less allowances for doubtful accounts, discounts and pricing chargebacks. An allowance for doubtful accounts, when needed, is based upon the financial condition and payment history of customers; collections experience on other accounts; and economic factors or events expected to affect future collections. The allowance for doubtful accounts was $0 million and $1.0 million as of June 30, 2022 and 2021, respectively, and allowance for discounts and chargebacks were $1.3 million and $1.2 million respectively, as of June 30, 2022 and $1.2 million and $1.0 million respectively, as of June 30, 2021.

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. Prior to regulatory approval, before economic benefit is probable, pre-launch inventories are expensed as research and development.

The Company periodically reviews the composition of its inventories in order to identify obsolete, slow-moving or otherwise unsaleable items. If evidence exists that the net realizable value of inventory is lower than its cost, the difference is recognized as a loss in the period the impairment is identified.

Going Concern Determination. In connection with the preparation for each annual and interim financial reporting period, management evaluates whether there are events that, in the aggregate, raise substantial doubt about the Company's ability to continue as a going concern within one year after the financial statements are issued. The evaluation is based on relevant conditions and events that are known and reasonably knowable within one year after the date that the financial statements are issued. Recurring operating losses or year over year negative cash flows from operating activities are considered negative trends.

Property and equipment. Property and equipment are recorded at cost less accumulated depreciation. Furniture and equipment are depreciated on a straight-line basis over their estimated useful lives which are generally two to seven years. Leasehold improvements are amortized over the shorter of the estimated useful life or remaining lease term. The Company begins depreciating assets when they are placed into service. Maintenance and repairs are expensed as incurred.

Leases. At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease. Lease classification, recognition and measurement are determined at the lease commencement date. Lease liabilities and right-of-use ("ROU") assets are recorded based on the present value of lease payments over the expected lease term, including options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. In determining the present value of the lease payments, the Company uses the implicit interest rate when readily determinable and uses the Company's incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the lease commencement date.

Fixed lease payments, or in substance fixed, are recognized over the expected term of the lease using the effective interest method. Variable lease payments are expensed as incurred. Fixed and variable lease expenses on operating leases are recognized within cost of goods sold and operating expenses in the Company's consolidated statements of operations. ROU asset amortization and interest costs on financing leases are recorded within cost of goods sold and interest expense, respectively, in the Company's consolidated statements of operations. The Company has elected to account for payments on short-term leases as lease expense on a straight-line basis over lease terms of 12 months or less.

Operating leases are included in other liabilities in the Company's consolidated balance sheets. Financing leases are included in property and equipment, net, current portion of long-term debt and long-term debt, net of current portion in the Company's consolidated balance sheets.

Fair Value of Financial Instruments.

***Acquisitions*.** In an acquisition of a business or a group of assets, the Company uses the acquisition method of accounting which identifies, recognizes, and measures the identifiable assets acquired, liabilities assumed and any non-controlling interest at their acquisition date fair values. Any excess of the purchase consideration over the fair values of the net identifiable assets acquired is recorded as goodwill. If the Company determines the assets acquired do not meet the definition of a business, the transaction is accounted for as an acquisition of assets, which records the assets acquired at the purchase price and does not result in goodwill. Contingent consideration is accounted for Acquired in-process research and development with no alternative future use is charged to expense.

Revenue Recognition. The Company generates revenue from product sales through its prescription pharmaceutical products segment ("BioPharma Segment") and its consumer healthcare products segment ("Consumer Health Segment"). The Company evaluates its contracts with customers to determine revenue recognition using the following five-step model: (1) identify the contract with the customer; (2) identify the performance obligations; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations; and (5) recognize revenue when (or as) a performance obligation is satisfied. There is not a recognized financing component related to product sales.

BioPharma segment

Net product sales for the BioPharma segment consist of sales of prescription pharmaceutical products under the Rx Portfolio, principally to a limited number of wholesale distributors and pharmacies in the United States. Rx product revenue is recognized at the point in time that control of the product transfers to the customer in accordance with shipping terms (i.e., upon delivery), which is generally "free-on-board" destination when shipped domestically within the United States and "free-on-board" shipping point when shipped internationally consistent with the contractual terms.

Rx product revenue is recognized net of consideration paid to the Company's customers and other adjustments to the transaction price (known as "Gross to Net" adjustments). Estimating adjustments to the transaction price and applying the constraint on variable consideration requires the use of significant management judgment and other market data. Gross to Net adjustments include provisions for product returns, wholesaler distribution fees and chargebacks for discounted pricing to participating entities, managed care rebate programs, savings programs for patients covered under commercial payor plans and other deductions.

Consumer Health segment

The Consumer Health segment generates its revenue from sales of various consumer health products through direct-to-consumer marketing channels utilizing the Company's proprietary Beyond Human marketing and sales platform and on e-commerce platforms. Revenue is 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 the Company 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 expenses the incremental costs to obtain a contract as incurred, since they are satisfied within one year.

Concentration of Credit Risk. Financial instruments that potentially subject the Company to credit risk concentrations consist of cash, cash equivalents and accounts receivable.

The Company maintains deposits in financial institutions in excess of federally insured limits. The Company periodically monitors the credit quality of the financial institutions with which it invests and believes that the Company is not exposed to significant credit risk due to the financial position of those institutions.

The Company is also subject to credit risk from accounts receivable related to product sales. The Company's customers, sometimes referred to as partners or customers, are primarily large wholesale distributors that resell the Company's products to retailers. The loss of one or more of these large customers could have a material adverse effect on the Company's business, operating results or financial condition. The Company does not charge interest or require collateral related to its accounts receivable. Credit terms are generally forty to sixty days.

The following table presents customers that contributed more than 10% of gross revenue and accounts receivable:

	Percentage of gross revenue		Percentage of accounts receivable	
			June 30,	
	2022	2021	2022	2021
Customer A	41 %	25 %	52 %	35 %
Customer B	20 %	15 %	25 %	29 %
Customer C	18 %	14 %	18 %	22 %

Costs of Sales. Costs of sales consists primarily of manufactured product cost, products acquired from third-party manufacturers, freight, production, and indirect manufacturing overhead costs and FDA fees for commercialized products. Certain of the Company's sales activities depend on licensing arrangements that may require periodic milestone payments or royalty payments, which are also included in costs of sales. In addition, distribution, shipping and handling costs invoiced by the Company's third-party logistics companies are included in costs of sales.

Stock-Based Compensation. The Company accounts for share-based payments compensation expense using a fair value based model.

Restricted stock and restricted stock unit grants are valued based on the estimated grant date fair value of the Company's common stock and recognized ratably over the requisite service period.

Stock option grants are valued using the Black-Scholes option pricing model and compensation costs are recognized ratably over the period of service using the graded method. The Black-Scholes option pricing model requires the Company to estimate the expected term of the award, the expected volatility, the risk-free interest rate, and the expected dividends. The expected term is determined using the "simplified method," which is the midpoint between the vesting date and the end of the contractual term. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for the expected term of the award. The Company doesn't anticipate paying any dividends in the near future. Forfeitures are recognized as they occur.

Research and Development. Research and development costs are expensed as incurred and include salaries and benefits, facilities costs, overhead costs, raw materials, laboratory and clinical supplies, clinical trial costs, contract services, milestone payments and fees paid to regulatory authorities for review and approval of the Company's product candidates and other related costs.

Intangible Assets. The Company records acquired intangible assets based on fair value on the date of acquisition. Finite-lived intangible assets are recorded at cost and amortized on a straight-line basis over the estimated lives of the assets. Indefinite-lived intangible assets are not subject to amortization

Impairment of Long-lived Assets and Goodwill. The Company assesses impairment of asset groups, including intangible assets, when events or changes in circumstances indicate that their carrying amount may not be recoverable. Long-lived assets consist of property and equipment, net, right of use assets and other intangible assets, net. Circumstances which could trigger a review include, but are not limited to: (i) changes in Company plans; (ii) competition; (iii) significant adverse changes in the business climate or legal or regulatory factors; (iv) or, expectations that the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. If the estimated future undiscounted cash flows, excluding interest charges, from the use of an asset are less than its carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value.

Goodwill is reviewed for impairment at least annually or whenever events or changes in circumstances, including a decline in the Company's stock price, indicate that its carrying amount is less than its fair value. If qualitative factors, such as general economic conditions, the Company's outlook and market performance of the Company's industry forecasted financial performance indicate that it is more likely than not that a reporting unit's fair value is less than its carrying amount, the Company performs a quantitative analysis of fair value. The Company determines the fair value of a reporting unit utilizing a discounted cash flow model. Significant assumptions inherent in the valuation methodologies include, but are not limited to, prospective financial information, growth rates, terminal value, discount rates and comparable multiples from publicly traded companies in the Company's industry.

Contingent consideration. The consideration for our acquired businesses and licenses often includes future payments that are contingent upon the occurrence of a particular event or events. The Company records an obligation for such contingent payments at fair value on the acquisition date. Changes in the fair value of contingent consideration obligations are recognized in the consolidated statements of income

Advertising Costs. Advertising costs consist of the direct marketing activities related to the Consumer Health Segment. The Company expenses all advertising costs as incurred. The Company incurred $13.6 million and $15.2 million of advertising costs for the years ended June 30, 2022 and 2021, respectively.

Income Taxes. The provision for income taxes is determined using the asset and liability approach of accounting for income taxes. Under this approach, deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and net operating loss and tax credit carryforwards. The amount of deferred taxes on these temporary differences is determined using the tax rates that are expected to apply to the period when the asset is realized or the liability is settled, as applicable, based on tax rates and laws in the respective tax jurisdiction enacted as of the balance sheet date. A valuation allowance is recorded to reduce the net deferred tax asset when it is more likely than not that some portion or all of its deferred tax asset will not be utilized.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of to be sustained upon an examination.

The Company recognizes interest and penalties related to uncertain tax positions in Income tax (provision) benefit in the consolidated statements of operations.

Debt issuance costs, discounts (premiums). Debt issuance costs reflect fees paid to lenders and third parties directly related to issuing debt. Debt issuance costs and discounts (premiums) related to term loans are reported as direct deductions (increases) to the outstanding debt and amortized over the term of the debt using the effective interest method as an addition (reduction) to interest expense. Debt issuance costs related to a line of credit facility are classified as assets and subsequently amortized over the term of the line of credit as additional interest expense.

Segment information. The Company's operating segments engage in business activities from which it may earn revenues and incur expenses and for which discrete information is available and regularly reviewed by the Company's chief operating decision maker, who is the Company's Chief Executive Officer, to make decisions about resources to be allocated to the segment and to assess performance. Operating segments are aggregated for reporting purposes when the operating segments are identified as similar in accordance with the basic principles and aggregation criteria in the accounting standards. The Company's reporting segments are based on product lines, which have different lines of management responsibility and marketing strategies . The Company has two reportable segments: the BioPharma segment (Rx division) and the Consumer Health segment.

Paragraph IV litigation costs. Legal costs incurred by the Company in the enforcement of the Company's intellectual property rights are charged to expense.

Business Combination and Contingent considerations. The Company recognizes the identifiable tangible and intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date. The excess of purchase price over the aggregate fair values is recorded as goodwill. The Company calculates the fair value of the identifiable tangible and intangible assets acquired and liabilities assumed to allocate the purchase price at the acquisition date.

The consideration for our acquisitions and certain licensing agreements often includes future payments that are contingent upon the occurrence of a particular event or events. The Company records an obligation for such contingent payments at fair value on the acquisition date. Management estimates the fair value of contingent consideration obligations through valuation models that incorporate probability-adjusted assumptions related to the achievement of the milestones and thus likelihood of making related payments. The Company revalues its contingent consideration obligations each reporting period using Monte Carlo simulation. Changes in the fair value of contingent consideration obligations are recognized in the consolidated statements of income.

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

the years ended June 30, 2022 and 2021, the Company incurred a net loss and did not include common equivalent shares in the computation of diluted net loss per share because the effect would have been anti-dilutive.

The following table sets-forth securities excluded from the calculation of diluted earnings per share

		June 30,	
		2022	2021
Warrant to purchase common stock	(Note 17)	8,688,576	1,279,057
Employee stock options	(Note 16)	80,377	109,588
Employee unvested restricted stock	(Note 16)	1,607,572	1,955,426
Employee unvested restricted stock units	(Note 16)	170,000	78,318
Total		10,546,525	3,422,389

Recently Adopted Accounting Pronouncements

Simplifying the Accounting for Income Taxes. In December 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2019-12, "*Simplifying the Accounting for Income Taxes*". ASU 2019-12 eliminates certain exceptions related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The Company adopted ASU 2019-12 on July 1, 2021, which did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

Debt—Debt with Conversion and Other Options. In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40)— "Accounting for Convertible Instruments and Contracts in an Entity's Own Equity"*, which simplifies the accounting for convertible instruments by removing major separation models currently required. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. ASU 2020-06 removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, which will permit more equity contracts to qualify for it. The standard also simplifies the diluted net income per share calculation in certain areas. The amendments in this update are effective for public entities that are smaller reporting companies, as defined by the Securities and Exchange Commission ("SEC"), for the fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted through a modified retrospective or full retrospective method. The Company will adopt the guidance on July 1, 2022 and does not expect the adoption of the standard to have any material impact on the Company's consolidated financial statements.

Financial Instruments – Credit Losses. In June 2016, the FASB issued *ASU 2016-13, "Financial Instruments – Credit Losses"* requiring 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 ASU 2016-13 is to provide additional information about the expected credit losses on financial instruments and other commitments to extend credit. The standard is effective for smaller reporting companies for fiscal periods beginning after December 15, 2022. In May 2019, the FASB issued ASU 2019-05, "*Financial Instruments – Credit Losses*", to allow entities to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost upon adoption of the new credit losses standard. The effective dates and transition for ASU 2019-05 aligns with those of ASU 2016-13. In March 2022, the FASB issued ASU 2022-02, "*Financial Instruments – Credit Losses (topic 326) Troubled Debt Restructurings and Vintage Disclosures*" which eliminates the accounting guidance for troubled debt restructurings by creditors and adds disclosure requirements for current period gross write-offs by year of origination for financing receivables and net investments in leases. The Company will adopt ASU 2016-13 and ASU 2019-05 for the fiscal year ended June 30, 2024. The effective dates for the amendments in ASU 2022-02 align with those of ASU 2016-13. The Company is evaluating the impact of adoption of ASUs 2016-13, 2019-05, and 2022-02 and does not anticipate the application of the new standards will have a material impact on the Company's consolidated financial statements.

Reference Rate Reform. In March 2020, the FASB issued ASU 2020-04, "*Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*", which provides elective amendments for entities that have contracts, hedging relationships and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. These amendments are effective immediately and may be applied prospectively to contract modifications made and hedging relationships entered into or evaluated on or before December 31, 2022. In January 2021, the FASB issued ASU 2021-01, "*Reference Rate Reform (Topic 848)*", to expand and clarify the scope of Topic 848 to include derivative instruments on discounting transactions. The amendments in ASU 2021-01 are effective in the same timeframe as ASU 2020-04. The Company is currently evaluating the impact this guidance will have on its consolidated financial statements.

Earnings Per Share. In May 2021, the FASB issued ASU 2021-04, "*Earnings Per Share (Topic 260), Debt – Modifications and Extinguishments (Subtopic 470-50), Compensation – Stock Compensation (Topic 718), and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*". The amendments in ASU 2021-04 provide guidance to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. ASU 2021.04 is effective for all entities for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted. The Company plans to adopt ASU 2021-04 and related updates on July 1, 2022 and does not expect it to have a material impact on its consolidated financial statements.

Management has evaluated other recently issued accounting pronouncements and does not believe that any of these pronouncements will have a significant impact on our consolidated financial statements and related disclosures.

3. Revenues from Contracts with Customers

The Company disaggregates its revenue into three product portfolios. The primary care portfolio is composed of ZolpiMist and Tuzistra. The pediatric portfolio is composed of Adzenys XR-ODT, Cotempla XR-ODT Poly-Vi-Flor, Tri-Vi-Flor, Karbinal ER and a generic Tussionex. The Consumer Health portfolio is composed of over twenty consumer health products competing in large healthcare categories.

As part of the realization of post-acquisition synergies and product prioritization, the Company has implemented a portfolio rationalization plan whereby it discontinued or divested non-core products including Cefaclor, Flexichamber, Tussionex, Tuzistra XR, and Zolpimist, effectively eliminating the primary care portfolio. These products, collectively, contributed $2.1 million in net revenue and $0.6 million in gross loss during the year ended June 30, 2022 (see Note 8 – Goodwill and Other Intangible Assets).

Revenues by Product Portfolio: Net revenue disaggregated by significant product portfolio for the years ended June 30, 2022 and 2021 were as follows.

	Year Ended June 30,	
	2022	2021
	(In thousands)	
ADHD portfolio	$ 42,855	$ 10,883
Pediatric portfolio	16,084	12,437
Consumer Health portfolio	35,548	32,954
Other	2,182	9,358
Consolidated revenue	$ 96,669	$ 65,632

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,	
	2022	2021
	(In thousands)	
U.S.	$ 94,606	$ 60,687
International	2,063	4,945
Total net revenue	$ 96,669	$ 65,632

4. Acquisitions

Neos Acquisition

On March 19, 2021, the Company acquired Neos, a commercial-stage pharmaceutical company. Neos merged into, a subsidiary of the Company ("the Neos Acquisition") and all outstanding Neos common stock was exchanged for approximately 5.5 million shares of the Company's common stock. The Company incurred (i) approximately $2.9 million of acquisition related costs, recognized as part of operating expense, and (ii) $0.1 million of issuance costs, recognized as a component of stockholders' equity.

The following table summarizes the fair value of assets acquired and liabilities assumed in the acquisition:

	March 19, 2021
	(In thousands, except share and per-share)
Considerations:	
Fair Value of Aytu Common Stock	
Total shares issued at close	5,471,804
Fair value per share of Aytu common stock	$ 9.73
Fair value of equity consideration transferred	$ 53,241
Cash	15,383
Estimated fair value of replacement equity awards	432
Total consideration transferred	$ 69,056

	March 19, 2021 (In thousands)
Total consideration transferred	$ 69,056
Recognized amounts of identified assets acquired and liabilities assumed	
Cash and cash equivalents	$ 15,722
Accounts receivable	24,696
Inventory	10,984
Prepaid expenses and other current assets	2,929
Operating leases right-to-use assets	3,515
Property, plant and equipment	5,519
Intangible assets	56,530
Other long-term assets	149
Accounts payable and accrued expenses	(56,718)
Short-term line of credit	(10,707)
Long-term debt, including current portion	(17,678)
Operating lease liabilities	(3,515)
Other long-term liabilities	(82)
Total identifiable net assets	31,344
Goodwill	$ 37,712

The fair values of the identifiable intangible assets acquired were as follows;

	March 19, 2021 (In thousands)
Identified intangible assets acquired:	
Developed technology right	$ 30,200
Developed products technology	22,700
In-process R&D	2,600
RxConnect	630
Trade name	400
Total intangible assets acquired	$ 56,530

The fair value of the Neos trade name, in-process R&D and developed product technology, which is the proprietary technology for the development of Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT and generic Tussionex, were determined using the relief from royalty method. The fair value of the developed technology right, which is a proprietary modified-release drug delivery technology, was determined using multi-period excess earnings method. The fair value of RxConnect was determined using the cost to recreate method. The finite-lived intangible assets are being amortized over a range of 1 to 17 years.

The following supplemental unaudited proforma financial information presents the Company's results as if the Neos acquisition had occurred on July 1, 2020:

	Year Ended June 30,	
	2022	2021
	Unaudited	Pro forma Unaudited
	(In thousands)	
Total revenues, net	$ 96,669	$ 98,085
Net loss	$ (110,173)	$ (74,710)

AR101 Acquisition

On April 12, 2021, the Company entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (together "Rumpus") pursuant to which the Company acquired commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin, or AR101. AR101 is initially being studied for the treatment of VEDS. This asset was acquired for an up-front fee of $1.5 million in cash and payment of aggregated fees of $0.6 million. Upon the achievement of certain regulatory and commercial milestones, the Company is obliged to pay up to $67.5 million in earn-out payments, which are payable in cash or shares of common stock, generally at the Company's option. The AR101 Acquisition was accounted for as an asset acquisition.

AR101 is an orally available investigational small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways (see Note 19 – Commitments and Contingencies).

5. Inventories

Inventories consist of the following:

	June 30, 2022	June 30, 2021
	(In thousands)	
Raw materials	$ 1,814	$ 2,269
Work in process	1,838	3,346
Finished goods	7,197	10,724
Inventory, net	$ 10,849	$ 16,339

The Company incurred charges of $4.2 million and $7.3 million to reduce the carrying value of inventory to net realizable value during the years ended June 30, 2022 and 2021, respectively, primarily as a result of the discontinuance of non-core products.

6. Property and Equipment

Property and equipment, net consist of the following:

	June 30, 2022	June 30, 2021
	(In thousands)	
Manufacturing equipment	$ 2,487	$ 3,070
Leasehold improvements	999	959
Office equipment, furniture and other	1,128	1,093
Lab equipment	832	832
Assets under construction	—	198
Property and equipment, gross	5,446	6,152
Less accumulated depreciation and amortization	(2,421)	(1,012)
Property and equipment, net	$ 3,025	$ 5,140

Depreciation expense was $1.6 million and $0.6 million for the years ended June 30, 2022 and 2021, respectively. During the year ended June 30, 2022 and 2021, the Company recognized a gain of $0.1 and a loss of $0.1 million on the disposal of equipment, respectively.

During the year ended June 30, 2022, in connection with the decision to divest Tussionex, the Company recorded a $0.2 million impairment charge related to manufacturing equipment associated with this product.

7. Leases

The Company's operating leases are for its offices, manufacturing facilities and equipment, and its finance leases are for equipment. These leases have original lease periods expiring between 2022 and 2027. Most leases include option provisions under which the parties may extend the lease term. Certain non-real estate leases also include options to purchase the leased property. The Company's lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

In connection with the Neos Acquisition, Aytu assumed an operating lease ROU asset and lease liability of $3.5 million, which represented the present value of the remaining lease payments as of the acquisition date, for the office space and manufacturing facilities at Grand Prairie, Texas. As the lease agreement does not provide an implicit rate, a borrowing rate of 6.7% was used to determine the present value of future lease payments. The finance leases are related to equipment finance leases with fixed contract terms and an implicit interest rate of approximately 5.9%.

In the fiscal years ended June 30, 2021 and June 30, 2022, the Company entered into a lease agreements for which the Company recorded operating lease and lease lia3bilities, together with related ROU assets of $0.5 million.

The components of lease expenses are as follows;

	Year Ended June 30,		
	2022	2021	Statement of Operations Classification
	(In thousands)		
Lease cost:			
Operating lease cost	$ 1,299	$ 476	Operating expenses
Short-term lease cost	152	109	Operating expenses
Finance lease cost:			
Amortization of leased assets	73	21	Cost of sales
Interest on lease liabilities	14	6	Other (expense), net
Total net lease cost	$ 1,538	$ 612	

Supplemental balance sheet information related to leases is as follows:

	June 30, 2022	June 30, 2021	Balance Sheet Classification
	(In thousands)		
Assets:			
Operating lease assets	$ 3,271	$ 3,563	Operating lease right-of-use asset
Finance lease assets	256	329	Property and equipment, net
Total leased assets	$ 3,527	$ 3,892	
Liabilities:			
Current:			
Operating leases	$ 1,227	$ 940	Other current liabilities
Finance leases	96	102	Current portion of debt
Non-current			
Operating leases	2,090	2,624	Other liabilities
Finance leases	84	180	Debt, net of current portion
Total lease liabilities	$ 3,497	$ 3,846	

Remaining lease terms and discount rates used are as follows;

	June 30, 2022	June 30, 2021
Weighted-Average Remaining Lease Term (years)		
Operating lease assets	2.63	3.42
Finance lease assets	1.73	2.72
Weighted-Average Discount Rate		
Operating lease assets	7.48 %	6.62 %
Finance lease assets	6.43 %	6.41 %

Supplemental cash flow information related to leases is as follows:

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Cash flow classification of lease payments:		
Operating cash flows from operating leases	$ 1,016	$ 467
Operating cash flows from finance leases	$ 15	$ 5
Financing cash flows from finance leases	$ 102	$ 25

As of June 30, 2022, the maturities of the Company's future minimum lease payments were as follows:

	Operating	Finance
	(In thousands)	
2023	$ 1,436	$ 105
2024	1,378	87
2025	749	—
2026	90	—
2027	46	—
Total lease payments	3,699	192
Less: Imputed interest	(382)	(12)
Lease liabilities	$ 3,317	$ 180

8. Goodwill and Other Intangible Assets

The carrying amount of goodwill by reportable segment and changes during the year ended June 30, 2022 are as follows:

	BioPharma	Consumer Health	Consolidated
		(In thousands)	
Balance as of June 30, 2020	$ 19,453	$ 8,637	$ 28,090
Goodwill acquired	37,712	—	37,712
Balance as of June 30, 2021	57,165	8,637	65,802
Goodwill impairment	(57,165)	(8,637)	(65,802)
Balance as of June 30, 2022	$ —	$ —	$ —

During the year ended June 30, 2022, the Company's market capitalization significantly declined. The decline was considered a qualitative factor that led management to reassess whether an impairment had occurred. Management's evaluation indicated that the goodwill related to its reporting units in both the BioPharma and Consumer Health segments were potentially impaired. The Company then performed a quantitative impairment test by calculating the fair value of the reporting unit and compared that amount to its carrying value. Significant assumptions inherent in the valuation methodologies include, but were not limited to prospective financial information, growth rates, terminal value, discount rates and comparable multiples from publicly traded companies in our industry. The decline in market capitalization was an indicator of increased risk thereby increasing the discount rates in the valuation models. The Company determined the fair value of the reporting unit utilizing the discounted cash flow model. Using Utilizing a risk adjusted weighted-average discount rate, the fair value of the reporting units was less than its carrying value. The Company recognized an impairment charge of $57.2 million in the BioPharma segment, associated with the Cerecor and Neos acquisition and a $8.6 million impairment charge in the Consumer Health segment related to the goodwill associated with the Innovus Acquisition.

The following table provides the summary of the Company's intangible assets as of June 30, 2022 and June 30, 2021, respectively.

	June 30, 2022				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted-Average Remaining Life (in years)
			(In thousands)		
Definite-lived intangibles:					
Acquired product technology right	45,400	(7,667)	(3,224)	34,509	12.33
Acquired technology right	30,200	(2,278)	—	27,922	15.75
Acquired product distribution rights	11,354	(3,581)	(2,172)	5,601	7.60
Other intangible assets	4,666	(3,004)	(1,662)	—	—
	91,620	(16,530)	(7,058)	68,032	13.35
Indefinite-lived intangibles:					
Acquired in-process R&D	2,600	—	—	2,600	Indefinite-lived
	2,600	—	—	2,600	
Total	$ 94,220	$ (16,530)	$ (7,058)	$ 70,632	13.35

	June 30, 2021			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (in years)
			(In thousands)	
Definite-lived intangibles:				
Acquired product technology right	45,400	(4,160)	41,240	12.88
Acquired technology right	30,200	(501)	29,699	16.75
Acquired product distribution rights	11,354	(2,073)	9,281	8.57
Other intangible assets	4,666	(2,022)	2,644	3.05
	91,620	(8,756)	82,864	13.47
Indefinite-lived intangibles:				
Acquired in-process R&D	2,600	—	2,600	Indefinite-lived
	2,600	—	2,600	
Total	$ 94,220	$ (8,756)	$ 85,464	13.47

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

	June 30, (In thousands)
2023	$ 6,086
2024	6,074
2025	5,934
2026	5,683
2027	5,653
Thereafter	38,602
Total future amortization expense	$ 68,032

Product Technology Rights

The acquired Product technology rights are related to the rights to production, supply and distribution agreements of various products pursuant to the acquisitions of Pediatric Portfolio in November 2019 and the Neos Acquisition in March 2021.

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.

Poly-Vi-Flor and 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.

ADHD Portfolio. As part of the Neos Acquisition, the Company acquired developed product technology for the production and sale of Adzenys XR-ODT and Cotempla XR-ODT. The formulations for the ADHD products are protected by patented technology. The estimated economic life of these proprietary technologies is 17 years.

Developed Technology Right

TRRP Technology. As part of the Neos Acquisition, the Company acquired Time Release Resin Particle ("TRRP") proprietary technology, which is a proprietary drug delivery technology protected by the Company as a trade secret that allows the Company to modify the drug release characteristics of each of its respective products. The TRRP technology underlines each of Neos' core products and can potentially be used in future product development initiatives as well.

Product distribution rights and customer list

In connection with the Innovus Acquisition, the Company obtained 35 products with a combination of over 300 registered trademarks and/or patent rights and customer lists. As of June 30, 2022, the customer list intangible asset was fully amortized.

In-Process R&D

IPR&D – NT0502. As part of the Neos Acquisition, the Company acquired in-process research and development associated with NT0502, a new chemical entity that is for the treatment of sialorrhea, which is excessive salivation or drooling. As this is an indefinite-lived intangible asset, this acquired assets remains indefinite-lived assets until the completion or abandonment of the associated research and development efforts. If a product using this technology is eventually approved for commercial sale, at that time, the IPR&D will begin amortizing on a straight-line over the life of the product.

Other intangible assets

Other intangible assets consist of customer lists, trade names and other technology and licenses.

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. Intangible assets are amortized using the straight-line method over the estimated useful lives. Amortization expense of intangible assets was $7.8 million and $7.1 million during the years ended June 30, 2022 and 2021, respectively.

During the year ended June 30, 2022, in connection with the decision to discontinue commercializing or divesting certain products within the BioPharma segment that have minimal revenue and gross margin contribution, the Company recorded $4.9 million impairment expense for the write-down of intangible assets consisting of (i) $2.6 million for AcipHex, (ii) $1.4 million for ZolpiMist, (iii) $0.5 million for Tussionex, (iv) $0.2 million for Cefaclor and (v) $0.2 million for the Neos tradename. Additionally, the Company's Consumer Health segment recorded an impairment of $2.2 million related to products no longer being marketed and products that have been underperforming.

During the year ended June 31, 2021, the Company recorded $12.8 impairment expense in the BioPharma segment consisting of (1) $4.3 million in connection with the divestiture of Natesto and (2) $8.5 million for write-down of Tuzistra licensed asset.

9. Accrued liabilities

Accrued liabilities consist of the following:

	June 30, 2022	June 30, 2021
	(In thousands)	
Accrued savings offers	$ 12,711	$ 20,148
Accrued program liabilities	9,468	8,689
Return reserve	5,770	6,367
Accrued compensation	4,765	5,939
Accrued customer and product related fees	7,817	12,346
Other accrued liabilities	3,656	3,745
Total accrued liabilities	$ 44,187	$ 57,234

Savings offers represent programs for the Company's patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted.

Accrued customer and product related fees include accrued expenses and deductions for rebates, wholesaler chargebacks and fees, and other product-related fees and deductions.

Other accrued liabilities consist of accrued license fees, professional fees, credit card liabilities, taxes payable, and samples expense, none of which individually represent greater than five percent.

10. Other Liabilities

	June 30, 2022	June 30, 2021
	(In thousands)	
Contingent consideration	$ 396	$ 12,057
Fixed payment arrangement	13,051	9,458
Operating lease liabilities	3,317	3,564
Contingent value rights	578	1,395
Other	827	355
Total other liabilities	18,169	26,829
Less: current portion	(5,359)	(8,347)
Total other liabilities, noncurrent	$ 12,810	$ 18,482

Fixed payment arrangements. Fixed payment arrangements represent obligations to an investor assumed as part of the acquisition of products from Cerecor, Inc. in 2019, including fixed and variable payments. These obligations included 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 2021. Monthly variable payments due to the same investor are equal to 15.0% of net revenue generated from a subset of the Pediatric Portfolio, subject to an aggregate monthly minimum of $0.1 million, except for January 2021, when a one-time payment of $0.2 million was due and paid. The variable payment obligation was to continue 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.

On June 21, 2021, the Company entered into a Waiver, Release and Consent pursuant to which the Company paid $2.8 million to the investor in early satisfaction of the fixed obligation. The Company agreed to pay the remaining fixed obligation of $3.0 million in six equal quarterly payments of $0.5 million each over six quarters beginning September 30, 2021. The Company accounted the Waiver, Release and Consent as a debt and remeasured the related liabilities using a discounted cash flow model. As of June 30, 2022, the fixed payment arrangement was $1.0 million. The Company recognized a $1.3 million loss on extinguishment of the fixed obligation for the year ended June 30, 2021.

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.

The Karbinal Agreement also contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units annually through 2025. 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 2025. The Karbinal Agreement make-whole payment is capped at $2.1 million each year. The annual payment is due in August of each year. The Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $3.0 million based on cumulative net sales, the first of which is triggered at $40.0 million of net revenues.

On May 12, 2022, the Company entered into an agreement with Tris to terminate the License, Development, Manufacturing and Supply Agreement dated November 2, 2018 (the “License Agreement”). Pursuant to such termination, the Company agreed to pay Tris a total of approximately $6.0 million to $9.0 million, which reduced our total liability for minimum payments by approximately $8.0 million from the original License Agreement. The settlement payment will be paid in three installments from December 2022 through July 2024. As of June 30, 2022, the balance was $6.7 million.

Contingent value rights. Contingent value rights (“CVRs”) represent contingent consideration related to the Company’s 2020 acquisition of Innovus of up to $16.0 million payable upon attainment of future performance milestones. Consideration can be satisfied in up to 470,000 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. In the fiscal years ended June 30, 2020 and 2021, the Company issued to the CVR holders 123,820 and 103,190 shares of common stock, respectively, upon achievement of specified revenues. No milestones were met during the fiscal year ended June

30, 2022. As of June 30, 2022, up to $5.0 million of future milestone payments potentially remain. As of June 30, 2022 and June 30, 2021, the CVRs were revalued at $0.6 million and $1.4 million, respectively. During the years ended June 30, 2022 and 2021, the Company recognized a gain of $0.8 million and $3.2 million, respectively, in the consolidated statements of operations related to the changes in fair values of CVRs.

Contingent consideration. Contingent consideration represents the fair value of potential future payments in connection with acquisitions that are contingent upon the occurrence of a particular event or events. The Company records an obligation for such contingent payments at fair value on the acquisition date. Subsequent changes in the fair value of contingent consideration obligations are recognized in the consolidated statements of income.

As of June 30, 2022, the Company's contingent consideration liabilities consist primarily of obligations related to the Company's 2020 acquisition of Innovus. In connection with the acquisition, the Company assumed a license agreement for patents and technology under which Innovus will pay a total milestone payment of $50,000 every other year beginning on July 1, 2021 for a total payment of $0.2 million. The fair value was based on a discounted value of the future contingent payment using a 26% discount rate based on the estimated risk that the milestones would be achieved.

In addition, Innovus recognized approximately $0.2 million in product related contingent consideration. The fair value was based on a discounted value of the future contingent payment using a 30% discount rate based on the estimated risk that the milestones are achieved. As of June 30, 2022 and June 30, 2021, the contingent consideration balance were $0.4 million and $0.3 million, respectively.

Prior to June 30, 2022, the Company's contingent consideration liabilities included obligations under licensing arrangements for Tuzistra XR. The royalty and make-whole milestone payments related to licensing agreements with TRIS Pharma, Inc. ("Tris") for Tuzistra XR were being accounted for as contingent consideration and revalued at each reporting period. As a result of the discontinuation of commercializing Tuzistra (see Note 3 – Revenue from Contracts with Customers) and a settlement agreement with Tris, the Company concluded that the product milestone payments underlying the contingent consideration liability ceased to exist. The Company reversed the remaining contingent consideration liabilities of $8.5 million and recorded a liability of $7.6 million related to the settlement payments payable to Tris for termination of the Tuzistra licensing agreement. The settlement payments are included in fixed payment arrangements at their present value using the Company's estimated borrowing rate. The Company recognized $0.9 million gain on settlement of the Tris contingent consideration liabilities in the consolidated statements of operations for the year ended June 30, 2022.

Prior to June 30, 2022, the royalty payments related to licensing agreements with Magna Pharmaceuticals, Inc. ("Magna") for ZolpiMist were being accounted for as contingent consideration and revalued at each reporting period. As a result of the discontinuation of commercializing ZolpiMist, the Company concluded that the royalty-based product milestone payments underlying the contingent consideration liability ceased to exist. In 2022, the Company reversed the remaining contingent consideration liabilities of $0.6 million and recorded the $50,000 payment due for termination of the Manga licensing agreements in other current liabilities. The Company recognized a $0.6 million gain from termination of the contingent consideration liability in the consolidated statements of operations for the year ended June 30, 2022.

During the year ended June 30, 2022 and 2021, the Company recognized a net a loss of $0.5 million and $1.7 million, respectively, from the changes in fair values of contingent considerations. The total accretion expense related to these contingent considerations was approximately $0.1 million and $0.4 million during the year ended June 30, 2022 and 2021, respectively.

Other. Consist of taxes payable and deferred cost related to our technology transfer.

11. Line of Credit

Upon closing of the Neos Acquisition in March 2021, the Company assumed obligations under the secured credit agreement that Neos had entered into with Eclipse Business Capital LLC (f/k/a Encina Business Credit, LLC)

("Eclipse") as agent for the lenders (the "Eclipse Loan Agreement"). Under the Eclipse Loan Agreement, Eclipse extended up to $25.0 million in secured revolving loans to Neos (the "Revolving Loans"), of which up to $2.5 million was available for short-term swingline loans, against 85% of eligible accounts receivable. The Revolving Loans thereunder accrued variable interest through maturity at the one-month Secure Overnight Financing Rate ("SOFR), plus 4.50%. The Eclipse Loan Agreement included an unused line fee of 0.50% of the average unused portion of the maximum revolving facility amount during the immediately preceding month. Interest is payable monthly in arrears. The original maturity date under the Eclipse Loan Agreement was May 11, 2022.

In connection with the Avenue Capital Agreement, described in Note 12 Long Term Debt below, the Company entered into a Consent, Waiver and Second Amendment to Eclipse Loan Agreement, dated as of January 26, 2022 (together, the "Eclipse Second Amendment"). Pursuant to the Eclipse Second Amendment, Eclipse (i) consented to Aytu and certain of its subsidiaries joining as obligors to the Revolving Loans provided by the Eclipse Loan Agreement, (ii) consented to the Company entering into the Avenue Capital Agreement, (iii) extended the maturity date of the Eclipse Loan Agreement to January 26, 2025, (iv) removed the requirement for the Company to comply with the ongoing fixed charge coverage ratio financial covenant applicable to the borrowers under the Eclipse Loan Agreement, (v) consented to the first priority lien granted by Aytu in favor of the Avenue Capital Agent, (vi) reduced the maximum availability under the Revolving Loans from $25.0 million to $12.5 million minus a $3.5 million availability block, (vii) increased the availability block from $1.0 million to $3.5 million, (viii) consented to the full repayment under the Deerfield Facility, defined below, and (ix) made certain other modifications to conform to the Avenue Capital Agreement and to reflect the consummation of the transactions thereof, in each case subject to the terms and conditions of the Eclipse Second Amendment.

The Company incurred $0.1 million in legal and other fees related to the Eclipse Second Amendment, all of which were recorded as deferred financing costs and are being amortized on a straight-line basis over the remaining term of the Eclipse Loan Agreement as interest expense. The unamortized cost of $0.1 million as of June 30, 2022 was included in other noncurrent assets in the condensed consolidated balance sheets.

In the event that, for any reason, all or any portion of the Eclipse Loan Agreement is terminated prior to the scheduled maturity date, in addition to the payment of all outstanding principal and unpaid accrued interest, the Company is required to pay a fee equal to (i) 2.0% of the Revolving Loans commitment if such event occurs on or before January 26, 2023, (ii) 1.0% of the Revolving Loans commitment if such event occurs after January 26, 2023 but on or before January 26, 2024, and (iii) 0.5% of the Revolving Loans commitment if such event occurs after January 26, 2024 but on or before January 26, 2025. The Company may permanently terminate the Eclipse Loan Agreement with at least five business days prior notice to Eclipse.

The Eclipse Loan Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restrict the Company's ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of Eclipse. A failure to comply with these covenants could permit Eclipse to declare the Company's obligations under the Eclipse Loan Agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of June 30, 2022, the Company was in compliance with the covenants under the Eclipse Loan Agreement as amended.

The Company's obligations under the Eclipse Loan Agreement are secured by substantially all of the Company's assets, with a first priority lien in favor of Eclipse on the ABL Priority Collateral, and a second priority lien in favor of Eclipse on the Term Loan Priority Collateral, as each is defined in the Replacement Term Loan Intercreditor Agreement, as defined in the Eclipse Loan Agreement, as amended by the Eclipse Second Amendment.

Total interest expense on the Revolving Loans, including amortization of deferred financing costs, was $0.4 million for the year ended June 30, 2022. Interest expense was $0.2 for the period beginning March 19, 2021, the date the Neos Acquisition was closed, through June 30, 2021. As of June 30, 2022 and 2021, the outstanding Revolving

Loans under the Eclipse Loan Agreement, as amended, were $3.8 million and $7.9 million, respectively. Unused line of credit amount as of June 30, 2022 was $0.3 million.

12. Long-term Debt

Deerfield Debt. Upon closing of the Neos Acquisition, the Company assumed a senior secured term credit facility (the "Deerfield Facility") with Deerfield Private Design Fund III, L.P. and Deerfield Partners, L.P. (collectively, "Deerfield") with an outstanding balance of $16.6 million.

The Company evaluated and determined that the fair value of the remaining outstanding debt was $17.4 million as of the March 19, 2021 acquisition date. Accordingly, the Company recorded a premium of $0.8 million, which was the difference between carrying amount and the fair value of the debt and was being amortized into interest expense using the effective interest method over the remaining term of the debt.

On January 26, 2022, the Company repaid the remaining principal outstanding in full, plus exit fees and accrued interest under the Deerfield Facility. The Company recognized a gain of $0.2 million during the year ended June 30, 2022 related to the extinguishment of the Deerfield Facility. Total interest expense on the facility, net of premium amortization, was $0.8 million for the period from July 1, 2021 through full repayment on January 26, 2022.

Avenue Capital Loan: On January 26, 2022 ("Closing Date"), the Company entered into a Loan and Security Agreement (the "Avenue Capital Agreement") with Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund II, L.P. as lenders (the "Avenue Capital Lenders"), and Avenue Capital Management II, L.P. as administrative agent (the "Avenue Capital Agent"), collectively ("Avenue Capital"), pursuant to which the Avenue Capital Lenders provided the Company and certain of its subsidiaries with a secured $15.0 million loan. The interest rate on the loan is the greater of the prime rate and 3.25%, plus 7.4%, payable monthly in arrears. The maturity date of the loan is January 26, 2025. The proceeds from the Avenue Capital Agreement were used towards the repayment of the Deerfield Facility.

Pursuant to the Avenue Capital Agreement, the Company will make interest only payments for the first 18 months following the Closing Date ("Interest-only Period"). The Interest-only Period could be extended automatically without any action by any party for six months provided as of the last day of the Interest-only Period then in effect, the Company received, prior to June 15, 2023, a specified amount of net proceeds from the sale and issuance of its equity securities ("Interest-only Milestone 1"). The Interest-only Period could further be extended automatically without any action by any party for an additional six months provided, the Company has achieved, prior to December 31, 2023, (i) Interest-only Milestone 1 and (ii) a specified amount of trailing 12 months revenue as of the date of determination.

In the event the Company prepays the outstanding principal prior to the maturity date, the Company will pay Avenue Capital a fee equal to (i) 3.0% of the loan if such event occurs on or before January 26, 2023, (ii) 2.0% of the loan if such event occurs after January 26, 2023 but on or before January 26, 2024, and (iii) 1.0% of the loan if such event occurs after January 26, 2024 but before January 26, 2025. In addition, upon the payment in full of the obligations, the Company shall pay to Avenue Capital a fee in the amount of $0.6 million ("Final Payment"). The Company accounted for the Final Payment as additional obligations on the debt, with the corresponding charge being recorded as debt discount.

The Company's obligations under Avenue Capital Agreement are secured by substantially all of the Company's assets, with a first priority lien in favor of the Avenue Capital Agent on the Term Loan Priority Collateral, and a second priority lien in favor of the Avenue Capital Agent on the ABL Priority Collateral, as each is defined in the Intercreditor Agreement, as defined in the Avenue Capital Agreement.

The Avenue Capital Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restricts the Company's ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities,

engage in mergers and acquisitions or make asset sales without the prior written consent of the Avenue Capital Lenders. A failure to comply with these covenants could permit the Avenue Capital Lenders to declare the Company's obligations under the agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of June 30, 2022, the Company was in compliance with the covenants under the Avenue Capital Agreement.

On January 26, 2022 ("Issuance Date"), as consideration for entering into the Avenue Capital Agreement, the Company issued warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price equal to $1.21 per share (the "Avenue Capital Warrants"). The Avenue Capital Warrants provided that in the event the Company were to engage in an equity offering at a price lower than $1.21 prior to June 30, 2022, the exercise price would be adjusted to the effective price of such equity offering and the number of shares of common stock to be issued under the Avenue Capital Warrants would be adjusted as set forth in the agreement. The Avenue Capital Warrants were immediately exercisable and expire on January 31, 2027. At inception and through the reclassification to equity on March 7, 2022, the Company accounted for the Avenue Capital Warrants as a liability as the number of warrants was not fixed at the Issuance Date. The fair value of the Avenue Capital Warrants was $0.6 million on January 26, 2022, with the corresponding debit being recorded as debt discount.

On March 7, 2022, the Company closed on an equity offering of shares of common stock and warrants, as described in Note 15 – Stockholders Equity, at an offering price of $1.25 per share. As this offering precludes the Company from pursuing any equity financing prior to July 7, 2022 and the effective price of the March 7, 2022 offering was more than the exercise price of the Avenue Capital Warrants, the number of shares of common stock issuable upon exercise of the Avenue Capital Warrants were set to 867,769 at an exercise price of $1.21. As a result, on March 7, 2022, the Company reclassified the Avenue Capital Warrants from a liability to equity and recorded the $0.4 million fair value as additional paid in capital in stockholders' equity in the Company's financial statements.

In addition to the debt discounts discussed above, the Company also incurred $0.4 million loan origination, legal and other fees. The debt discount and issuance costs are being amortized over the term of the loan, using the effective interest method resulting in an effective rate of 16.59%. Total interest expense on the Avenue Capital loan, including debt discount amortization, was $0.9 million for the year ended June 30, 2022

Long-term debt consists of the following;

	June 30, 2022
	(In thousands)
Long-term debt, due on January 26, 2025	$ 15,000
Long-term, final payment fee	638
Unamortized discount and issuance costs	(1,443)
Financing leases, maturing through May 2024	180
Total debt	14,375
Less: current portion	(96)
Non-current portion of debt	$ 14,279

Future principal payments of long-term debt, including financing leases, are as follows;

	June 30, (In thousands)
2023	$ 96
2024	8,418
2025	7,304
Future principal payments	15,818
Less unamortized discount and issuance costs	(1,443)
Less current portion	(96)
Non-current portion of debt	$ 14,279

13. Fair Value Measurements

We determine the fair value of financial and non-financial assets using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value 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 financial instruments include cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, warrant derivative liability, contingent consideration liabilities, and short-term and long-term debt. The carrying amounts of certain short-term financial instruments, including cash and cash equivalents, restricted cash, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. Short-term and long-term debt are reported at their amortized costs on our consolidated balance sheets. The remaining financial instruments are reported on our consolidated balance sheets at amounts that approximate current fair values. The Company's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

Recurring Fair Value Measurement

The following table presents the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of June 30, 2022 and 2021, by level within the fair value hierarchy:

	Fair Value at June 30, 2022	Fair Value Measurements at June 30, 2022		
		(Level 1)	(Level 2)	(Level 3)
		(In thousands)		
Assets:				
Cash and cash equivalents	$ 19,360	$ 19,360	$ —	$ —
Total	$ 19,360	$ 19,360	$ —	$ —
Liabilities:				
Contingent consideration	$ 396	$ —	$ —	$ 396
CVR liability	578	—	—	578
Warrant	—	—	—	—
Total	$ 974	$ —	$ —	$ 974

	Fair Value at June 30, 2021	Fair Value Measurements at June 30, 2021		
		(Level 1)	(Level 2)	(Level 3)
		(In thousands)		
Assets:				
Cash and cash equivalents	$ 49,649	$ 49,649	$ —	$ —
Total	$ 49,649	$ 49,649	$ —	$ —
Liabilities:				
Contingent consideration	$ 12,057	$ —	$ —	$ 12,057
CVR liability	1,395	—	—	1,395
Total	$ 13,452	$ —	$ —	$ 13,452

Non-Recurring Fair Value Measurement

The following able represents Company's financial assets and liabilities that were accounted for at fair value on a non-recurring basis as of June 30, 2022 and 2021, by level within the fair value hierarchy:

	Fair Value at June 30, 2022	Fair Value Measurements at June 30, 2022		
		(Level 1)	(Level 2)	(Level 3)
		(In thousands)		
Non-recurring				
Fixed payment arrangements	$ 13,051	$ —	$ —	$ 13,051
Total	$ 13,051	$ —	$ —	$ 13,051

	Fair Value at June 30, 2021	Fair Value Measurements at June 30, 2021		
		(Level 1)	(Level 2)	(Level 3)
		(In thousands)		
Non-recurring				
Fixed payment arrangements	$ 9,458	$ —	$ —	$ 9,458
Total	$ 9,458	$ —	$ —	$ 9,458

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, 2022:

	CVR Liability	Contingent Consideration	Fixed Payment Arrangements	Warrant Liability
		(In thousands)		
Balance as of June 30, 2021	$ 1,395	$ 12,057	$ 9,458	$ —
Included in earnings	(817)	604	1,148	(211)
Purchases, issues, sales and settlements:				
Issues	—	—	7,645	590
Settlements*	—	(12,265)	(5,200)	(379)
Balance as of June 30, 2022	$ 578	$ 396	$ 13,051	$ —

** Including $9.1 million reversal of contingent consideration liabilities see Note 10 Other Liabilities and $0.4 million liability warrants reclassified to equity.*

Level 3 Inputs

Changes in the fair value of contingent liabilities in subsequent periods are recorded as a loss (gain) in the statements of operations. Significant assumptions used in valuing the CVRs were as follows:

	June 30,	
	2022	2021
Leveraged Beta	0.85	0.91
Market risk premium	6.22 %	6.00 %
Risk-free interest rate	2.86 %	0.36 %
Discount	20.50 %	13.00 %
Company specific discount	10.00 %	5.00 %

Significant assumptions used in valuing the warrants were as follows:

	January 26, 2022
Expected volatility	56.75 %
Equivalent term (years)	5.00
Risk-free rate	1.66 %
Dividend yield	0.00 %

The fixed payment arrangements are recognized at their amortized cost basis using market appropriate discount rates and are accreted up to their ultimate face value over time. Significant assumptions used in valuing the Fixed Payment Arrangements were as follows:

	June 30,	
	2022	2021
Discount rate - minimum	10.0 %	10.0 %
Discount rate - maximum	15.4 %	12.4 %

14. Income Taxes

The provision for income taxes consisted of the following:

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Current:		
Federal	$ —	$ —
State	7	16
Total current tax expense	7	16
Deferred:		
Federal	(91)	200
State	(26)	43
Total deferred tax expense	(117)	243
Provision for income taxes	$ (110)	$ 259

Income tax benefit resulting from applying statutory rates in jurisdictions in which the Company is taxed (Federal and various states) differs from the income tax provision (benefit) in the financial statements. Reconciliation of the U.S. federal statutory income tax rates to our effective tax rate is as follows.

	Year Ended June 30,			
	2022		2021	
	(In thousands)			
Tax at statutory rate	$ (23,159)	(21.00)%	$ (12,185)	(21.00)%
State income taxes, net of federal benefit	601	0.55 %	(2,461)	(4.24)%
Permanent difference	—	— %	—	— %
Stock based compensation	273	0.27 %	43	0.07 %
Contingent consideration	(155)	(0.14)%	(667)	(1.15)%
162(m) limitation	76	0.08 %	235	0.40 %
Goodwill impairment	9,733	8.83 %	—	— %
Transaction costs	—	— %	160	0.28 %
Change in tax rate	—	— %	—	— %
Remeasurement of deferred taxes	—	— %	—	— %
Effect of phased-in tax rate	—	— %	—	— %
Loss on debt extinguishment and interest expense	—	— %	—	— %
Change in valuation allowance	12,472	11.31 %	14,483	24.96 %
Derivative income	—	— %	—	— %
Other	49	0.01 %	651	1.13 %
Net income tax provision (benefit)	$ (110)	(0.09)%	$ 259	0.45 %

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:

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Deferred tax assets:		
Net operating loss carry forward	$ 114,443	$ 106,712
Accrued Rebates	5,944	8,412
Share-based compensation	2,773	2,330
Accrued expenses	817	1,507
R&D credits	2,423	2,115
Interest	2,975	2,064
Inventory	1,177	1,704
Lease liability	799	1,031
Other	1,301	1,526
Total deferred tax assets	132,652	127,401
Less: valuation allowance	(128,966)	(116,494)
Deferred tax assets, net of valuation allowance	3,686	10,907
Deferred tax liabilities:		
Intangibles	(2,717)	(9,396)
ROU asset	(308)	(1,009)
Fixed assets	(788)	(745)
Total deferred tax liabilities	(3,813)	(11,150)
Net deferred tax liabilities	$ (127)	$ (243)

In 2022, the impairment of goodwill decreased net deferred tax liabilities by $0.1 million resulting in an income tax benefit of $0.1 million. As of June 30, 2022, the Company had $0.1 million deferred tax liabilities included in other long-term liabilities in the consolidated balance sheet.

The Company has recorded a valuation allowance of $129.0 million and $116.5 million at June 30, 2022 and 2021, respectively, to reserve its net deferred tax assets. The change in valuation allowance is due to the change in inventory of deferred items exclusive of indefinite lived deferred tax liabilities which cannot be fully offset with existing attributes. 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 had federal net operating losses of approximately $503.2 million and $466.7 million as of June 30, 2022, and June 30, 2021, respectively that, subject to limitation, may be available in future tax years to offset taxable income. Of the available federal net operating losses, approximately $171.5 million can be carried forward indefinitely while the remaining balance will begin to expire in 2024. As of June 30, 2022, the Company had research and development credits of $3.0 million, which begin to expire in 2024. The available state net operating losses, if not utilized to offset taxable

Income in future periods, will begin to expire in 2025 through 2039. 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, 2022, 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.

The Company recognizes interest and penalties related to uncertain tax positions in income tax expense. The Company has no accrued interest related to its uncertain tax positions as they all relate to timing differences that would adjust the Company's net operating loss carryforward, interest expense carryover or research and development credit carryover and therefore do not require recognition. As a result of these timing differences, at June 30, 2022 and 2021, the Company had gross unrecognized tax benefits related to uncertain tax positions of $9.8 million and $11.5 million, respectively. Changes in unrecognized benefits in any given year are recorded as a component of deferred tax expense. A tabular roll-forward of the Company's gross unrecognized tax benefits is below.

	June 30,	
	2022	2021
	(In thousands)	
Beginning balance	$ 11,537	$ —
Increase resulting from prior period tax positions	—	12,017
Increase resulting from current period tax positions	—	2
Decrease resulting from current period tax positions	(1,704)	(482)
Ending balance	$ 9,833	$ 11,537

The change in the Company's gross unrecognized tax benefits relates to the acquisition of Neos, whereby historic tax positions of Neos were inherited in the acquisition.

Additionally, Neos pre-acquisition tax years are subject to the same general statute of limitations, resulting in its tax years back to 2004 being subject to examination.

15. Stockholders Equity

The Company has 200.0 million shares of common stock authorized with a par value of $0.0001 per share and 50.0 million shares of preferred stock authorized with a par value of $0.0001 per share. As of June 30, 2022 and June 30, 2021, the Company had 38,578,825 and 27,490,412 common shares issued and outstanding, respectively, and no preferred shares issued and outstanding.

Included in the common stock outstanding are 1,707,730 shares of unvested restricted stock issued to executives, directors, and employees.

On June 8, 2020, the Company filed a shelf registration statement (the "2020 Shelf"), which was declared effective by the SEC on June 17, 2021, covering up to $100.0 million of its common stock, preferred stock, debt securities, warrants, rights, and units. As of June 30, 2022, approximately $43.0 million remains available under the 2020 Shelf.

On June 4, 2021, the Company entered into an agreement with an agent for the sale of up to $30.0 million of its common stock from time to time in "at-the-market" offerings under the 2020 Shelf (the "ATM Sales Agreement"). During the year ended June 30, 2022, the Company issued 2,430,784 shares of common stock under the ATM Sales Agreement, with total gross proceeds of approximately $5.1 million before deducting underwriting discounts, commissions, and other offering expenses of $0.2 million. As of June 30, 2022, approximately $12.2 million of the Company's common stock remained available to be sold pursuant to the ATM Sales Agreement.

On September 28, 2021, the Company filed a shelf registration statement (the "2021 Shelf"), which was declared effective by the SEC on October 7, 2021, covering up to $100.0 million of its common stock, preferred stock, debt securities, warrants, rights, and units. As of June 30, 2022, approximately $92.4 million remain available under the 2021 Shelf.

On March 7, 2022, the Company closed on an underwritten public offering utilizing the 2021 Shelf, pursuant to which, the Company sold, (i) 3,030,000 shares of the Company's common stock, (ii) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 3,030,000 shares of common stock, and (iii) common stock purchase warrants (the "Common Warrants") to purchase up to 6,666,000 shares of common stock (the "March 2022 Offering"). The shares of common stock and the Pre-Funded Warrants were each sold in combination with corresponding Common Warrants, with one Common Warrant to purchase 1.1 shares of common stock for each share of common stock or each Pre-Funded Warrant sold. The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and were exercised in full in April 2022. The Common Warrants have an exercise price of $1.30 per share of common stock and are exercisable six months after the date of issuance and have a term of five years from the date of exercisability. The Company raised gross proceeds of $7.6 million through the March 2022 Offering before commission and other costs of $0.8 million. The Pre-Funded and Common Warrants have a combined fair value of approximately $6.3 million and are classified as additional paid in capital in stockholders' equity in the Company's financial statements (see Note 17 - Warrants).

On January 26, 2022, as consideration for entering into the Avenue Capital Agreement, the Company issued the Avenue Capital Warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price equal to $1.21 per share. The Avenue Capital Warrants are immediately exercisable and expire on January 31, 2027. On March 7, 2022, the Company closed on an equity offering of shares of common stock and warrants, as described above, at an offering price of $1.25 per share. As this offering precluded the Company from pursuing any equity financing prior to July 7, 2022 and the effective price of the March 7, 2022 offering was more than the exercise price of the Avenue Capital Warrants, the number of common stock issuable upon exercise of the Avenue Capital Warrants were set to 867,769 shares at an exercise price of $1.21. As a result, on March 7, 2022, the Company reclassified the Avenue Capital Warrants from a liability to equity and recorded the $0.4 million fair value as additional paid in capital in stockholders' equity in the Company's financial statements (see Note 12 – Long-term Debt and Note 13 – Fair Value Considerations).

16. Equity Incentive Plans

Aytu 2015 Plan. On June 1, 2015, the Company's stockholders approved the Aytu BioPharma 2015 Stock Option and Incentive Plan (the "Aytu 2015 Plan"), which, as amended in July 2017, provides for the award of stock options, stock appreciation rights, restricted stock, and other equity awards. On February 13, 2020, the Company's stockholders approved an increase to 5.0 million total shares of common stock in the Aytu 2015 Plan. 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 Aytu 2015 Plan will be added back to the shares of common stock available for issuance under the Aytu 2015 Plan. Stock options granted under this plan have contractual terms of 10 years from the grant date and a vesting period ranging from 3 to 4 years. The restricted stock awards have a vesting period ranging from 4 to 10 years, and the restricted stock units have a vesting period 4 years. As of June 30, 2022, the Company had 2,383,061 shares available for grant under the Aytu 2015 Plan.

Neos 2015 Plan. Pursuant to the Neos Acquisition, the Company assumed 69,721 stock options and 35,728 restricted stock units (RSUs) previously granted under Neos plan. Accordingly, on April 19, 2021, the Company registered 105,449 shares of its common stock under the Neos Therapeutics, Inc. 2015 Stock Options and Incentive Plan (the "Neos 2015 Plan") with the SEC. The terms and conditions of the assumed equity securities will stay the same as they were under the previous Neos plan. The Company allocated costs of the replacement awards attributable to pre- and post-combination service periods. The pre-combination service costs were included in the considerations transferred. The remaining costs attributable to the post-combination service period are being recognized as stock-based compensation expense over the remaining terms of the replacement awards. Stock options granted under this plan have contractual terms of 10 years from the grant date and a vesting period ranging from 1 to 4 years. As of June 30, 2022, the Company had 45,294 shares available for grant under the Neos 2015 Plan.

Stock Options

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2021	109,588	$ 14.52	8.07
Forfeited/Cancelled	(15,569)	7.98	
Expired	(13,642)	9.65	
Outstanding at June 30, 2022	80,377	$ 16.61	7.77
Exercisable at June 30, 2022	54,649	$ 20.58	7.77

The following table details the options outstanding at June 30, 2022 by range of exercise prices:

Range of Exercise Prices	Number of Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life of Options Outstanding	Number of Options Exercisable	Weighted Average Exercise Price
$ 6.2 - 9.70	38,998	$ 6.44	7.65	19,882	$ 6.50
$ 9.80 - 14.70	41,225	$ 14.13	7.90	34,613	$ 14.28
$ 2,800.00 - 4,200.00	154	$ 3,255.06	3.80	154	$ 3,255.06
	80,377	$ 16.61	7.77	54,649	$ 20.58

No stock options were granted during the year ended June 30, 2022. The weighted-average grant date fair value of options granted during the years ended June 30, 2022 and June 30, 2021 was $0 and $3.81, respectively. As of June 30, 2022, there was $0.2 million of total unrecognized compensation cost adjusted for estimated forfeitures, related to non-vested stock options granted under the Company's equity incentive plans. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.6 years.

Restricted Stock

During the year ended June 30, 2022, the Company granted a total of 295,000 shares of restricted stock, with certain accelerated vesting conditions, to members of its management team pursuant to the Aytu 2015 Plan, of which 1/3 vest on the grant date and 1/12 on the first day of each quarter thereafter, subject to continuing employment with the Company through each vesting date. These restricted stock grants have a grant date fair value ranging from $2.65 per-share to $4.02 per-share.

Restricted stock activity under the Aytu 2015 Plan is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2021	1,955,268	$ 7.83
Granted	295,000	3.67
Vested	(642,696)	6.81
Unvested at June 30, 2022	1,607,572	$ 7.47

As of June 30, 2022, there was $9.6 million of total unrecognized compensation costs adjusted for estimated forfeitures, related to non-vested restricted stock granted under the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.7 years. The total fair value of restricted stock vested during the year ended June 30, 2022 was $1.6 million.

The Company previously issued 158 shares of restricted stock outside of the Aytu 2015 Plan, which vest in July 2026. On January 17, 2022, the Company granted 100,000 shares of restricted stock to a member of its management team outside of the Aytu 2015 Plan, of which 1/3 vest on January 17, 2023 and 1/12 each quarter thereafter, subject to continuing employment with the Company through each vesting date until January 17, 2025. This restricted stock grant has a grant date fair value of $1.35 per-share. As of June 30, 2022, there was $0.9 million total unrecognized costs adjusted for estimated forfeitures, related to non-vested restricted stock outside of the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 3.4 years.

Restricted Stock Units

The year ended June 30, 2022, the Company granted a total of 170,000 shares of restricted stock units ("RSUs"), to members of its management pursuant team to the Aytu 2015 Plan, of which 1/3 vest on the grant date and 1/12 on the first day of each quarter thereafter, subject to continuing employment with the Company through each vesting date. These RSUs have grant date fair value ranging from $1.06 per share to $1.86 per-share.

RSUs activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2021	78,318	$ 7.20
Granted	170,000	1.29
Vested	(15,396)	6.20
Forfeited	(62,922)	7.44
Unvested at June 30, 2022	170,000	$ 1.29

As of June 30, 2022, there was $0.2 million of total unrecognized compensation costs adjusted for estimated forfeitures, related to non-vested RSUs granted under the Company's equity incentive plans. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.6 years. The total fair value of RSUs vested during the year ended June 30, 2022 was $0.1 million.

Stock-based compensation expense related to the fair value of stock options and restricted stock and RSUs was included in the statements of operations as set forth in the below table:

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Cost of sales	$ 31	$ 16
Research and development	536	68
Selling and marketing	24	27
General and Administrative	4,657	3,463
Total stock-based compensation expense	$ 5,248	$ 3,574

17. Warrants

Equity Classified Warrants

On March 7, 2022, the Company closed on an underwriting agreement, pursuant to which, the Company sold, (i) 3,030,000 shares of the Company's common stock, (ii) Pre-Funded Warrants to purchase up to 3,030,000 shares of common stock, and (iii) Common Warrants to purchase up to 6,666,000 shares of common stock. The shares of common stock and the Pre-Funded Warrants were each sold in combination with corresponding Common Warrants, with one Common Warrant to purchase 1.1 shares of common stock for each share of common stock or each Pre-Funded Warrant sold. The Pre-Funded Warrants have an exercise price of $0.0001 per share of common stock and were exercised in full in April 2022. The Common Warrants have an exercise price of $1.30 per share of common stock and are exercisable six months after the date of issuance and have a term of five years from the date of exercisability (see Note 15 – Stockholders Equity).

On January 26, 2022, as consideration for entering into the Avenue Capital Agreement, the Company issued Avenue Capital Warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price of $1.21 per share, subject to adjustment. The Avenue Capital Warrants were immediately exercisable and expire on January 31, 2027. On March 7, 2022, the Company closed on an equity offering of shares of common stock and warrants at an offering price of $1.25 per share. As this offering precluded the Company from pursuing any equity financing prior to July 7, 2022 and the effective price of the March 7, 2022 offering was more than the exercise price of the Avenue Capital Warrants, the number of common stock issuable upon exercise of the Avenue Capital Warrants were set to 867,769 shares at an exercise price of $1.21. As a result, on March 7, 2022, the Company reclassified the Avenue Capital Warrants from a liability to equity (see Note 12 – Long-term Debt, Note 13 – Fair Value Considerations and Note 15 – Stockholders Equity).

Significant assumptions used in valuing these warrants were as follows:

	March 7, 2022
Valuation method	Black-Scholes
Expected volatility	54.45 %
Equivalent term (years)	4.89 - 5.00
Risk-free rate	1.71 %
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, 2021	1,254,952	$ 35.85	2.83
Warrants issued	10,563,769	0.92	5.12
Warrants exercised	(3,030,000)	0.00	—
Warrants expired	(124,250)	124.69	—
Outstanding June 30, 2022	8,664,471	$ 4.63	4.73

During the year ended June 30, 2022, 124,250 warrants with a weighted-average exercise price of $124.7 expired.

Liability 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 warrants are valued using a Black-Scholes model. Changes in the fair value of liability classified derivative financial instruments in subsequent periods are recorded as derivative income or expense in the statements of operations.

As of June 30, 2022 and 2021, the Company had 24,105 liability warrants outstanding with a weighted-average exercise price of $720.0. These warrants are expected to expire on August 25, 2022.

18. Employee Benefit Plan

Subsequent to the merger with Neos, Aytu has two 401(k) plans the ("Neos Plan") and the ("Aytu Plan') both plans allow participants to contribute a portion of their salary, subject to eligibility requirements and annual IRS limits. The Neos Plan matches 100% of the first 3% contributed by employees and matches 50% on the next 4% and 5% contributed by the employees. The Company's match for the Neos Plan was approximately $0.4 million and $0.1 million for the years ended June 30, 2022 and 2021, respectively. The Aytu Plan matches 50% of the first 6% contributed to the plan by employees. The Company's match for the Aytu Plan was approximately $0.2 million and $0.2 million during the years ended June 30, 2022 and 2021, respectively.

19. Commitments and Contingencies

Pediatric Portfolio Fixed Payments and Product Milestone

The Company assumed two fixed, periodic payment obligations to an investor (the "Fixed Obligation"). Under the first fixed obligation, the Company was to pay monthly payment of $0.1 million beginning November 1, 2019 through January 2021, with a balloon payment of $15.0 million that was to be due in January 2021 ("Balloon Payment Obligation"). A second fixed obligation requires the Company pay a minimum of $0.1 million monthly through February 2026, except for $0.2 million paid in January 2020.

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 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 remained 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. The first fixed obligation was fully paid as of January 2021.

On June 21, 2021, the Company entered into a Waiver, Release and Consent pursuant to which the Company paid $2.8 million to the investor in satisfaction of the second fixed obligation. The company agreed to pay the remaining fixed obligation of $3.0 million in six equal quarterly payments of $0.5 million over the next six quarters commencing September 30, 2021.

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.

The Karbinal Agreement also contains minimum unit sales commitments, which is based on a commercial year that spans from August 1 through July 31, of 70,000 units annually through 2025. 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 2025. The Karbinal Agreement make-whole payment is capped at $2.1 million each year. The annual payment is due in August of each year. The Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $3.0 million based on cumulative net sales, the first of which is triggered at $40.0 million of net revenues.

Prior to June 30, 2022, the Company's contingent consideration liabilities included obligations under licensing arrangements for Tuzistra XR. The royalty and make-whole milestone payments related to licensing agreements with TRIS Pharma, Inc. ("Tris") for Tuzistra XR were being accounted for as contingent consideration and revalued at each reporting period. As a result of the discontinuation of commercializing Tuzistra (see Note 3 – Revenue from Contracts with Customers) and a settlement agreement with Tris, the Company concluded that the product milestone payments underlying the contingent consideration liability ceased to exist. The Company reversed the remaining contingent consideration liabilities of $8.5 million and recorded a liability of $7.6 million related to the settlement payments payable to Tris for termination of the Tuzistra licensing agreement. The settlement payments are included in fixed payment arrangements at their present value using the Company's estimated borrowing rate. The Company recognized $0.9 million gain on settlement of the Tris contingent consideration liabilities in the consolidated statements of operations for the year ended June 30, 2022.

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 five additional payments of $0.5 million when certain levels of FlutiCare sales are achieved.

Pursuant to the UIRD Agreement, Innovus will pay to UIRD a total milestone payment of $50,000 every other year beginning on July 1, 2021 for a total payment of $0.2 million. The discounted value as of June 30, 2022, was approximately $0.1 million. The first milestone cash payment of $50,000 was made in July 2021.

Rumpus Earn Out Payments

On April 12, 2021, the Company acquired substantially all of the assets of Rumpus, pursuant to which the Company acquired certain rights and other assets, including key commercial global licenses with Denovo Biopharma LLC ("Denovo") and Johns Hopkins University ("JHU"), relating to AR101. Upon the achievement of certain regulatory and commercial milestones, up to $67.5 million in earn-out payments, which are payable in cash or shares of common stock, generally at the Company's option, are payable to Rumpus. Under the license agreement with Denovo, the Company assumed the responsibility for paying annual maintenance fees of $25,000, a license option fee of $0.6 million payable in April 2022, and upon the achievement of certain regulatory and commercial milestones, up to $101.7 million, and escalating royalties based on net product sales ranging in percentage from the low teens to the high teens. Finally, under the license agreement with Johns Hopkins, the Company assumed the responsibility for paying minimum annual royalties escalating from $5,000 to $20,000 beginning in calendar year 2022, royalties of 3.0% of net product sales, and upon the achievement of certain regulatory and commercial milestones, up to $1.6 million.

During the year ended June 30, 2022, AR101 received Orphan Drug Designation ("ODD") and Fast Track designation from the FDA, resulting in total milestone payments of $4.0 million, which were paid in 2,188,940 shares of common stock and $2.6 million in cash.

20. License Agreements

Healight

In April 2020, the Company entered into a licensing agreement with Cedars-Sinai Medical Center to secure worldwide rights to various potential esophageal and nasopharyngeal uses of Healight, an investigational medical device platform technology.

The agreement with Cedars-Sinai grants the Company a license to all patent and development related technology rights for the intra-corporeal therapeutic use of ultraviolet light in the field of endotracheal and nasopharyngeal applications. The term of the agreement is on a country-by-country basis and will expire on the latest of the date upon which the last to expire valid claim shall expire, ten years after the first bona fide commercial sale of such licensed product in a country, or the expiration of any market exclusivity period granted by a regulatory agency. Pursuant to the terms of the agreement, the Company paid an initial $0.3 million license fee and approximately $0.1 million in earlier patent prosecution fees.

NeuRx

In October 2018, Neos entered into an Exclusive License Agreement ("NeuRx License") with NeuRx Pharmaceuticals LLC ("NeuRx"), pursuant to which NeuRx granted Neos an exclusive, worldwide, royalty-bearing license to research, develop, manufacture, and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX-101, referred to by Neos as NT0502. NT0502 is a new chemical entity that is being developed by Neos for the treatment of sialorrhea, which is excessive salivation or drooling. The Company may be required to make certain development and milestone payments and royalties based on annual net sales, as defined in the NeuRx License. Royalties are to be paid on a country-by-country and licensed product-by-licensed product basis, during the period of time beginning on the first commercial sale of such licensed product in such country and continuing until the later of: (i) the expiration of the last-to-expire valid claim in any licensed patent in such country that covers such licensed product in such country; and/or (ii) expiration of regulatory exclusivity of such licensed product in such country.

Teva

On December 21, 2018, Neos and Teva Pharmaceuticals USA, Inc. ("Teva") entered into an agreement granting Teva a non-exclusive license to certain patents owned by Neos by which Teva has the right to manufacture and market its generic version of Cotempla XR-ODT under an Abbreviated New Drug Application ("ANDA") filed by Teva beginning on July 1, 2026, or earlier under certain circumstances.

Actavis

On October 17, 2017, Neos entered into an agreement granting Actavis a non-exclusive license to certain patents owned by Neos by which Actavis has the right to manufacture and market its generic version of Adzenys XR-ODT under its ANDA beginning on September 1, 2025, or earlier under certain circumstances.

Shire

In July 2014, Neos entered into a Settlement Agreement and an associated License Agreement (the "2014 License Agreement") with Shire LLC ("Shire") for a non-exclusive license to certain patents for certain activities with respect to Neos' New Drug Application (the "NDA") No. 204326 for an extended-release orally disintegrating amphetamine polistirex tablet. In accordance with the terms of the 2014 License Agreement, following the receipt of the approval from the FDA for Adzenys XR-ODT, Neos paid a lump sum, non-refundable license fee of an amount less than $1.0 million in February 2016. Neos is paying a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents.

In March 2017, Neos entered into a License Agreement (the "2017 License Agreement") with Shire, pursuant to which Shire granted Neos a non-exclusive license to certain patents owned by Shire for certain activities with respect to Neos' NDA No. 204325 for an extended-release amphetamine oral suspension. In accordance with the terms of the 2017 License Agreement, following the receipt of the approval from the FDA for Adzenys ER, Neos paid an up-front, non-refundable license fee of an amount less than $1.0 million in October 2017. Neos is paying a single digit royalty on net sales of Adzenys ER during the life of the patents. Adzenys ER was discontinued as of September 30, 2021.

The royalties are recorded as cost of goods sold in the same period as the net sales upon which they are calculated.

Additionally, each of the 2014 and 2017 License Agreements contains a covenant from Shire not to file a patent infringement suit against Neos alleging that Adzenys XR-ODT or Adzenys ER, respectively, infringes the Shire patents.

21. Segment Information

The Company's chief operating decision maker, 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.

The Company manages and aggregates its operational and financial information in accordance with two reportable segments: BioPharma and Consumer Health. The BioPharma segment consists of the Company's prescription products. The Consumer Health segment contains the Company's consumer healthcare products.

During the year ended June 30, 2022, the BioPharma Segment recognized a total impairment loss of $64.6 million related to impairment of goodwill and write-down of assets due to the discontinuance of five non-core products, our Consumer Health segment recognized $10.8 million of goodwill and intangible assets write downs (see Note 8 Goodwill and Other intangible Assets).

Select financial information for these segments is as follows:

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Consolidated revenue:		
BioPharma	$ 61,121	$ 32,678
Consumer Health	35,548	32,954
Consolidated revenue	$ 96,669	$ 65,632

	Year Ended June 30,	
	2022	2021
	(In thousands)	
Consolidated net loss:		
BioPharma	$ (92,708)	$ (50,529)
Consumer Health	(17,465)	(7,760)
Consolidated net loss	$ (110,173)	$ (58,289)

	June 30,	
	2022	2021
	(In thousands)	
Total assets:		
BioPharma	$ 121,377	$ 236,449
Consumer Health	16,246	29,219
Consolidated assets	$ 137,623	$ 265,668

22. Subsequent Events

In August 2022, the Company completed an underwritten public offering of (i) 21,505,814 shares of its common stock, and, in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 1,750,000 shares of its common stock, and (ii) accompanying warrants (the "Common Warrants") to purchase

23,255,814 shares of its common stock (the "Offering") resulting in gross and net proceeds of $10.0 million and $9.1 million, respectively, assuming none of the accompanying Common Warrants issued in the Offering are exercised. The pre-funded warrants were exercised in full in August 2022. The Company intends to use the net proceeds from the Offering for advancing the development of its pipeline assets, including for advancing the PREVEnt Trial evaluating AR101 for the treatment of VEDS, for growth of the company's commercial business, and for working capital and general corporate purposes.

DESCRIPTION OF SECURITIES

General

This describes the general terms of our capital stock. For a more detailed description of our capital stock, you should read the applicable provisions of the Delaware General Corporation Law, or DGCL, and our charter and bylaws.

Our certificate of incorporation provides that we may issue up to 200,000,000 shares of common stock, par value $0.0001 per share, and up to 50,000,000 shares of preferred stock, par value $0.0001 per share, and permits our board of directors, without stockholder approval, to amend the charter to increase or decrease the aggregate number of shares of stock or the number of shares of stock of any class or series that we have authority to issue. As of September 19, 2022, there were 62,432,727 shares of our common stock outstanding and no shares of our preferred stock outstanding. Under Delaware law, stockholders generally are not personally liable for our debts or obligations solely as a result of their status as stockholders.

Common Stock

Holders of our common stock generally have no preference, conversion, exchange, sinking fund, redemption or appraisal rights and have no preemptive rights to subscribe for any of our securities. Holders of our common stock are entitled to receive dividends when authorized by our board of directors out of assets legally available for the payment of dividends. They are also entitled to share ratably in our assets legally available for distribution to our stockholders in the event of our liquidation, dissolution or winding up, after payment of or adequate provision for all of our known debts and liabilities. These rights are subject to the preferential rights of any other class or series of our stock. The outstanding shares of common stock are, and any shares offered by this prospectus will be when issued and paid for, fully paid and nonassessable.

Each outstanding share of common stock entitles the holder to one vote on all matters submitted to a vote of stockholders, including the election of directors. Except as provided with respect to any other class or series of stock, the holders of our common stock will possess the exclusive voting power. In uncontested elections, directors are elected by a majority of all of the votes cast in the election of directors, and in contested elections, directors are elected by a plurality of all of the votes cast in the election of directors.

Preferred Stock

Our board of directors has the authority, without stockholder approval, to issue, at any time and from time to time, up to 50,000,000 shares of our preferred stock in one or more classes or series. Each such class or series shall have such preferences, conversion or other rights, voting powers, restrictions, limitations as to dividends or other distributions, qualifications and terms or conditions of redemption as shall be determined by our board of directors and set forth in articles supplementary relating to such class or series. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of holders of any preferred stock that may be issued in the future. Such rights may include voting and conversion rights which could adversely affect the holders of the common stock. Satisfaction of any dividend or liquidation preferences of outstanding preferred stock would reduce the amount of funds available, if any, for the payment of dividends or liquidation amounts on common stock.

A prospectus supplement, relating to any offered class or series of preferred stock, will specify the following terms of such class or series, as applicable:

- the designation and par value of such class or series of preferred stock,
- the number of shares of such class or series of preferred stock offered, the liquidation preference per share and the offering price of such class or series of preferred stock,

- the dividend rate(s), period(s), and/or payment date(s) or method(s) of calculation thereof applicable to such class or series of preferred stock,
- whether dividends on such class or series of preferred stock are cumulative or not and, if cumulative, the date from which dividends on such class or series of preferred stock shall accumulate,
- the provision for a sinking fund, if any, for such class or series of preferred stock,
- the provision for redemption, if applicable, of such class or series of preferred stock,
- any listing of such class or series of preferred stock on any securities exchange,
- the preemptive rights, if any, of such class or series of preferred stock,
- the terms and conditions, if applicable, upon which shares such class or series of preferred stock will be convertible into shares of our common stock or shares of any other class or series of our stock or other securities, including the conversion price (or manner of calculation thereof),
- a discussion of any additional material federal income tax consequences applicable to an investment in such class or series of preferred stock,
- the relative ranking and preferences of such class or series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of our Company,
- any limitations on issuance of any class or series of stock ranking senior to or on parity with such class or series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of our Company,
- any voting rights of such class or series of preferred stock, and
- any other specific terms, preferences, rights, limitations or restrictions of such class or series of preferred stock.

Warrants

We may issue warrants to purchase the securities described in this prospectus. Unless otherwise provided in the applicable prospectus supplement, each series of warrants will be issued under a separate warrant agreement to be entered into between us and a warrant agent. Additional information regarding any warrants we may offer and the related warrant agreement will be set forth in the applicable prospectus supplement. As of September 23, 2022, the following warrants were outstanding:

- 162,790 warrants, issued in March 2018, exercisable into 162,790 shares of Aytu common stock, with a $108.00 strike price and set to expire in March 2023;
- 419,160 warrants issued in October 2018, exercisable into 419,160 shares of Aytu common stock, with a $15.00 strike price and set to expire in October 2023;
- 50,870 Placement Agent Warrants issued March 13, 2020, exercisable into 50,870 shares of Aytu common stock, with a $14.38 strike price and set to expire in March 2025;
- 104,000 Placement Agent Warrants issued March 13, 2020, exercisable into 104,000 shares of Aytu common stock, with a $15.63 strike price and set to expire in March 2025;
- 81,505 Placement Agent Warrants issued March 23, 2020, exercisable into 81,505 shares of Aytu common stock, with a $19.94 strike price and set to expire in March 2025;
- 919 warrants assumed as part of the February 14, 2020 Merger with Innovus Pharmaceuticals, Inc., exercisable into approximately 919 shares of Aytu common stock, with a weighted-average strike price of $196.88 and a weighted-average expiration date of March 2023;
- 311,458 Placement Agent Warrants issued December 15, 2020. Exercisable into 311,458 shares of Aytu common stock, with a $7.50 strike price and set to expire in December 2025;
- 867,769 warrants, issued in January 2022, exercisable into 867,769 shares of Aytu common stock, with a $1.21 strike price and set expire in January 2027;
- 6,666,000 warrants, issued in March 2022, exercisable into 6,666,000 shares of Aytu common stock, with a $1.30 strike price and set to expire in March 2027; and
- 23,255,814 warrants, issued in August 2022, exercisable into 23,255,814 shares of Aytu common stock, with a $0.43 strike price and set to expire in August 2027.

Each of these warrants entitles the holder to purchase one share of common stock at prices ranging between $0.43 and $196.88, as converted, per share, with a weighted average exercise price of $1.55 per share. Certain of these warrants has a net exercise provision under which its holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise of the warrant after deduction of the aggregate exercise price. Each of these warrants also contains provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations. Certain of these warrants contain a provision requiring a reduction to the exercise price in the event we issue common stock, or securities convertible into or exercisable for common stock, at a price per share lower than the warrant exercise price.

Options

On June 1, 2015, our stockholders approved the 2015 Stock Option and Incentive Plan, which 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 us 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 August 31, 2017, we had outstanding options to purchase an aggregate of 38,263 shares of our common stock at a weighted average exercise price of $16.31 per share. Of these, an aggregate of 23,385 are exercisable. The outstanding options have vesting requirements with an aggregate of 3,748 vesting one third on each of November

11, 2016, 2017 and 2018, an aggregate of 1,560 vesting one quarter on each of November 11, 2016, 2017, 2018 and 2019, an aggregate of 104 vesting one quarter on each of August 7, 2016, 2017, 2018 and 2019, an aggregate of 7,966 vesting one third on each of July 7, 2017, 2018 and 2019 and an aggregate of 1,500 vesting in full on November 4, 2017.

The 2015 Plan is administered by our Board or a committee designated by the Board (as applicable, the Administrator). The Administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2015 Plan. The Administrator may delegate to our Chief Executive Officer the authority to grant stock options and other awards to employees who are not subject to the reporting and other provisions of Section 16 of the Exchange Act and not subject to Section 162(m) of the Code, subject to certain limitations and guidelines.

Persons eligible to participate in the 2015 Plan are full or part-time officers, employees, non-employee directors, directors and other key persons (including consultants and prospective officers) of our company and its subsidiaries as selected from time to time by the Administrator in its discretion. Approximately 30 individuals are currently eligible to participate in the 2015 Plan, which includes officers, employees who are not officers, non-employee director, former employees and other individuals who are primarily consultants.

The 2015 Plan provides that upon the effectiveness of a "sale event" as defined in the 2015 Plan, except as otherwise provided by the Administrator in the award agreement, all stock options, stock appreciation rights and other awards will be assumed or continued by the successor entity and adjusted accordingly to take into account the impact of the transaction. To the extent, however, that the parties to such sale event do not agree that all stock options, stock appreciation rights or any other awards shall be assumed or continued, then such stock options and stock appreciation rights shall become fully exercisable and the restrictions and conditions on all such other awards with time-based conditions will automatically be deemed waived. Awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the Administrator's discretion. In addition, in the case of a sale event in which our stockholders will receive cash consideration, we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration and the exercise price of the options or stock appreciation rights in exchange for the cancellation thereto.

Quotation on the NASDAQ Capital Market

Our common stock is quoted on the Nasdaq Capital Market under the symbol "AYTU".

Transfer Agent

The transfer agent of our common stock is Issuer Direct Corporation. Their address is 500 Perimeter Park Drive, Suite D, Morrisville, NC 27560.

Delaware Anti-Takeover Law and Provisions of Our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law. We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding specified shares; or

- at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation to or with the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an "interested stockholder" as any person that is:

- the owner of 15% or more of the outstanding voting stock of the corporation;
- an affiliate or associate of the corporation who was the owner of 15% or more of the outstanding voting stock of the corporation at any time within three years immediately prior to the relevant date; or
- the affiliates and associates of the above.

Under specific circumstances, Section 203 makes it more difficult for an "interested stockholder" to effect various business combinations with a corporation for a three-year period, although the stockholders may, by adopting an amendment to the corporation's certificate of incorporation or bylaws, elect not to be governed by this section, effective 12 months after adoption.

Our certificate of incorporation and bylaws do not exclude us from the restrictions of Section 203. We anticipate that the provisions of Section 203 might encourage companies interested in acquiring us to negotiate in advance with our board of directors since the stockholder approval requirement would be avoided if a majority of the directors then in office approve either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder.

Certificate of Incorporation and Bylaw. Provisions of our certificate of incorporation and bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, these provisions include:

- the authorization of 50,000,000 shares of "blank check" preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval;
- limiting the removal of directors by the stockholders;
- allowing for the creation of a staggered board of directors;

- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

Exhibit 21.1

SUBSIDIARIES OF AYTU BIOPHARMA, INC.

	Name of Subsidiary	State Jurisdiction
1.	Aytu Therapeutics, LLC	Delaware
2.	Innovus Pharmaceuticals, Inc.	Nevada
3.	Semprae Laboratories, Inc	Delaware
4.	Supplement Hunt, Inc.	Nevada
5.	Delta Prime Savings Club, Inc	Nevada
6.	Neos Therapeutics, Inc.	Delaware
7.	Neos Therapeutics Brands, LLC	Delaware
8.	Neos Therapeutics, LP	Texas
9.	PharmaFab Texas, LLC	Texas

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in Aytu BioPharma, Inc. and Subsidiaries' Registration Statements on Form S-8 (No. 333-255325,333 – 205462 and 333-236598) and Form S-3 (Nos. 333-259862, 333-235548, 333-236599 and 333-239010), Form S-4 (File No. 333-252450, 333-235695 and 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, 333-223385, 333-227243 and 333 -227706) of our report dated September 27, 2022 relating to the fiscal year 2022 consolidated financial statements that appear in this Annual Report on Form 10-K.

/s/Plante & Moran, PLLC

Denver, Colorado

September 27, 2022

Exhibit 31.1

AYTU BIOPHARMA, INC.
Certification by 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, 2022 of Aytu BioPharma, 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: September 27, 2022

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

Exhibit 31.2

AYTU BIOPHARMA, INC.
Certification by Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Mark Oki, certify that:

1. I have reviewed this report on Form 10-K for the year ended June 30, 2022 of Aytu BioPharma, 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: September 27, 2022

By: /s/ Mark Oki
Mark Oki
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION OF 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

I Joshua R. Disbrow, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of Aytu BioPharma, Inc. for the fiscal year ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Aytu BioPharma, Inc.

Date: September 27, 2022

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

I Mark Oki, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge, the Annual Report on Form 10-K of Aytu BioPharma, Inc. for the fiscal year ended June 30, 2022 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Aytu BioPharma, Inc.

Date: September 27, 2022

By: /s/ Mark Oki
Mark Oki
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)