Table of Contents

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, 2021

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 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, 2020 was $88.4 million based on the closing price of $5.98 as of that date.

As of September 10, 2021, there were 27,555,120 shares of common stock issued and outstanding.

TABLE OF CONTENTS

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, Aytu BioPharma, Apeaz, Cotempla, Diabasens, FlutiCare, Innovus Pharma, Neos, OmepraCare, Poly-Vi-Flor, Regoxidine, Tri-Vi-Flor, Tuzistra, Urivarx, Zestra, and ZolpiMist which are protected under applicable intellectual property laws and are our property or the property of our subsidiaries. This Form 10-K also contains trademarks, service marks, copyrights and trade names of other companies which are the property of their respective owners. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

We obtained statistical data, market and product data, and forecasts used throughout this Form 10-K from market research, publicly available information and industry publications. While we believe that the statistical data, industry data and forecasts and market research are reliable, we have not independently verified the data, and we do not make any representation as to the accuracy of the information.

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, 2021. 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 Financial Position and Capital Resources

- 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 of senior secured credit facilities with Deerfield and our secured revolving loans with Encina 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 COVID-19

- The coronavirus ("COVID-19") pandemic has and may continue to adversely affect our business, results of operations and financial condition.

Risks Related to Commercialization of Our Products

- 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 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 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 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 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.
- 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 Clinical Development and Regulatory Approval of AR101 for the Treatment of vascular Ehlers-Danlos Syndrome ("vEDS"), Healight for the Treatment for SARS-CoV-2 and Other Viral and Bacterial Respiratory Infections and Our Other Product Candidates

- The design and execution of clinical trials to support FDA-approval of AR101 for the treatment of 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 Reliance on Third Parties

- If we encounter difficulties in maintaining commercial manufacturing and supply agreements with our third-party manufacturers and suppliers of our commercial prescription products or if we encounter issues with our contract manufacturers or suppliers, our ability to commercialize and manufacture commercial prescription products would be impaired.
- If we encounter difficulties in transferring our production of our ADHD products to our third-party contract manufacturing organization ("CMO"), or unable to negotiate a long term supply contract on acceptable terms, our ability to commercialize and manufacture commercial prescription products would be impaired, and our financial conditions could be harmed.

Risks Related to Our Business Operations and Industry

- 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.

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 Ownership 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.

AYTU BIOPHARMA, INC.

PART I

Item 1. Business

Company Overview

We are a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address needs in both prescription and consumer health categories. Through our prescription business, and following our recent merger with Neos Therapeutics, Inc. ("Neos"), which closed on March 19, 2021, we market a portfolio of prescription products addressing large markets with a focus on general pediatric conditions, attention deficit/hyperactivity disorder ("ADHD") and insomnia. We also market a portfolio of consumer health products also addressing large categories through our consumer health subsidiary, acquired in February 2020. Our goal is to become a leading specialty pharmaceutical company focused on large prescription and consumer health categories while building a late-stage development pipeline addressing significant medical needs.

Commercial Prescription Products

Our prescription ADHD portfolio (the "ADHD Portfolio"), which was acquired through the merger with Neos, includes branded products marketed in the United States using our internal commercial organization.

These commercial ADHD products are extended-release ("XR") medications formulated in patient-friendly, orally disintegrating tablet ("ODT") or oral suspension dosage forms that utilize Neos' microparticle modified-release drug delivery technology platform. Neos received approval from the U.S. Food and Drug Administration ("FDA") for three ADHD products and were subsequently launched as displayed below.

Branded Product	Approved Indication	FDA Approval Date	Commercial Launch Date
Adzenys XR-ODT (amphetamine)	Treatment of ADHD in patients 6 years and older	January 2016	May 2016
Cotempla XR-ODT (methylphenidate)	Treatment of ADHD in patients 6 to 17 years old	June 2017	September 2017
Adzenys ER (amphetamine) oral suspension	Treatment of ADHD in patients 6 years and older	September 2017	February 2018

Products containing amphetamine or methylphenidate are the most commonly prescribed medications in the United States for the treatment of ADHD. We believe Adzenys XR-ODT and Cotempla XR-ODT are the first amphetamine and methylphenidate extended-release, orally disintegrating tablets, respectively, marketed for the treatment of ADHD. In 2020, to facilitate improved patient access to our ADHD products, Neos deployed a Neos-sponsored patient support program, called Neos RxConnect. This program now operates through a network of approximately 1,200 pharmacies as of June 30, 2021. Following the Neos merger we rebranded the program as Aytu RxConnect, and we expect to integrate our legacy prescription products into this program with a focus on adding Poly-Vi-Flor, Tri-Vi-Flor, ZolpiMist and Karbinal ER to the program. We expect to have the legacy products incorporated into the program during the second half of calendar 2021, and for our patients and their health care providers to benefit from this state-of-the-art patient support program starting in the first half of calendar 2022.

Our legacy prescription pediatric portfolio includes Cefaclor, a second-generation cephalosporin antibiotic suspension, Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions 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 (Cefaclor, Karbinal ER and Poly-Vi-Flor and Tri-Vi-Flor, collectively the "Pediatric Portfolio"). These products serve large pediatric markets and offer distinct clinical features and patient benefits.

Our primary care portfolio includes ZolpiMist, the only FDA-approved oral spray prescription sleep aid and Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup (ZolpiMist and Tuzistra XR together are known as our "Primary Care Portfolio"). In addition to our legacy Primary Care Portfolio products, through the Neos merger we now sell our generic equivalent to the branded product Tussionex®, an extended-release oral suspension of hydrocodone and chlorpheniramine indicated for the relief of cough and upper respiratory symptoms of a cold ("generic Tussionex").

Our Aytu RxConnect program (rebranded following the combining of Neos' RxConnect program with our Pharmacy Partner Program) offers affordable and predictable copays to all commercially insured patients, regardless of their individual insurance plan and 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 Division

We acquired our consumer health division, Aytu Consumer Health, previously known as Innovus Pharmaceuticals, Inc. ("Innovus"), in February 2020. This division is an emerging over-the-counter ("OTC") specialty pharmaceutical company engaged in the commercialization, licensing and development of safe and effective non-prescription medicine, consumer care products, supplements and medical devices to improve men's and women's health and vitality. The products focus in five core categories including diabetes management (with a concentration on neuropathy), pain management, digestive health, sexual and urological health and general wellness for men and women. 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 continuous use.

The consumer health division is dedicated to being a leader in developing and marketing new OTC and branded Abbreviated New Drug Application ("ANDA") products, supplements and medical devices. The division actively pursues opportunities where existing prescription drugs have recently, or are expected to, change from a prescription (or Rx) to OTC. These "Rx-to-OTC switches" required FDA approval through a process initiated by the New Drug Application ("NDA") holder.

The division currently sells directly to consumers in both the United States and Canada through its proprietary Beyond Human Sales & Marketing platform which focuses direct mail marketing, which includes pamphlets, postcards, tear sheets and newspaper advertisements, allowing consumers to purchase directly through call centers with shipments to their residence. We currently issue over 17 million pieces of mail annually across the United States and Canada. Additionally, products are marketed on e-commerce platforms including the division's website and the Amazon.com platform. Our consumer health marketing strategies focus on search engine optimization and search engine marketing and affiliate marketing. The division also sells to domestic and international distributors on both an exclusive and non-exclusive basis.

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

- developing a diversified product portfolio of exclusive and unique non-prescription OTC and branded ANDA drugs, devices, consumer health products and clinical 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, supplements and devices; and (c) the acquisition of products or obtaining exclusive licensing rights to market such products; and

- building an innovative, U.S. and global sales and marketing model through direct-to-consumer approaches such as our proprietary Beyond Human® sales and marketing platform, the addition of e-commerce platforms, through our own websites both nationally and internationally and commercial partnerships with established domestic and international entities that both generate revenue and require a lower cost structure compared to traditional pharmaceutical companies.

Development Portfolio

On April 12, 2021, we, acquired substantially all the assets of Rumpus Therapeutics, LLC through an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (together with Rumpus VEDS, LLC and Rumpus Therapeutics LLC, "Rumpus"). Upon closing the transaction, we hired Rumpus' principal executive officers, Christopher Brooke and Nathaniel Massari, as employees. Pursuant to the Rumpus transaction, we acquired certain rights and other assets, including key commercial licenses, including a global license to enzastaurin (which we now refer to as AR101) for rare, inherited connective tissue disorders specifically inclusive of vascular Ehlers-Danlos Syndrome ("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. Dr. Hal Dietz 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 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 inhibition proved efficacious in multiple pre-clinical and murine (mice) models and indeed prevented death due to vascular rupture.

Pivotal Phase 3 studies for both newly-diagnosed diffuse large B-cell lymphoma ("DLBCL") and glioblastoma multiforme ("GBM") are currently being conducted by Denovo Biopharma LLC ("Denovo"), enzastaurin's owner, following Denovo's acquisition of enzastaurin from Eli Lilly & Company. Enzastaurin received orphan drug designation in DLBCL and GBM from the FDA and the European Medicines Agency ("EMA"). In July 2020, the FDA granted Fast Track qualification for enzastaurin as the first-line treatment of GBM. Through our transaction with Rumpus, we have secured exclusive global rights to enzastaurin/AR101 from Denovo in the fields of rare genetic pediatric onset or congenital disorders outside of oncology. We expect to receive Orphan Drug Designation by the first calendar quarter of 2022, allowing for seven years' marketing exclusivity in the United States and ten years in Europe and Japan. 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. We expect to advance AR101 to a pivotal study in the first calendar quarter of 2022 following submission and FDA acceptance of an Investigational New Drug ("IND") application.

Our other clinical-stage pharmaceutical asset, N-desethyloxybutynin (which we acquired through our merger with Neos and Neos historically referred to as NT0502), is an active metabolite of the active ingredient in Ditropan® (oxybutynin chloride), an FDA-approved medication for a urological condition. NT0502 is a new chemical entity ("NCE") and selective anticholinergic agent that we are developing as an oral, once- or twice-daily treatment to reduce chronic sialorrhea in patients with neurological conditions associated with excessive salivation and drooling. Based on preclinical data, we believe that NT0502 is preferential for blocking muscarinic receptors in the salivary glands and may offer the potential for an improved tolerability profile and an easier-to-dose oral formulation compared to existing treatment options. We intend to utilize the regulatory pathway provided by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for NT0502. In January 2020, we announced that we had completed dosing in a Phase 1 pilot pharmacokinetic study for NT0502. The Phase 1 trial was a single-dose open-label, randomized, parallel study to assess the systemic exposure and safety of four ion-resin, modified-release ODT formulations of NT0502 and oxybutynin in 30 healthy adults. The top-line results from this study confirmed a formulation for further clinical development. NT0502 entered our pipeline on October 23, 2018, when Neos entered into an Exclusive License Agreement with NeuRx Pharmaceuticals, LLC ("NeuRx") pursuant to which NeuRx granted an exclusive, worldwide, royalty bearing license to us to develop, manufacture and commercialize certain pharmaceutical products containing NeuRx's proprietary compound designated as NRX-101, now NT0502.

Our clinical-stage medical device asset, an ultraviolet (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 (the virus implicated in COVID-19). In April 2020 we licensed global rights to the Healight technology platform from Cedars-Sinai Medical Center ("Cedars-Sinai"). The research team at the Medically Associated Science and Technology (MAST) Program at Cedars-Sinai has been developing the patent-pending Healight platform since 2016 and has produced a growing body of scientific evidence demonstrating pre-clinical safety and effectiveness of the technology as a potential antiviral and antibacterial treatment. The Healight technology employs proprietary methods of administering intermittent ultraviolet (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, inclusive of human coronavirus. 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 (ICU). Beyond the initial pursuit of a coronavirus indication, additional data suggest broader clinical applications for the technology across a range of viral and bacterial pathogens. This includes bacteria implicated in ventilator associated pneumonia ("VAP"). A randomized, controlled, sham-controlled study is currently being planned to further evaluate Healight in SARS-CoV-2, and additional clinical applications (including VAP) are being considered.

Our Strategy

Our goal is to become a leading specialty 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 prevalent conditions frequently developed in childhood, including ADHD. We also commercialize consumer healthcare products through efficient direct-to-consumer and e-commerce 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 current development pipeline includes a pivotal study-ready therapeutic that, if proven safe and effective and ultimately approved, would be the world's first and only approved treatment for vEDS.

Our strategic priorities are to continue to increase revenues from our prescription and consumer health portfolios, advance our late-stage product pipeline, expand our patient access programs for our prescription products and grow our commercial portfolio through additional in-licensing or acquisition. 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, and Tri-Vi-Flor. 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;

- 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 direct-to-consumer and e-commerce commercial strategies to sell existing and forthcoming products, we expect to reach an increasing number of healthcare consumers and drive incremental revenue growth;

- drive expansion and adoption of our Aytu RxConnect network which is designed to reduce barriers to access to medicines facing patients and HCPs by providing coverage for all commercially insured patients, regardless of their individual insurance plan, 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; and

- rapidly advance the development of AR101 (enzastaurin) to address a significant unmet need in vEDS, an ultra-rare, devastating, pediatric-onset disease with no currently approved therapies. The vEDS patient

support community, with which we are highly engaged, recognizes the importance of advancing novel treatments to address this deadly, life-shortening, inherited disorder, and we take seriously our goal of advancing this treatment to regulatory approval.

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 successfully 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 is scalable and lends itself to additional on-market assets and future product candidates that fit within our core pediatric 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 and rare disease asset pipeline.

Corporate History

We were initially incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado.

Vyrix Pharmaceuticals, Inc., or Vyrix, was incorporated under the laws of the State of Delaware on November 18, 2013 and was wholly-owned by Ampio Pharmaceuticals, Inc. (NYSE American: AMPE), or Ampio, immediately prior to the completion of the Merger (defined below). Vyrix was previously a carve-out of the sexual dysfunction therapeutics business, including the late-stage men's health product candidates, Zertane and Zertane-ED, from Ampio, which was announced in December 2013. Luoxis Diagnostics, Inc., or Luoxis, was incorporated under the laws of the State of Delaware on January 24, 2013 and was majority-owned by Ampio immediately prior to the completion of the Merger. Luoxis was initially focused on developing and advancing the RedoxSYS System. The MiOXSYS System was developed following the completed development of the RedoxSYS System.

On March 20, 2015, Rosewind formed Rosewind Merger Sub V, Inc. and Rosewind Merger Sub L, Inc., each a wholly-owned subsidiary formed for the purpose of the Merger. On April 16, 2015, Rosewind Merger Sub V, Inc. merged with and into Vyrix and Rosewind Merger Sub L, Inc. merged with and into Luoxis, and Vyrix and Luoxis became subsidiaries of Rosewind. Immediately thereafter, Vyrix and Luoxis merged with and into Rosewind with Rosewind as the surviving corporation (herein referred to as the Merger). Concurrent with the closing of the Merger, Rosewind abandoned its pre-merger business plans, solely to pursue products in the specialty pharmaceuticals, devices and diagnostics markets, focusing on large areas of medical need, including the business of Vyrix and Luoxis.

On June 8, 2015, we reincorporated as a domestic Delaware corporation under Delaware General Corporate Law and changed our name from Rosewind Corporation to Aytu BioScience, Inc.

On November 1, 2020, we acquired the established prescription pediatric portfolio of Cerecor, Inc. The acquired products include Cefaclor, a second-generation cephalosporin antibiotic suspension, Karbinal ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions 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.

In February 2020, we acquired Innovus, a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve people's health and vitality. Innovus commercializes over 30 consumer health products competing in large healthcare categories including diabetes, pain management, digestive health, sexual and urological health and general wellness for men and women. The Innovus product portfolio is commercialized through both direct-to-consumer and e-commerce marketing channels utilizing our proprietary Beyond Human® marketing and sales platform.

On March 10, 2020, we announced the licensing of a COVID-19 IgG/IgM Rapid Test from L.B. Resources, Ltd. This agreement grants us the right to distribute the product in the United States for a period of three years, with additional three-year autorenewals thereafter. The COVID-19 IgG/IgM Rapid Test is a solid phase

immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. We also distributed a COVID-19 rapid antigen test as part of our effort to aid in the fight against COVID-19. In April 2020, we signed an exclusive worldwide licensing agreement with Cedars-Sinai for a medical device platform technology called Healight™. This technology, which has been studied in the laboratory and clinical setting, is being investigated as a potential treatment for COVID-19 in hospitalized, intubated patients. In collaboration with researchers from the Medically Associated Science and Technology Program (MAST) at Cedars-Sinai Medical Center, we expect to advance the development of Healight in the near term.

Our Board of Directors approved a 1-for-10 reverse stock split of our common stock on December 7, 2020, which became effective on December 8, 2020. Our shares began trading on a split-adjusted basis on the Nasdaq Capital Market commencing upon market open on December 9, 2020. The reverse stock split was previously approved by shareholders at an Annual Meeting of Stockholders on April 23, 2020.

On December 10, 2020 we announced a definitive merger agreement with Neos Therapeutics whereby we agreed to acquire all outstanding shares of Neos stock in an all-stock transaction valued at $44.9 million. Through this merger transaction, which was completed on March 19, 2021, we increased our footprint in the prescription pediatric market through the acquisition of Neos' established, growing multi-brand ADHD portfolio. We closed the Neos merger on March 19, 2021. Following the Neos merger, we changed our name to Aytu BioPharma, Inc.

On April 12, 2021, we entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, Christopher Brooke and Nathaniel Massari pursuant to which we acquired certain rights and other assets, including key commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin (now referred to as AR101), which is a pivotal study-ready therapeutic being studied for the treatment of vascular Ehlers-Danlos Syndrome or vEDS. We acquired this asset for $1.5 million in cash and, 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 our option.

Our Products and Markets

Our prescription products are sold solely in the United States and are distributed through multiple channels, including sales to pharmaceutical wholesalers, on a sell-through basis using third-party logistics enterprises. Our consumer health products are sold primarily in the United States and Canada directly to consumers via traditional consumer channels, such as print advertising and direct mail, and e-commerce channels including various websites and consumer web commerce platforms such as Amazon,com in the United States and Amazon.ca in Canada.

Prescription Products

ADHD Portfolio (the Neos legacy product portfolio)

Through the merger with Neos, we acquired ADHD brands Adzenys XR-ODT, Adzenys ER, and Cotempla XR-ODT.

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 and 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 2020, approximately 75.1 million prescriptions for medications with ADHD labeling were written in the United States and generated approximately $8.5 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 $2.6 billion and $5.6 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 54% 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 the proprietary microparticle delivery technology developed by Neos.

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 name Dyanavel XR®; 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) Osomotica Pharmaceuticals plc under the name Methylphenidate HCl ER 72 mg Tablets, (vi) Novartis under the brand names Focalin XR® and Ritalin LA® and (vii) Adlon Therapeutics L.P., a subsidiary of Purdue Pharma L.P., under the name Adhansia XR®. Azstarys™, a product developed by KemPharm, recently received FDA approval and it is anticipated will be commercially launched by Corium, Inc. in the second half of 2021.

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 Sunovion, NLS Pharma and Neurovance, a subsidiary of Otsuka Pharmaceutical Co., Ltd. A non-stimulant treatment Qelbree™, a non-stimulant treatment for ADHD was recently approved by the FDA and commercially launched by Supernus in the U.S.

Our ADHD and Central Nervous System (CNS) Product Portfolio

Neos’ modified-release drug delivery technology platform has enabled Neos 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 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

Neos received approval on January 27, 2016 from the FDA for Adzenys XR-ODT for the treatment of ADHD in patients six years and older. We believe Adzenys XR-ODT is the first 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 Neos’ 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, Neos entered into a settlement agreement with Actavis Laboratories FL, Inc. (“Actavis”), which resolved all ongoing litigation involving Neos’ Adzenys XR-ODT patents and Actavis’ ANDA with the FDA for a generic version of Adzenys XR-ODT. Under the agreement with Actavis, 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.

Neos included a Paragraph IV certification in the NDA submission for Adzenys XR-ODT, which required a Paragraph IV certification notification to the producer of Adderall XR®, Shire Pharmaceuticals (“Shire”), in accordance with the Hatch-Waxman Amendments. In July 2014, Neos entered into a 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 Adzenys XR-ODT. Under the terms of the agreement, Neos paid a lump sum, non-refundable license fee of an amount less than $1.0 million in February 2016 and agreed to pay Shire a single digit royalty on net sales of Adzenys XR-ODT during the life of the patents. Additionally, the license agreement contains a covenant from Shire not to file a patent infringement suit against Neos alleging that Adzenys XR-ODT infringes the relevant Shire patents.

In conjunction with the approval of the Adzenys XR-ODT NDA, Neos committed to the FDA to conduct certain clinical studies in preschool (age four to five years) children with ADHD as a post-marketing requirement. Neos completed a pharmacokinetic study in this population in 2018, and, following the merger, we have engaged 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

Neos received approval of Cotempla XR-ODT from the FDA for the treatment of ADHD in patients 6 to 17 years old, on June 19, 2017. 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 Neos’ 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. These patents are listed in the Orange Book. In addition, Neos entered into the 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, Neos committed to the FDA to perform additional clinical studies in preschool (age four to five years) children with ADHD as a post-marketing requirement. Neos completed a pharmacokinetic study in this population 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 following the merger, we have engaged in discussions with the FDA to gain concurrence on the design of the protocols required to meet the remaining post-marketing requirements.

Adzenys ER: Amphetamine XR liquid suspension for the treatment of ADHD

Neos received approval of Adzenys ER from the FDA for the treatment of ADHD in patients six years and older, on September 15, 2017. The NDA for Adzenys ER 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 ER clinical program. There are no post-marketing requirements for this product. Adzenys ER contains amphetamine loaded onto a mixture of immediate-release and polymer coated delayed-release resin particles, and using Neos' patented dynamic time release suspension ("DTRS") technology, Neos created an amphetamine XR oral suspension. Adzenys ER is designed to be shelf stable for 36 months, without requiring refrigeration or reconstitution. The composition-of-matter patents for Adzenys ER are scheduled to expire in 2032. These patents are listed in the Orange Book.

Neos included a Paragraph IV certification in the NDA submission for Adzenys ER, which required a Paragraph IV certification notification to the producer of Adderall XR®, Shire Pharmaceuticals, in accordance with the Hatch Waxman-Amendments. On March 6, 2017, Neos entered into a 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 Adzenys ER. Under the terms of the agreement, Neos paid a lump sum, non-refundable license fee of an amount less than $1.0 million in October 2017 and has been paying a single digit royalty on net sales of the Adzenys ER during the life of the patents. Additionally, the license agreement contains a covenant from Shire not to file a patent infringement suit against us alleging that Adzenys ER infringes the relevant Shire patents.

Following the merger and in conjunction with the integration of the Aytu and Neos sales forces and product portfolios, we evaluated the market potential of Adzenys ER and made the decision to discontinue the product. We believe this discontinuation will enable a higher level of promotional focus on the core ADHD and pediatric brands while reducing the regulatory and commercial expenses associated with Adzenys ER. Revenue for Adzenys ER has been minimal since launching the product February 2018.

ZolpiMist: Oral spray zolpidem tartrate for the short-term treatment of insomnia

ZolpiMist is an FDA-approved prescription oral spray indicated for the short-term treatment of insomnia. We believe ZolpiMist is the only oral spray formulation of zolpidem tartrate, the most widely prescribed prescription sleep aid in the U.S. ZolpiMist competes in the non-barbituate prescription sleep aid category, a $5.2 billion prescription drug category with over 35 million prescriptions written in 2020. Over 70 percent of the prescriptions in this category were written for a branded or generic formulation of zolpidem tartrate. The zolpidem tartrate brands marketed in the U.S. include Ambien®, Ambien® CR, Intermezzo®, Edluar® and ZolpiMist®, but the vast majority of prescriptions written are filled with generic versions of zolpidem tartrate. Zolpidem tartrate is approved in multiple formulations including

immediate-release, controlled release and orally dissolving tablet formulations, but immediate release tablets are most widely prescribed and dispensed.

Insomnia is among the most common conditions affecting Americans and patients around the world in general. Approximately 30 percent of adults experience insomnia, and it is estimated that ten percent or more suffer daytime consequences as a result of their poor sleep. Prescription sleep aids are prescribed to enable more rapid onset of sleep for patients experiencing short-term insomnia, and ZolpiMist's oral spray formulation rapidly absorbs into the patient's bloodstream to potentially enable faster sleep onset. In a randomized, controlled clinical trial, patients taking 5 mg and 10 mg of ZolpiMist achieved higher levels of blood plasma significantly faster than patients taking zolpidem tartrate oral tablets. Additionally, these patients experienced faster onset of sedation as measured by the validated Digital Symbol Substitution Test (DSST). By virtue of bypassing first-pass liver metabolism, the oral spray delivery afforded through ZolpiMist enables rapid absorption, fast sleep onset and may offer distinct patient benefits not afforded by oral tablets. Additionally, since ZolpiMist does not require swallowing, it may be appropriate for patients with dysphagia or who otherwise find tablets difficult to tolerate.

In June 2018, we acquired an exclusive license to ZolpiMist in the U.S. and Canada from Magna Pharmaceuticals. This agreement allows for our exclusive distribution throughout the U.S. and the ability to sublicense the product in Canada. The agreement can only be terminated for a material breach as defined in the agreement or by convenience by us upon sixty days' written notice and payment of a $50,000 termination fee. Per the agreement, we pay a low double-digit royalty for the first seven years of the agreement, following which the license becomes a royalty-free perpetual license as long as the terms of the agreement remain satisfied. We do not have a signed supply agreement with the ZolpiMist contract manufacturer, but we have an ongoing relationship with the manufacturer and have received multiple product deliveries to date. ZolpiMist is not currently covered by any patents, but we maintain an active trademark in the United States.

Pediatric Portfolio

Prior to the closing of the Neos merger on March 19, 2021, we were focused on the commercialization of the Pediatric and Aytu legacy Portfolio inclusive of core products Poly-Vi-Flor, Tri-Vi-Flor, Karbinal ER, ZolpiMist and Natesto. Prior to November of 2019 we primarily commercialized Natesto, Tuzistra XR and ZolpiMist through our U.S. sales force, but upon the closing of the asset purchase of a portfolio of prescription pediatric products with Cerecor on November 1, 2019 ("Cerecor Asset Purchase"), we expanded our portfolio to include AcipHex® Sprinkle, Poly-Vi-Flor, Tri-Vi-Flor, Karbinal ER, Cefaclor and Flexichamber. We have since de-prioritized Cefaclor and Flexichamber, given that these products have contributed immaterial revenue. Further, we have discontinued AcipHex Sprinkle and returned rights to Natesto to the product's licensor Acerus Pharmaceuticals. With respect to the Aytu legacy products, going forward we expect to focus our promotional efforts on Poly-Vi-Flor, Tri-Vi-Flor, Karbinal ER and ZolpiMist. ZolpiMist is now being promoted by the CNS-focused sales force in conjunction with the ADHD brands to take advantage of overlapping call points. Poly-Vi-Flor, Tri-Vi-Flor and Karbinal ER are being promoted by our pediatric-focused sales representatives.

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 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 tooth 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 2020, 13.1 million multi-vitamin prescriptions were written in the U.S. Of those, prescription multi-vitamins containing sodium fluoride accounted for 1.6 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. While the multi-vitamin market is dominated by generic products, brands account for 3.4% of the multivitamin plus fluoride market. Poly-Vi-Flor and Tri-Vi-Flor collectively account for 2.4% of total prescriptions in the multi-vitamin plus fluoride market. 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-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.

Poly-Vi-Flor and Tri-Flor Product Line Description

Product Name	Ingredients	Sodium Fluoride – Metafolin - Iron Dosage
Poly-Vi-Flor Chewable Tablet (.25 MG)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin C, Vitamin D, Vitamin E, Sodium Fluoride, Metafolin	.25 MG - 200 MCG
Poly-Vi-Flor Chewable Tablet (.5 MG)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin C, Vitamin D, Vitamin E, Sodium Fluoride, Metafolin	.50 MG - 200 MCG
Poly-Vi-Flor Chewable Tablet (1 MG)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin C, Vitamin D, Vitamin E, Sodium Fluoride, Metafolin	1 MG - 200 MCG
Poly-Vi-Flor Chewable Tablet w/ Iron (.5 MG - 10 MG)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin, C, Vitamin D, Vitamin E, Sodium Fluoride, Metafolin, Iron	.50 MG - 200 MCG – 10 MG
Poly-Vi-Flor Oral Suspension (.25 MG/ML)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin, C, Vitamin D, Vitamin E, Sodium Fluoride, Sodium Benzoate, Metafolin	.25 MG – 200 MCG
Poly-Vi-Flor Oral Suspension w/ Iron (.25 MG/ML – 7 MG)	Vitamin A, Vitamin B1, B2, B3, B6, Vitamin C, Vitamin D, Vitamin E, Sodium Fluoride, Sodium Benzoate, Metafolin, Iron (as Ferrous Bisglycinate Hydrochloride)	.25 MG – 200 MCG – 7 MG
Tri-Vi-Flor Oral Suspension .25 MG/ML	Vitamin A, Vitamin C, Vitamin D3, Sodium Fluoride, Sodium Benzoate, Metafolin	.25 MG – 200 MCG
Tri-Vi-Flor Oral Suspension .50 MG/ML	Vitamin A, Vitamin C, Vitamin D3, Sodium Fluoride, Sodium Benzoate, Metafolin	.50 MG – 200 MCG

We acquired Poly-Vi-Flor and Tri-Vi-Flor through the Cerecor Asset Purchase. Through the acquisition we acquired multiple licenses surrounding both brands. We own or exclusively license from Mead Johnson & Company, LLC to the trademarks Poly-Vi-Flor and Tri-Vi-Flor, and we pay a sales-based royalty for the use of these trademarks. We also pay a single-digit royalty to Merck & Cie through a commercial supply and license agreement for exclusive use of the proprietary ingredient Metafolin (and the follow-on L-methylfolate ingredient Arcofolin®). The commercial supply and license agreement was originally between Merck and Zylera Pharmaceuticals, which was subsequently acquired by Cerecor, and it was assigned to us upon closing of the Cerecor Asset Purchase. Subsequent to that assignment, we signed a new commercial supply and license agreement to include Arcofolin that was effective February 1, 2020. Arcofolin is an improved formulation of L-methylfolate, and, if granted, the core patent covering Arcofolin would expire in 2033. Through the supply and license agreement with Merck we have exclusive rights to Merck's L-methylfolate in the pediatric field (birth to twelve years of age) in the United States. The term of the agreement extends through January 2025, with an automatic renewal for two years following the initial term unless either party terminates the agreement within one year of the then current term. The agreement requires, among other items, that we provide a rolling twelve-month forecast containing our requirements for either Metafolin or Arcofolin each quarter. The first six months forecast of each rolling forecast is binding.

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.

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.

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 over 50 million prescriptions written in 2020. 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 16% of 2020 total prescriptions, while non-sedating, second generation antihistamines accounted for 84% 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.

We acquired rights to Karbinal ER through the Cerecor Asset Purchase. Through the acquisition we assigned an exclusive supply and distribution agreement with Tris, the developer and manufacturer of the product. This agreement allows us to exclusively distribute Karbinal ER in the U.S. through the term of the agreement, which is through August 2032, unless the agreement is terminated earlier pursuant to the termination provisions in the agreement. Tris originally licensed Karbinal to FSC Laboratories. Prior to Cerecor's acquisition of Karbinal through its acquisition of the pediatric assets of Avadel Pharmaceuticals ("Avadel"), through a transaction with FSC Laboratories, Flamel Technologies and Eclat Pharmaceuticals that formed Avadel, Avadel owned rights to the Karbinal ER supply and distribution agreement. As part of the agreement, we pay Tris sales-based royalties based on net revenue. Additionally, we are committed to make annual minimum payments to Tris through 2023. We provide Tris with a rolling 12-month forecast containing estimates of our product requirements for the upcoming year. The first three months of each forecast is binding.

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.

Our Prescription Antitussive Products: Tuzistra® XR and Generic Tussionex®

Tuzistra® XR

In November 2018 we acquired U.S. rights to be supplied by and to market Tuzistra XR from Tris, the developer and manufacturer of the product. Tuzistra XR is the only FDA-approved 12-hour codeine-based antitussive.

Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension. Tuzistra XR is a patented combination of codeine, an opiate agonist antitussive, and chlorpheniramine, a histamine-1 receptor antagonist, indicated for relief of cough and symptoms associated with upper respiratory allergies or a common cold in adults aged 18 years and older. Tuzistra XR is protected by two Orange Book-listed patents extending to 2027 and 2029 both of which are owned by Tris.

According to MediMedia, the U.S. cough cold prescription market is worth in excess of $3 billion, with 30-35 million annual prescriptions. The antitussive market is dominated by short-acting treatments, which require dosing 4-6 times a day. Tuzistra XR was developed using Tris' liquid sustained release technology, LiquiXR®, which allows for extended drug delivery throughout a 12-hour dosing period. On September 1, 2019, we entered into a co-promotion agreement for Tuzistra XR with Poly Pharmaceuticals ("Poly") whereby Poly will promote Tuzistra XR in select geographies throughout the U.S. through their sales force. Poly receives a commission payment for each prescription generated according to the terms of the agreement. Poly is a privately-held specialty pharmaceutical company focused primarily on cough, allergy, and other respiratory conditions and has actively promoted prescription antitussives since its founding in 1980. The co-promotion agreement expires in September 2022 and can be extended beyond the initial term upon the companies' mutual agreement. Poly will receive commission payments based on Tuzistra XR prescriptions generated from physician targets within Poly's geographic footprint. Poly's geographic footprint covers approximately 750,000 antitussive prescriptions annually. We revised the Poly co-promotion agreement in December 21, 2020 to expand their promotional rights.

Generic Tussionex

Through the merger with Neos in March 2021 we acquired their generic Tussionex product. Generic Tussionex is a hydrocodone polistirex and chlorpheniramine polistirex XR oral suspension that is a Schedule II narcotic, antitussive and antihistamine combination. This product is indicated for the relief of cough and upper respiratory symptoms associated with allergies or colds in adults and children six years of age and older.

Since its launch in September 2013, Neos has manufactured and utilized Neos' DTRS technology in the production of the generic Tussionex product at the Neos facility in Grand Prairie, Texas. In August 2014, Neos acquired all commercialization and profit rights to this formulation of the generic Tussionex product from Cornerstone BioPharma, Inc. and Coating Place, Inc. In October 2014, the product was re-launched under Neos' own label. We sell our product to drug wholesalers in the United States. We have also established indirect contracts with drug, food and mass retailers that order and receive our product through wholesalers. We have obtained required state licenses, set up distribution channels and established trade relations in order to commercialize our generic Tussionex.

Divested and Out-Licensed Products

Natesto®

In 2016, we acquired exclusive U.S. rights to Natesto® (testosterone) nasal gel, a novel formulation of testosterone delivered via a discreet, easy-to-use nasal gel, including a license to four Orange Book-listed patents. We exclusively commercialized Natesto in the U.S. beginning September 2016 through March 31, 2021, and Natesto was a key promotional priority through this timeframe.

On July 29, 2019, we agreed to amend and restate the License and Supply Agreement with Acerus. The effectiveness of the amended Agreement was conditioned upon Acerus obtaining new financing within six months of signing of the amended Agreement, which was achieved on December 1, 2019. Upon the execution of the Amendment, Aytu continued to serve as the exclusive U.S. supplier to purchasers of Natesto, and Acerus received performance-based commissions on prescriptions generated by urology and endocrinology specialties. Acerus assumed regulatory and clinical responsibilities and associated expenses and began serving a primary role in the development of key opinion leaders in urology and endocrinology. Aytu focused on commercial channel management, sales to wholesalers and other purchasing customers, and directs sales efforts in all other physician specialties. On December 1, 2019, we officially launched the co-promotion program and transferred five of our dedicated sales employees to Acerus until such time that

they could establish their own dedicated sales force. In July 2020, Acerus launched its dedicated sales team to promote Natesto to urologists and endocrinologists across the United States.

In anticipation of the planned merger with Neos, and to enable an increased focus on ADHD, pediatrics and adjacent specialty areas, in late 2020 we negotiated an agreement with Acerus whereby we would return all rights to Natesto in exchange for cash consideration. Following the closing of the Neos merger, on March 31, 2021 we entered into a termination and transition agreement (the "Termination Agreement") with Acerus, pursuant to which Aytu and Acerus agreed to terminate the Amended and Restated License and Supply Agreement. On April 1, 2021 we ceased all sale, marketing and promotion of Natesto. In exchange Acerus has agreed to pay us an aggregate amount equal to $7.5 million, payable in equal monthly installment payments for a period of 30 consecutive months. In addition, Acerus agreed to repurchase all Natesto inventory at cost. Finally, we agreed to perform all of our distribution related obligations under the License and Supply Agreement and to assist Acerus and book Acerus' sales of Natesto to third parties from the Effective Date until such date that Acerus was able to book Natesto sales without Aytu's assistance (but in no event later than July 31, 2021 and pay to Acerus an amount equal to gross sales less applicable deductions and direct costs attributable to sales made during the transition period.

MiOXSYS®

Upon the formation of Aytu in April 2015, the technology underpinning MiOXSYS (originally the RedoxSYS System) was a core commercial asset that aligned to our strategic priorities at that time. As we evolved and shifted focus to therapeutics, MiOXSYS became non-strategic. As we shifted focus to pediatrics and specialty pharmaceuticals, we pursued monetizing the asset. As such, and in anticipation of the closing of the Neos merger, on January 20, 2021 we signed an exclusive license agreement to license the intellectual property surrounding the use and commercialization of the MiOXSYS commercial system ("MiOXSYS Product"). The Agreement was entered into with Avrio Genetics, LLC ("Avrio"). Under this agreement, Avrio was obligated to purchase existing inventory, commercialize and market the MiOXSYS Product under a royalty on Product net sales with a minimum annual payment fee structure for a term of ten years, with the term continuing in perpetuity with a fixed royalty rate based on MiOXSYS sales, payable annually to us. Avrio did not perform under the terms of the agreement, and on July 1, 2021, we and Avrio mutually agreed to terminate the Avrio agreement, effective as of June 29, 2021. In connection with the termination of the agreement, we entered into a termination agreement with Avrio. Pursuant to the terms of this termination agreement, the original Avrio agreement and its amendments were terminated in their entirety, except for certain provisions that survived the termination as specified in such agreement.

Subsequent to the Avrio termination, on July 1, 2021 we signed an Asset Purchase Agreement with UAB "Caerus Biotechnologies" ("UAB"). Pursuant to the terms and conditions of the agreement, UAB has acquired all existing intellectual property rights, technical information and know-how related to MiOXSYS as well as all existing inventory and all rights attached and related to the product and manufacturing thereof. As consideration, UAB agreed to pay us approximately $0.5 million and make royalty payments to us of five percent of net global revenue of the MiOXSYS Product for five years from the closing date of the transactions contemplated in the Asset Purchase Agreement.

Accordingly, both Natesto and MiOXSYS have been divested and are no longer material aspects of our business.

Aytu Consumer Health Portfolio

We acquired our consumer health business through the acquisition of Innovus Pharmaceuticals, Inc. in February 2020. The consumer health business is focused on OTC and consumer health care 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 30 products in the U.S. and Canada and more than seven products in other countries through two distinct marketing channels: direct-to-consumer

marketing channels utilizing our proprietary Beyond Human marketing and sales platform and our e-commerce platforms.

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 have a strong presence in the neuropathy/pain relief category; and
- personal care products, which are proprietary products with strong scientific and clinical support for everyday life in categories such as urology and sexual health.

The following represents the core Aytu Consumer Health products:

- Urivarx® - dietary supplement to support healthy bladder function consisting of a proprietary blend of well published botanical ingredients.
- Vesele® - nitric oxide supplement to relax blood vessels and allow for healthy blood flow throughout the body.
- 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.
- Beyond Human® Testosterone Booster – daily dietary supplement that naturally increases testosterone levels, supporting natural stamina, endurance and strength.
- ProstaGorx® - clinical strength, multi-response prostate supplement, scientifically formulated to effectively maintain good prostate health.
- Sensum+® - combination of natural oils to condition the specialized skin of the glans and shaft of the penis to provide just the right amount of biofeedback for a majority of men to increase sensitivity.
- 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.
- FlutiCare® - allergy relieving nasal spray proven to offer 24-hour relief of both nose and sinus-related allergy symptoms.
- 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.
- Apeaz® - arthritis cream to temporarily relieve aches and pains or muscles and joints associated with simple backache, lumbago, strains and sprains, and arthritis.
- Steroxin® - dietary supplement to support health bladder function with a naturally sourced blend including pumpkin seed extract allowing for a reduction in urination urgency.

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 2021, 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 and sell over 20 products in the U.S.

We own 267 trademarks for products in our consumer health portfolio and own or license patents covering 15 of these products.

Other Products

The COVID-19 IgG/IgM Rapid Test

In March 2020, we signed an agreement to distribute a COVID-19 IgG/IgM rapid test with L.B. Resources Limited. This test is a serology-based rapid test detecting IgG and IgM antibodies specific to the COVID-19 virus. This test is intended for professional use and delivers clinical results between 2 and 10 minutes. The COVID-19 IgG/IgM rapid test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the COVID-19 virus in human whole blood, serum or plasma. The test has been clinically validated and can be distributed in the U.S. We actively commercialized the COVID-19 IgG/IgM rapid test in the U.S. through the first three quarters of our fiscal 2021. Aytu does not own or license any patents covering the COVID-19 IgG/IgM rapid test.

The CovID RAD Rapid Antigen Detection Test and Additional Rapid Antigen Test

In September 2020, we signed an agreement to distribute the Pinnacle CovID RAD Rapid Antigen Detection Test worldwide. The rapid antigen test, which delivers results in 15 minutes, tests for the presence of the SARS-CoV-2 virus antigen via a nasopharyngeal sample and can be conducted without the use of laboratory equipment. The CovID RAD Rapid Antigen Detection Test was developed by U.S.-based Pinnacle IVD Corporation. The Pinnacle CovID RAD Rapid Antigen Detection Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigens from SARS-CoV-2 in nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider. Subsequent to the signing of this agreement, and due to the fact that Pinnacle did not receive Emergency Use Authorization for the CovID RAD Rapid Antigen Detection Test, we acquired a separate Emergency Use Authorized rapid antigen to meet the demand of customers requiring rapid antigen testing. We continued the sale of this antigen test through 2021.

With the Emergency Use Authorization and subsequent rollout of COVID-19 vaccines beginning in late calendar 2020, the demand for rapid COVID-19 testing diminished, negatively impacting demand across the rapid testing market. As such we are no longer actively commercializing the COVID-19 IgG/IgM Rapid Test or the rapid antigen test.

Our prescription portfolio commercialization efforts

We are commercializing our prescription products in the United States using our internal commercial infrastructure. We sell our products to drug wholesalers in the United States, the largest three of which accounted for approximately 55% of our total gross revenues in fiscal 2021.

We are using our own sales force of approximately 50 sales representatives who target approximately 10,000 physician targets. We focus the efforts of this sales force on the most profitable, high-volume prescribers of the medication classes treating our respective products' indications. The sales force is divided into six regions, each managed by a regional sales manager. There are five regions totaling 40 sales representatives dedicated to promoting the ADHD brands and ZolpiMist (the CNS sales team), given the fact that this sales team calls on psychiatrists for our ADHD brands. Psychiatrists commonly prescribe sleep aids, so this physician specialty affords an overlapping promotional opportunity in these adjacent neuro-psychiatric conditions. An additional region consisting of ten sales representatives and one regional sales manager is dedicated to promoting Poly-Vi-Flor, Tri-Vi-Flor, and Karbinal ER in focused geographies with high volumes of fluoride and/or antihistamine prescriptions.

We align our sales territories geographically and resource areas with high prescription potential and favorable commercial dynamics, and we continuously evaluate reimbursement trends and other market factors to optimize sales efforts. We use multi-channel tactics to reach physicians, payers, patients and patient caregivers with the right frequency to drive clinician prescribing and patient adherence.

Our commercialization efforts are focused on delivering the right message for each of our products to the appropriate targeted clinician. With respect to our ADHD brands, our messaging focuses on the anticipated benefits of our XR-ODT dosage form with balancing important product safety information. With respect to the Aytu pediatric and legacy brands, our messaging focuses on the patient-friendly features of a pleasant tasting, effective antihistamine liquid (Karbinal ER) and the benefits of Metalofin® as a key, differentiating ingredient contained in Poly-Vi-Flor and Tri-Vi-Flor that provides a 'body-ready' L-methylfolate in a convenient, multi-strength multi-vitamin.

To expand distribution, in 2019, Neos launched and deployed Neos RxConnect, a best-in-class Neos-sponsored patient support program that operates through a network of pharmacies throughout the U.S. Neos created this program based upon research and feedback from HCPs centered on their frustration with the hassle associated with insurance restrictions, access and cost. Aytu developed a similar program to meet these challenges, so upon the closing of the merger we began integrating the programs to form the newly branded Aytu RxConnect program. The goal of RxConnect is to reduce barriers to access to medications facing patients and HCPs by providing coverage for all commercially insured patients, regardless of their individual insurance plan, 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 our products at participating pharmacies. Since the inception of this program in early 2019, the number of pharmacies participating in the network has increased to approximately 1,200 as of June 30, 2021.

Competition

Prescription pharmaceuticals

The healthcare industry is highly competitive and subject to significant and rapid technological change as researchers learn more about diseases and develop new technologies and treatments. Our products compete, and our product candidates may in the future compete, with currently existing therapies, product candidates currently under development by others and/or future product candidates, including new chemical entities that may be safer, more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive.

In particular, our products and most advanced product candidates face or may face competition as described below:

- Our branded ADHD products face competition from commercially available generic and branded medications currently produced by companies that are promoting products in the ADHD market, including Takada Pharmaceutical Company (Vyvanse, Adderall XR, Mydayis), Janssen (Concerta), Novartis (Focalin XR and Ritalin LA), Tris Pharmaceuticals (Dyanavel XR, Quillivant XR and QuilliChew ER), Rhodes Pharmaceuticals (Aptensio XR), Osomotica Pharmaceuticals (Methylphenidate HCl ER 72 mg Tablet), Ironshore Pharmaceuticals, a subsidiary of Highland Therapeutics (Jornay PM), Adlon Therapeutics L.P., a subsidiary of Purdue Pharma L.P. (Adhansia XR) and related generics. Qelbree™, a non-stimulant treatment for ADHD was recently approved by the FDA and commercially launched in the U.S. by Supernus. Azstarys™, a product developed by KemPharm, recently received FDA approval and it has been commercially launched by Corium, Inc. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Cingulate Therapeutics, Sunovion, NLS Pharma and Neurovance, a subsidiary of Otsuka Pharmaceutical Co., Ltd. Tris Pharmaceuticals is also working in this therapeutic category to reformulate existing methylphenidate and amphetamine medications.

- ZolpiMist competes in a large prescription category with over 43 million prescriptions written annually and generating $1.8 billion in wholesale sales. The non-benzodiazepine prescription sleep aid market is dominated by generic zolpidem tartrate (brand name Ambien), which accounts for approximately 30 million prescriptions annually. Various forms of zolpidem tartrate are commercially available, including both immediate release and controlled release tablets as well as orally dissolving tablets. ZolpiMist is the only oral spray formulation of zolpidem tartrate in the U.S. No zolpidem tartrate products are actively marketed in the U.S.

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

- 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.

- Cefaclor (cefaclor oral suspension) faces significant competition from the generic antibiotic amoxicillin as well as Omnicef, Ceftin, Suprax and others.

Consumer health

The OTC pharmaceutical market is highly competitive with many established manufacturers, suppliers and distributors that are actively engaged in all phases of the business. We believe that competition in the sale of our products will be based primarily on efficacy, regulatory compliance, brand awareness, availability, product safety and price. Our brand name OTC monograph pharmaceutical products may be subject to competition from alternate therapies during the period of patent protection and thereafter from generic or other competitive products. All of our existing products compete with generic and other competitive 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. We anticipate that our branded product offerings will support our existing lines of therapeutic focus. Based upon business conditions and other factors, we regularly reexamine our business strategies and may from time to time reallocate our resources from one therapeutic area to another, withdraw from a therapeutic area or add an additional therapeutic area in order to maximize our overall growth opportunities.

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

Manufacturing

We contract with third parties for the manufacture and testing of Karbinal, Tuzistra XR, Cefaclor, Poly-Vi-Flor and Tri-Vi-Flor and ZolpiMist. Cefaclor, 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.

- A supply agreement with Tris for the supply of Tuzistra XR. This agreement terminates in December 2038, subject to earlier termination or extension in accordance with the terms of the agreement.

- Cefaclor is purchased under a supply agreement with Yung Shin Pharm. Ind., Ltd. This agreement terminates on December 31, 2024 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 do not have a signed supply agreement with the ZolpiMist contract manufacturer, but we have an ongoing relationship with a CMO based in Sweden (or Europe), from whom we purchase product on a purchase order basis.

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 and our generic Tussionex, 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 XR-ODT and ER oral suspension. 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 have operated this facility dating back to when Neos and its predecessor corporation, PharmaFab, Inc., or PharmaFab operated as a contract manufacturer. In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction, or the Consent Decree, against PharmaFab, one of its subsidiaries and two of its officials. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation, or DESI, drugs that we no longer manufacture. In July 2019, Neos filed a motion with the U.S. District Court of North Texas to vacate the Consent Decree, which was unopposed by the Department of Justice and the FDA and was granted by the court on July 11, 2019. While the Consent Decree has been vacated, there can be no assurance that we will not become subject to similar orders in the future, which may result in us continuing to expend resources and attention to observe its terms, and there can be no assurance that we will be in compliance with its requirements.

We believe that our current facility has the manufacturing capacity for commercial production of our approved products in quantities sufficient to meet what we believe will be our commercial needs for our ADHD products.

We currently purchase the active pharmaceutical ingredients, or APIs, used in Adzenys XR-ODT and Adzenys ER (amphetamine), and Cotempla XR-ODT (methylphenidate), anionic resins, excipients and other materials from third-party providers on a purchase order basis from manufacturers based outside and within the U.S. We have entered into commercial supply agreements with several of these manufacturers and may enter into commercial supply agreements with additional manufacturers in the future.

Both amphetamine and methylphenidate are classified as controlled substances under U.S. federal law. All of our ADHD products are classified by the DEA as Schedule II controlled substances, meaning that these drug products

have a high potential for abuse and dependence among drugs that are recognized as having an accepted medical use. Consequently, the procurement, manufacturing, shipping, dispensing and storing of our products, and potentially product candidates, will be subject to a high degree of regulations, as described in more detail under the captions “Governmental Regulation” and “DEA Regulation” included elsewhere in this Annual Report on Form 10-K.

In our experience, contract manufacturers are generally cost-efficient and reliable and therefore we have begun the process of outsourcing the manufacture of Adzenys XR-ODT and Cotempla XR-ODT to a CMO. We have selected a CMO, conducted pilot studies and continue to transfer analytical methods and evaluate engineering and validation of intermediates and tablets. We plan to conduct bioequivalence studies versus our internally manufactured products. The process to transfer the technology to make our ADHD ODT products is complex and requires compliance with both FDA and DEA regulations. This is time consuming, and there is no guarantee we will be successful in our efforts. Although we have entered into technology transfer contracts for each of the products, we still have to enter into a formal supply contracts as the process proceeds. There is no guarantee that we will reach terms that are affordable or cost effective.

The Aytu Consumer Health division 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 and no annual 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 option 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. 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.

In April 2021, we announced the acquisition of substantially all the assets of Rumpus Therapeutics (“Rumpus”), which had executed an exclusive option agreement with Denovo to enzastaurin for use in specific clinical fields. Through the transaction we converted the Rumpus-Denovo option agreement into an exclusive license agreement and secured exclusive global rights to AR101 from Denovo in the fields of rare genetic pediatric onset or congenital disorders, and specifically including vEDS, outside the field of oncology. AR101 is a pivotal study-ready therapeutic candidate initially targeting the treatment of vEDS, and we are now planning the pivotal study and preparing the IND application.

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 is a devastating condition; 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. Hal Dietz. 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. Research findings were published in the Journal of Clinical Investigation in February 2020. The vEDS knock-in murine (mice) 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 molecular signature for excessive PKC/ERK cell signaling that is 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. The development plan includes a well-controlled global clinical trial designed to demonstrate that AR101 reduces 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. During development, we expect to receive Orphan Drug Designation for AR101 in vEDS, allowing for seven years' marketing exclusivity in the United States and ten years in other regions such as Europe and Japan.

As progress is achieved with AR101, certain milestones will be met that require accompanying payments. Under the terms of the transaction with Rumpus, Aytu will pay up to $22.5 million in milestone payments if certain regulatory milestones are met, including $15.0 million in milestone payments if AR101 receives approval by the FDA and another major market regulatory authority. Commercial milestones of up to an additional $45.0 million may be paid if a series of global commercial milestones are met over the life of the product. In addition, we received assignments of third-party licenses from Denovo and Johns Hopkins and took over royalty obligations and performance-based milestones under these licenses. As part of the license with Denovo, Aytu will pay up to $28.0 million in milestone payments if certain regulatory milestones are met, including $14.0 million in milestone payments if AR101 receives approval by the FDA and another major market regulatory authority. Commercial milestones of up to an additional $72.0 million may be paid if a series of global commercial milestones are met over the life of the product. As part of the license with Johns Hopkins, we will pay up to $1.6 million in milestone payments if certain regulatory milestones are met. Commercial milestones of up to an additional $1.65 million may be paid to Johns Hopkins if a series of global commercial milestones are met over the life of the product.

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 the therapeutic candidate (AR101) 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 pending patent provides targeted epigenetic therapy for inherited aortic aneurysm conditions and has a priority date of September 1, 2017, also in select geographies.

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”). This medical device technology platform 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 SARS-CoV-2 and other 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 are engaging 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. In conjunction with this research, we are evaluating regulatory pathways to potentially enable marketing clearance in the U.S. and other markets.

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. Pursuant to the terms of the agreement, we paid an initial $250,000 license fee and approximately $140,000 in earlier patent prosecution fees. We are responsible for paying a low double-digit royalty in the U.S., which decreases as net sales increase, and a lower royalty for net sales outside of the U.S., as well as various product development and sales milestones throughout the life of the agreement.

As part of the Healight development plan we also 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.

Severe acute respiratory syndrome coronavirus 2 (“SARS-CoV-2”) is the virus that causes COVID-19, the respiratory illness responsible for the COVID-19 pandemic. The World Health Organization (“WHO”) declared the outbreak a Public Health Emergency of International Concern on January 30, 2020, and a pandemic on March 11, 2020. SARS-CoV-2 is a positive-sense single-stranded RNA virus that is contagious in humans. As described by the U.S. National Institutes of Health, it is the successor to SARS-CoV-1, the virus that caused the 2002 to 2004 SARS outbreak. Over 600,000 Americans have died to date as a result of the COVID-19 pandemic, and very few treatment options have proven broadly effective against severe cases of SARS-CoV-2.

The Healight technology is being developed initially as an endotracheal catheter-based treatment for patients infected with SARS-CoV-2 who are mechanically ventilated in the intensive care unit. Numerous pre-clinical studies have been performed, and the first Healight clinical study was completed in January 2021. That study was an open-label single-center trial and was conducted at Cedars-Sinai in Los Angeles, California. The study’s objective was to establish safety and early signs of potential efficacy of the Healight device and was overseen by an independent data and safety monitoring board. A total of five critically ill, mechanically ventilated COVID-19 patients underwent UVA light therapy with the Healight device for five consecutive days. The UVA light catheter was inserted into an endotracheal tube and illuminated for 20 minutes during each treatment. The endotracheal (“ET”) treatment resulted in significant logarithmic reduction of the SARS-CoV-2 viral load of the ET aspirate, which was the study's primary endpoint. Average log changes from baseline to day five and day six were -2.41 (>99%, p=0.0018) and -3.2 (>99.9%, p=0.0005), respectively. WHO clinical severity scores improved by an average of 1.6 and 3.6 points on day 15 and day 30, respectively. Excluding one subject, who had undetectable viral load, WHO clinical severity scores improved by 4.75 points on day 30. Importantly, no serious adverse device effects were observed, and no early treatment discontinuation occurred.

A separate pre-clinical study titled, “Ultraviolet-A light increases mitochondrial anti-viral signaling protein via cell-cell communication”, established that UVA light increases the expression of mitochondrial antiviral-signaling (“MAVS”) protein within cells, and the results suggest that this transmission of an increase in intracellular MAVS involves cell-to-cell communication. An additional pre-clinical study, “Ultraviolet-A light reduces cellular cytokine release from human endotracheal cells infected with Coronavirus”, demonstrated that infected tracheal epithelial cells showed reduced cytokine release, including IL-6, TNF, IL-8, and MCP-1, following UVA exposure.

A larger clinical study is planned to begin at leading medical center in Europe during fiscal 2022. The randomized, controlled (single blind) trial is planned to enroll a total of 40 critically ill, mechanically ventilated COVID-19 patients. Enrolled patients will be randomized (1:1) to receive treatment with the UVA device or a sham control device. Patients will be administered 20 minutes of therapy each day for five consecutive days. The study will primarily evaluate change in viral load in endotracheal tube aspirates from the beginning to end of therapy. Secondary endpoints will include overall reduction or change of bacterial load in patients' upper airways, reduction in SARS-CoV-2 serum viral load, days to extubation, percentage of development of ventilator-associated pneumonia (VAP), days to discharge, mean ordinal scale days 15 and 30, change in inflammatory markers and COVID-19 prognostic markers.

Upon the readout of this larger clinical study, we will evaluate the data and determine an appropriate pathway toward gathering additional clinical data in COVID-19 and for other potential respiratory applications. In conjunction with that, we expect to explore various commercialization and regulatory options in key markets around the world.

Intellectual Property

We hold ownership, trademark rights and/or exclusivity to develop and commercialize our products and product candidates covered by patents and patent applications. Our portfolio of patents includes patents or patent applications with claims directed to compositions of matter, including compounds, pharmaceutical formulations, methods of use, methods of manufacturing the compounds, or a combination of these claims. Depending upon the timing, duration and specifics of FDA approval of the use of a compound for a specific indication, some of our U.S. patents may be eligible for a limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. Patent life determination depends on the date of filing of the application and other factors as promulgated under the patent laws. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Additional market exclusivity is available through various programs with the FDA, including its orphan drug designation program, which we expect to access for AR101, as further described below.

Patents Rights

Our ADHD and Neos technology intellectual property portfolio consists of 13 patents and 2 patent applications, which includes one on which a notice of allowance was received subsequent to fiscal year-end, in the United States, and 4 patents and 4 patent applications in foreign countries and regions. Our intellectual property strategy emphasizes specific drug products, product groups, and technology platforms. Our patents and patent applications covering specific drug products include claims to the drug products and to methods of using those products. Our patents and patent applications covering technology platforms include claims to methods of making products as well as claims to the products made by those methods. Certain of these patents and patent applications cover more than one product. We own all of the above patents and pending applications.

The Adzenys XR-ODT patent portfolio includes five granted U.S. patents and one pending U.S. non provisional applications. The issued patents contain pharmaceutical composition of matter claims covering controlled release direct compression ODT with drug resin particles and, among other things, composition of matter for Adzenys XR-ODT. The composition of matter patents are scheduled to expire in 2026 and 2032, respectively. These patents are listed in the Orange Book. Adzenys XR-ODT is protected in Europe by one granted patent scheduled to expire in 2032; however, Adzenys XR-ODT is not currently protected by patents outside of the United States and Europe. As such, competitors may be free to sell products that incorporate the same or similar technologies that are used in Adzenys XR-ODT in countries outside of the United States or Europe.

The Cotempla XR-ODT patent portfolio includes three granted U.S. patents, including pharmaceutical composition of matter claims covering controlled release direct compression ODT with drug resin particles and, among other things, composition of matter for Cotempla XR-ODT. These patents are scheduled to expire in 2026 and 2032, respectively. These patents are listed in the Orange Book. Cotempla XR-ODT also has an FDA marketing exclusivity period of three years which bars approval of an ANDA. The Cotempla XR-ODT portfolio also includes two other pending U.S. non provisional applications; a notice of allowance was received for one of these subsequent to year-end and pending patent applications in Australia, Europe, Japan and South Korea. As such, competitors may be free to sell

products that incorporate the same or similar technologies that are used in Cotempla XR-ODT in countries outside of the United States, Australia, Europe, Japan or South Korea.

The Adzenys ER patent portfolio contains nine granted U.S. patents and one other pending U.S. non-provisional application. These patents contain claims directed to, among other things, compositions of matter, as well as methods of preparing liquid controlled-release formulations and for predicting bioequivalence for liquid suspension. The longest-term composition-of-matter patent is scheduled to expire in 2032, and the method patents are scheduled to expire in 2025, 2029 and 2031, respectively. The composition of matter patents are listed in the Orange Book. Adzenys ER is currently protected by patents only in the United States, Canada and Mexico. As such, competitors may be free to sell products that incorporate the same or similar technologies that are used in Adzenys ER in countries outside of the United States, Canada and Mexico.

Our generic Tussionex is covered by six of our granted U.S. patents which include claims directed to, among other things, a composition-of-matter, as well as methods-of-making, and for predicting bioequivalence for liquid suspension. Our generic Tussionex is also covered by one other pending non-provisional application. The composition-of-matter patent is scheduled to expire in 2031. We expect protection under certain other granted patents and/or a patent granted on the pending application to also extend until 2031. Our generic Tussionex is currently protected by patents only in the United States, Canada and Mexico. As such, competitors may be free to sell products that incorporate the same or similar technologies that are used in our product in countries outside of the United States, Canada and Mexico.

On July 25, 2016, we received a Paragraph IV certification from Actavis advising us that Actavis has filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. The certification notice alleges that the four U.S. patents listed in the FDA's Orange Book for Adzenys XR-ODT, one with an expiration date in April 2026 and three with expiration dates in June 2032, will not be infringed by Actavis's proposed product, are invalid and/or are unenforceable. On September 1, 2016, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Actavis that automatically stayed, or barred, the FDA from approving Actavis's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. On October 17, 2017, we entered into a settlement and licensing agreement with Actavis ("Actavis Agreement"), which resolved all ongoing litigation involving our Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Agreement, we have 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. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Actavis Agreement has been submitted to the applicable governmental agencies.

On October 31, 2017, we received a Paragraph IV certification from Teva advising us that Teva has filed an ANDA with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. On December 13, 2017, we filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva. This case alleged that Teva infringed our Cotempla XR-ODT patents by submitting to the FDA an ANDA seeking to market a generic version of Cotempla XR-ODT prior to the expiration of our patents. This lawsuit automatically stayed, or barred, the FDA from approving Teva's ANDA for 30 months or until a district court decision that is adverse to the asserted patents is rendered, whichever is earlier. On December 21, 2018, we entered into a settlement and licensing agreement with Teva ("Teva Agreement"), which resolved all ongoing litigation involving our Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Agreement, 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. A stipulation and order of dismissal was entered by the U.S. District Court for the District of Delaware. The Teva Agreement has been submitted to the applicable governmental agencies.

On October 23, 2018, we signed a licensing agreement with NeuRx Pharmaceuticals, LLC ("NeuRx") for NRX 101, now known as NT0502, a selective muscarinic receptor antagonist drug candidate for the treatment of sialorrhea. Under the terms of this licensing agreement, we have assumed responsibility for the NeuRx intellectual property portfolio protecting NT0502, currently consisting of one granted U.S. patent and one U.S. non provisional patent application. The granted patent includes claims directed to, among other things, methods of treatment with NT0502. The granted patent would be expected to expire in 2032.

Adzenys XR-ODT is not currently protected by patents or patent applications outside of the United States and Europe, and Cotempla XR-ODT is not currently protected by patents or patent applications outside of the United States, Australia, Europe, Japan and South Korea. Our generic Tussionex and Adzenys ER are currently protected by patents only in the United States, Canada and Mexico. As such, competitors may be free to sell products that incorporate the same or similar technologies that used in our products in countries in which the relevant product does not have patent protection.

License Rights

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

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

Consumer Health

We currently hold 8 patents in the U.S. and 12 patents registered outside the U.S. We currently have 12 patent applications pending in the U.S. and 17 patent applications pending in countries other than the U.S.

We own or license 93 trademark registrations in the U.S. and have 42 trademark applications pending in the U.S. We also own or license 124 trademarks registered outside of the U.S. (including 21 Madrid Protocol registrations), with 58 applications currently pending.

AR101

Among the assets of Rumpus which we acquired are license agreements which provide access to four patent applications. The cornerstone of the intellectual property family is a pivotal study-ready therapeutic candidate 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 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 a 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 pending patent provides targeted epigenetic therapy for inherited aortic aneurysm conditions and has a priority date of September 1, 2017, also in select geographies.

Healight

The licensed patent portfolio surrounding Healight currently includes four patent families at various stages of prosecution. The first family discloses the use of ultraviolet-A light for internal therapeutic treatment, including through an endotracheal tube. This application is filed in the U.S. and in 14 other countries. The 20-year patent term for this family expires in 2037. The second family discloses a preferred ultraviolet wavelength range within the UV-A range for internal therapeutic treatment, including endotracheal and nasopharyngeal applications. This application is filed in the United States and internationally as a PCT application with a first national phase filing deadline in April 2022. The 20-

year patent term for this family expires in 2040. The third family discloses pre-clinical data developed in support of the Healight technology and details of the structure of the Healight device. This application is filed as a PCT application with a first national phase filing deadline of September 2022. The 20-year patent term for this family expires in 2041. The fourth patent family is directed to methods of increasing expression of mitochondrial antiviral-signaling protein in epithelial cells to mediate innate antiviral responses for use in treatment of viral conditions. The methods include exposure of tissue to ultraviolet-A light.

Trade secret and other protection

In addition to patented intellectual property, we also rely on trade secrets and proprietary know how to protect our technology and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. Our policy is to require each of our employees, consultants and advisors to execute a confidentiality and inventions assignment agreement before beginning their employment, consulting or advisory relationship with us. The agreements generally provide that the individual must keep confidential and not disclose to other parties any confidential information developed or learned by the individual during the course of the individual's relationship with us except in limited circumstances. These agreements generally also provide that we shall own all inventions conceived by the individual in the course of rendering services to us.

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, Delta Prime Club, 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.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and other specific aspects of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, if any of our NDAs are approved, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond the current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Other Regulatory Exclusivities

The Hatch-Waxman Act provides periods of regulatory exclusivity for products that would serve as reference listed drugs ("RLDs") for an ANDA or 505(b)(2) application. If a product is a "new chemical entity," or NCE, generally meaning that the active moiety has never before been approved in any drug, there is a period of five years from the product's approval during which the FDA may not accept for filing any ANDA or 505(b)(2) application for a drug with the same active moiety. An ANDA or 505(b)(2) application may be submitted after four years, however, if the sponsor of the application makes a Paragraph IV certification.

A product that is not an NCE may qualify for a three-year period of exclusivity if the NDA contains new clinical data, (other than bioavailability studies) derived from studies conducted by or for the sponsor, that were necessary for approval. In that instance, the exclusivity period does not preclude filing or review of an ANDA or 505(b)(2) application; rather, the FDA is precluded from granting final approval to the ANDA or 505(b)(2) application until three years after approval of the RLD. Additionally, the exclusivity applies only to the conditions of approval that required submission of the clinical data.

Once the FDA accepts for filing an ANDA or 505(b)(2) application containing a Paragraph IV certification, the applicant must within 20 days provide notice to the RLD or listed drug NDA holder and patent owner that the application has been submitted, and provide the factual and legal basis for the applicant's assertion that the patent is invalid or not infringed. If the NDA holder or patent owner files suit against the ANDA or 505(b)(2) applicant for patent infringement within 45 days of receiving the Paragraph IV notice, the FDA is prohibited from approving the ANDA or 505(b)(2) application for a period of 30 months or the resolution of the underlying suit, whichever is earlier. If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay does extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

If the RLD has NCE exclusivity and the notice is given and suit filed during the fifth year of exclusivity, the regulatory stay extends until 7.5 years after the RLD approval. The FDA may approve the proposed product before the expiration of the regulatory stay if a court finds the patent invalid or not infringed or if the court shortens the period because the parties have failed to cooperate in expediting the litigation.

Pediatric Exclusivity. Section 505A of the Federal Food, Drug and Cosmetic Act (“FDCA”) provides for six months of additional exclusivity or patent protection if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data does not need to show that the product is effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or Orange Book listed patent protection that cover the drug are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve an ANDA or 505(b)(2) application owing to regulatory exclusivity or listed patents. When any product is approved, we will evaluate seeking pediatric exclusivity as appropriate.

Orphan Drug Exclusivity. The Orphan Drug Act provides incentives for the development of drugs intended to treat rare diseases or conditions, which generally are diseases or conditions affecting less than 200,000 individuals in the U.S. If a sponsor demonstrates that a drug product qualifies for orphan drug designation, the FDA grants orphan drug designation to the product for that use. The benefits of orphan drug designation include research and development tax credits and exemption from user fees. A drug that is approved for the orphan drug designated indication generally is granted seven years of orphan drug exclusivity. During that period, the FDA generally may not approve any other application for the same product for the same indication, although there are exceptions, most notably when the later product is shown to be clinically superior to the product with exclusivity. The FDA can revoke a product’s orphan drug exclusivity under certain circumstances, including when the product sponsor is unable to assure the availability of sufficient quantities of the product to meet patient needs. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

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. Although the discussion below focuses on regulation in the U.S., 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.

Pharmaceutical Regulations

Preclinical Testing. Before testing any compound in human patients in the U.S., a company must generate extensive preclinical data. 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. Certain animal studies must be performed in compliance with the FDA's Good Laboratory Practice (“GLP”) regulations and the U.S. Department of Agriculture's Animal Welfare Act.

IND Application. Human clinical trials in the U.S. cannot commence until an investigational new drug or IND application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND becomes effective 30 days following its receipt by the FDA, and the clinical trial proposed in the IND may begin. Once human clinical trials have commenced, the FDA may stop a clinical trial by placing it on "clinical hold" because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA's bioresearch monitoring regulations and Good Clinical Practice (“GCP”) requirements, which establish standards for conducting, recording data from, and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND. In addition, each clinical trial must be reviewed and approved by, and conducted under the auspices of, an Institutional Review Board (“IRB”) for each clinical site. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with, as applicable, regulations and guidelines for obtaining informed consent from the study patients, following the protocol and investigational plan, adequately monitoring the clinical trial, and timely reporting of adverse events (“AEs”). Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to publicly post specified details about certain clinical trials and clinical trial results on government or independent websites (e.g., http://clinicaltrials.gov). Human clinical trials typically are conducted in three sequential phases, although the phases may overlap, be combined, or be subdivided in some cases:

- 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.

The sponsoring company, the FDA, or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

NDA Submission and Review. The FDCA provides two pathways for the approval of new drugs through an NDA. An NDA under Section 505(b)(1) of the FDCA is a comprehensive application to support approval of a product candidate that includes, among other things, data and information to demonstrate that the proposed drug is safe and effective for its proposed uses, that production methods are adequate to ensure its identity, strength, quality, and purity of the drug, and that proposed labeling is appropriate and contains all necessary information. A 505(b)(1) NDA contains results of the full set of preclinical studies and clinical trials conducted by or on behalf of the applicant to characterize and evaluate the product candidate. We intend to seek FDA approval of AR101 through the Section 505(b)(1) regulatory approval pathway.

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to obtain FDA approval that permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely to some extent upon the FDA's findings of safety and effectiveness for an approved product that acts as the reference drug and submit its own product-specific data — which may include data from preclinical studies or clinical trials conducted by or on behalf of the applicant — to address differences between the product candidate and the reference drug. We obtained FDA approval of our ADHD products through the Section 505(b)(2) regulatory approval pathway, with in the case of Adzenys XR-ODT and Adzenys ER, Adderall XR® and in the case of Cotempla XR-ODT, Metadate CD® as the reference drugs. Adderall XR contains amphetamine, and Metadate CD contains methylphenidate, which are also the active ingredients in our Adzenys products and Cotempla XR-ODT, respectively.

The submission of an NDA under either Section 505(b)(1) or Section 505(b)(2) generally requires payment of a substantial user fee to the FDA. The FDA reviews applications to determine, among other things, whether a product is safe and effective for its intended use and whether the manufacturing controls are adequate to assure and preserve the product's identity, strength, quality, and purity. For some NDAs, the FDA may convene an advisory committee to seek insights and recommendations on issues relevant to approval of the application. Although the FDA is not bound by the recommendation of an advisory committee, the agency considers such recommendations carefully when making decisions.

The FDA may determine that a Risk Evaluation and Mitigation Strategy ("REMS") is necessary to ensure that the benefits of a new product outweigh its risks, and the product can therefore be approved. A REMS may include various elements, ranging from a medication guide or patient package insert to limitations on who may prescribe or dispense the drug, depending on what the FDA considers necessary for the safe use of the drug. Under the Pediatric Research Equity Act ("PREA"), certain applications for approval must also include an assessment, generally based on clinical study data, of the safety and effectiveness of the subject drug in relevant pediatric populations. We are currently conducting programs for both Adzenys XR-ODT and Cotempla XR-ODT under PREA guidelines. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Once the FDA accepts an NDA submission — which occurs, if at all, within 60 days after submission of the NDA — the FDA's goal for a non-priority review of an NDA is ten months. In the case of product candidates for orphan indications which receive priority review, as further discussed below, the FDA's goal for review of an NDA is six months. The review process can be and often is significantly extended, however, by FDA requests for additional

information, studies, or clarification. After review of an NDA and the facilities where the product is manufactured, the FDA either issues an approval letter or a complete response letter (“CRL”) outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional preclinical or clinical data or additional work relating to Chemistry, Manufacturing, and Controls (CMC) requirements. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. Data from clinical trials are not always conclusive, and the FDA may interpret data differently than the sponsor.

Obtaining regulatory approval often takes a number of years, involves the expenditure of substantial resources, and depends on a number of factors, including the severity of the disease in question, the availability of alternative treatments, and the risks and benefits demonstrated in clinical trials. Additionally, as a condition of approval, the FDA may impose restrictions that could affect the commercial success of a drug or require post-approval commitments, including the completion within a specified time period of additional clinical studies, which often are referred to as "Phase 4" or "post-marketing" studies.

Post-approval modifications to the drug, such as changes in indications, labeling, or manufacturing processes or facilities, may require a sponsor to develop additional data or conduct additional preclinical studies or clinical trials, to be submitted in a new or supplemental NDA, which would require FDA approval.

Medical Device Regulations

Our Healight product candidate is classified as an investigational medical device and is subject to restrictions under domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders, including, but not limited to, FDCA. The FDCA requires these products, when sold in the United States, to be safe and effective for their intended uses and to comply with the regulations administered by the FDA. The FDA regulates the design, development, research, preclinical and clinical testing, introduction, manufacture, advertising, labeling, packaging, marketing, distribution, import and export and record keeping for such products. Many medical device products are also regulated by comparable agencies in non-U.S. countries in which they are produced or sold.

Unless an exemption applies, 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 type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device’s safety and effectiveness.

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. A predecessor device is referred to as “predicate device.” As a result, FDA clearance requirements may extend the development process for a considerable length of time.. 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.

A claim of substantial equivalence does not mean the new and predicate devices needs to be identical. FDA first establishes that the new and predicate devices have the same intended use and any differences in technological characteristics do not raise different questions of safety and effectiveness. FDA then determines whether the device is as safe and effective as the predicate device by reviewing the scientific methods used to evaluate differences in technological characteristics and performance data. This performance data can include clinical data and non-clinical bench performance data, including engineering performance testing, sterility, electromagnetic compatibility, software validation, biocompatibility evaluation, among other data.

Unless specifically exempt from requiring pre-market clearance, a device may not be marketed in the U.S. until the submitter receives a letter finding the device substantially equivalent. If FDA determines that a device is not substantially equivalent, the applicant may:

- resubmit another 510(k) with new data;
- request a Class I or II designation through the De Novo Classification process;
- file a reclassification petition, or
- submit a premarket approval application (PMA).

Medical devices can be marketed only for the indications for which they are cleared or approved. After a device has received 510(k) clearance for a specific intended use, any change or modification that significantly affects its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, may require a new 510(k) clearance or PMA approval and payment of an FDA user fee. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained.

Any medical devices we may manufacture and distribute are subject to pervasive and continuing regulation by the FDA and certain state and non-U.S. agencies. These include product listing and establishment registration requirements, which help facilitate inspections and other regulatory actions. The manufacturing facilities for any medical devices we market are subject to inspection on a routine basis by the FDA and are required to adhere to GMP requirements, as set forth in the Quality Systems Regulation ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process.

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.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission. Medical devices approved or cleared by the FDA may not be promoted for unapproved or uncleared uses, otherwise known as "off-label" promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

In the European Union ("EU"), our product candidate would be subject to the medical device and in vitro medical device laws of the various member states, which for many years were based on Directives of the European Commission ("Directives"). However, in May 2017, the EU adopted new, formal regulations to replace such Directives; specifically, the EU Medical Device Regulation (the "EU MDR") and In Vitro Diagnostic Regulation (the "EU IVDR"), each of which imposes stricter requirements for the marketing and sale of medical devices and in vitro devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. The EU regulations were

adopted with staggered transitional periods that have since been updated. The full application of the EU MDR was implemented May 2021, while the EU IVDR will be fully applicable in May 2022.

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.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements and product-specific regulations enforced by the FDA and other regulatory agencies. Compliance with cGMP includes adhering to requirements relating to organization and training of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, quality control and quality assurance, packaging and labeling controls, holding and distribution, laboratory controls, and records and reports. The FDA regulates and inspects equipment, facilities, and processes used in manufacturing pharmaceutical products prior to approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. The FDA also conducts regular, periodic visits to re-inspect equipment, facilities, and processes following the initial approval of a product. Failure to comply with applicable cGMP requirements and conditions of product approval may lead the FDA to take enforcement action or seek sanctions, including fines, issuance of warning letters, civil penalties, injunctions, suspension of manufacturing operations, operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution.

Advertising and Promotion. The FDA and other federal regulatory agencies closely regulate the marketing and promotion of drugs through, among other things, standards and regulations for direct-to-consumer advertising, advertising and promotion to healthcare professionals, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. A product cannot be commercially promoted before it is approved. After approval, product promotion can include only those claims relating to safety and effectiveness that are consistent with the labeling approved by the FDA. Healthcare providers are permitted to prescribe drugs for "off-label" uses — that is, uses not approved by the FDA and not described in the product's labeling — because the FDA does not regulate the practice of medicine. However, FDA regulations impose restrictions on manufacturers' communications regarding off-label uses. Broadly speaking, a manufacturer may not promote a drug for off-label use, but under certain conditions may engage in non-promotional, balanced, scientific communication regarding off-label use. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry.

Failure to comply with applicable FDA requirements and restrictions in this area may subject a company to adverse publicity and enforcement action by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes a drug.

Other Requirements. NDA holders must comply with other regulatory requirements, including submitting annual reports, reporting information about adverse drug experiences and maintaining certain records.

Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) establishes two abbreviated approval pathways for pharmaceutical products that are in some way follow-on versions of already approved products.

Generic Drugs. A generic version of an approved drug is approved by means of an ANDA, by which the sponsor demonstrates that the proposed product is the same as the approved, brand-name drug, which is referred to as the RLD. Generally, an ANDA must contain data and information showing that the proposed generic product and RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This is instead of independently demonstrating the proposed product's safety and effectiveness, which are inferred from the fact that the product is the same as the RLD, which the FDA previously found to be safe and effective.

505 (b)(2) NDAs. As discussed above, if a product is similar, but not identical, to an already approved product, it may be submitted for approval via an NDA under section 505(b)(2) of the FDCA. Unlike an ANDA, this does not excuse the sponsor from demonstrating the proposed product's safety and effectiveness. Rather, the sponsor is permitted to rely to some degree on information from investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference, and must submit its own product- specific data of safety and effectiveness to an extent necessary because of the differences between the products. An NDA approved under 505(b)(2) may in turn serve as an RLD for subsequent applications from other sponsors.

RLD Patents. In an NDA, a sponsor must identify patents that claim the drug substance or drug product or a method of using the drug. When the drug is approved, those patents are among the information about the product that is listed in the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is referred to as the Orange Book. The sponsor of an ANDA or 505(b)(2) application seeking to rely on an approved product as the RLD must make one of several certifications regarding each listed patent. A “Paragraph I” certification is the sponsor’s statement that patent information has not been filed for the RLD. A “Paragraph II” certification is the sponsor’s statement that the RLD’s patents have expired. A "Paragraph III" certification is the sponsor's statement that it will wait for the patent to expire before obtaining approval for its product. A "Paragraph IV" certification is an assertion that the patent does not block approval of the later product, either because the patent is invalid or unenforceable or because the patent, even if valid, is not infringed by the new product.

U.S. Healthcare Reform

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, which we refer to together as the Affordable Care Act, is a sweeping measure intended to expand healthcare coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. This law substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry.

Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program (commonly known as the "donut hole"), rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service Act's 340B drug pricing program (340B Program), fraud and abuse, and enforcement. These changes impact existing government healthcare programs and have resulted in the development of new programs, including Medicare payment for performance initiatives.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the Affordable Care Act. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products and product candidates for which we receive regulatory approval, and our business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the Affordable Care Act, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Certain provisions of the Affordable Care Act have been subject to judicial challenges, as well as efforts to repeal or replace, or otherwise modify them or to alter their interpretation and implementation. For example, on December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (the Tax Act), which includes a provision repealing, effective January 1, 2019, the tax-based shared

responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Further, the Bipartisan Budget Act of 2018, among other things, amended the Medicare statute to reduce the coverage gap in most Medicare drug plans, commonly known as the "donut hole," by raising the required manufacturer point-of-sale discount from 50% to 70% off the negotiated price effective as of January 1, 2019. On November 10, 2020, the Supreme Court heard oral argument over the constitutionality of the individual mandate. Although on June 17, 2021, the Supreme Court rejected the challenge on the basis that the plaintiffs lacked legal standing, it is unclear how other efforts to repeal, replace or otherwise modify, or invalidate, the Affordable Care Act or its implementing regulations, or portions thereof, will affect the Affordable Care Act or our business.

Additional legislative changes, regulatory changes, and further judicial challenges related to the Affordable Care Act remain possible. Any such changes could decrease the number of individuals with health coverage. It is possible that the Affordable Care Act, as currently enacted or as it may be amended, repealed, or replaced or otherwise modified in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our products or product candidates for which we receive regulatory approval or to successfully commercialize our products and product candidates.

Additionally, on December 20, 2019, then-President Trump signed the Further Consolidated Appropriations Act for 2020 into law that includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or "the CREATES Act." The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms."

Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Federal Anti-Kickback Statute, the Federal False Claims Act, and other state and federal laws and regulations. The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. Violation of the Federal Anti-Kickback Statute can also be the basis for liability under the Federal False Claims Act, described below. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid.

The Federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. For example, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off- label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory

civil penalties of between $10,000 and $25,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals can bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

In addition to the privacy and security requirements of the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, (which we refer to collectively as "HIPAA"), described below, HIPAA also expanded and created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items or services.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The Physician Payments Sunshine Act, implemented as the Open Payments Program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

In addition, HIPAA, and its implementing regulations impose certain obligations on entities subject to the law, such as health plans and most healthcare providers, and their business associates who provide certain services involving the use or disclosure of HIPAA protected health information on their behalf, with respect to the privacy and security of such protected health information. Further, most states have enacted laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. For example, pharmaceutical manufacturers have been subject to liability under the Federal Anti-Kickback Statute for operation of certain patient assistance programs, because if implemented incorrectly those programs can be perceived as providing payment to prescribers or patients to induce the prescriber or patient to utilize a particular drug product. Accordingly, it will be important that our RxConnect patient assistance program be implemented in accordance with all health care fraud and abuse laws. A challenge under any health care fraud and abuse laws could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or

individual from participation in government health care programs, criminal fines and individual imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Further, we may be subject to contractual damages and reputational harm as result of such non-compliance. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

Coverage and Reimbursement for our Products

The cost of pharmaceuticals and medical devices continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures, given the trend toward managed healthcare, the increasing influence of managed care organizations and pharmacy benefit managers (PBMs), and additional regulatory and legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies, as well as healthcare legislative reforms.

Additionally, we must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, including: the Centers for Medicare & Medicaid Services' Medicaid Drug Rebate Program, Medicare Part B Program and Medicare Part D Coverage Gap Discount Programs, the U.S. Department of Veterans Affairs' Federal Supply Schedule Program, and the Health Resources and Services Administration's 340B Drug Pricing Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B Program. The calculations necessary to determine the prices reported are complex, and the failure to report prices accurately may expose us to penalties.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, including any changes to any Medicare reimbursement program, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

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 U.S. Drug Enforcement Administration ("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. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance. In addition, special permits and notification requirements apply to imports and exports of narcotic drugs.

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

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action that could have a material adverse effect on our business, results of operations and financial condition. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

Individual states also independently regulate controlled substances. We and our manufacturers will be subject to state regulation on distribution of these products, including, for example, state requirements for licensures or registration. Additionally, we use third-party logistics firms to inventory and fill sales orders for our commercial portfolio.

Human Capital

As of June 30, 2021, we employed 175 full time employees, including 67 who are involved in operations, 7 who are directly involved in research and development, 35 who are involved in commercialization and 66 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 – compliance, collaboration, integrity and high performance – 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. For further information regarding the impact of COVID-19 and actions taken in response to the pandemic, including with respect to our employees, see Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations.

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, *http://aytubio.com*.

Item 1A. Risk Factors

Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in this Annual Report 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 a limited operating history, have incurred losses, and can give no assurance of profitability.

We are a commercial-stage specialty pharmaceutical company with a limited operating history. Prior to implementing our commercial strategy in the fourth calendar quarter of 2015, we did not have a focus on profitability. Since then, we have incurred losses in each year since our inception. Our net loss for the years ended June 30, 2021 and 2020 was $58.3 million and $13.6 million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date. Even though we expect to have revenue growth in the next several fiscal years, it is uncertain that the revenue growth will be significant enough to offset our expenses and generate a profit in the future. We have a very limited operating history on which investors can evaluate our potential for future success. Potential investors should evaluate us in light of the expenses, delays, uncertainties, and complications typically encountered by early-stage healthcare businesses, many of which will be beyond our control. These risks include the following:

- uncertain market acceptance of our products and product candidates;
- 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, if any, may never succeed in these activities and, even if we do, or one of our collaborators does, we may never generate revenues that are sufficient enough for us to achieve profitability.

We may need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our product expansion and development efforts or other operations.

We are expending resources to expand the market for our products and develop our product candidates, none of which might be as successful as we anticipate or at all and all of which might take longer and be more expensive than we anticipate. As of June 30, 2021, our cash, cash equivalents and restricted cash totaling $49.9 million. During the year ended June 30, 2021, we raised approximately $40.1 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 may need to seek additional funds sooner than planned, through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements or a combination of these approaches. In any event, we may require additional capital to continue the expansion of commercialization efforts for our pharmaceutical, device and commercial health products, and to obtain regulatory approval for, and to commercialize, our current product candidates. Raising funds in the current economic environment, as well as our limited operating history, may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to expand any existing product or develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities could dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be unable to expand the market for our pharmaceutical, device and consumer health products, and/or be required to significantly curtail, delay or discontinue one or more of our research or development programs for 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 will incur increased costs associated with, and our management will need to devote substantial time and effort to, compliance with public company reporting and other requirements.

As a public company, we incur significant legal, accounting and other expenses. In addition, the rules and regulations of the SEC and any national securities exchange to which we may be subject in the future impose numerous requirements on public companies, including requirements relating to our corporate governance practices, with which we will need to comply. Further, we will continue to be required to, among other things, file annual, quarterly and current reports with respect to our business and operating results. Our management and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations, and our efforts and initiatives to comply with those requirements could be expensive.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to Section 404 of the Sarbanes-Oxley Act, our management conducted an assessment of the effectiveness of our internal controls over financial reporting for the year ended June 30, 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 have 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.

However, if in the future we were to conclude that our internal control over financial reporting were not effective, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effect on our operations because there is presently no precedent available by which to measure compliance adequacy. As a consequence, we may not be able to complete any necessary remediation process in time to meet our deadline for compliance with Section 404 of the Sarbanes-Oxley Act. Also, there can be no assurance that we will not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes-Oxley Act. The presence of material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results.

If we are unable to conclude that we have effective internal control over financial reporting or if our independent auditors are unwilling or unable to provide us, when required, with an attestation report on the effectiveness of internal control over financial reporting as required by Section 404 of the Sarbanes-Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes-Oxley Act, we may not be able to maintain listing on the NASDAQ Capital Market.

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.

As of closing of the Neos merger, we indirectly assumed $16.6 million of senior secured credit facility with Deerfield, of which $16.0 million was outstanding as of June 30, 2021, and up to $25.0 million of secured revolving loans with Encina. As of June 30, 2021, $7.9 million was outstanding under the secured revolving loan. All obligations under our credit facilities 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 20, 2021, we had accumulated deficit of $178.3 million. Although we have strategies and plans to achieve profitability through revenue growth, we expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future as we continue to market our approved products and continue to develop and seek marketing approval for our current and future product candidates.

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 credit facilities with Deerfield or Encina 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.

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

As of June 30, 2021, we had federal net operating loss carryforwards of approximately $466.7 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. Because Ampio’s equity ownership interest in our company fell to below 80% in January 2016, we were deconsolidated from Ampio’s consolidated federal income tax group. As a result, certain of our net operating loss carryforwards may not be available to us and we may not be able to use them to offset our U.S. federal taxable income. As a consequence of the deconsolidation, it is possible that certain other tax attributes and benefits resulting from U.S. federal income tax consolidation may no longer be available to us. Our company and Ampio do not have a tax sharing agreement that could mitigate the loss of net operating losses and other tax attributes resulting from the deconsolidation or our incurrence of liability for the taxes of other members of the consolidated group by reason of the joint and several liability of group members. In addition to the deconsolidation risk, an “ownership change” (generally a 50% change in equity ownership over a three-year period) under Section 382 of the Code could limit our ability to offset, post-change, our U.S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income a corporation may offset with pre-ownership change net operating loss carryforwards and certain recognized built-in losses. We believe that the June 2021 transaction with 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 same transaction may have caused, together with equity ownership changes in the past 5 years, an ownership change resulting in limitation of our ability to us our pre-acquisition net operating loss carryovers. Either the deconsolidation or the ownership change scenarios could result in increased future tax liability to us.

The success of the Company will depend on its ability to obtain, commercialize and grow.

We currently have a limited number of products and may not be successful in marketing and commercializing these products. In addition, we may seek to develop current or new product candidates. The testing, manufacturing and marketing of these product candidates would require regulatory approvals, including approval from the FDA and similar bodies in other countries. To the extent that we seek to develop product candidates, our future growth would be negatively affected if we fail to obtain requisite regulatory approvals within the expected time frames, or at all, in the United States and internationally for products in development and approvals for our existing products for additional indications.

RISKS RELATED TO COMMERCIALIZATION

We are heavily dependent on the commercial success of our commercial products. We have generated relatively small revenues from the sales of these products, or any sales revenues from any of our product candidates, if approved, and we may never achieve or maintain profitability.

Our ability to become profitable depends upon our ability to generate revenues from sales of our prescription and consumer health product portfolios. We have limited commercial experience as a newly combined commercial entity, having only generated revenues from the sale of our sleep product, Zolpimist, since June 2018, from 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**.**

We have limited experience selling our current products as they were acquired from other companies or were recently approved for sale. As a result, we may be unable to successfully commercialize our products and product candidates.

Despite our management's extensive experience in launching and managing commercial-stage healthcare companies, we have limited marketing, sales and distribution experience with our current product portfolio as it is currently comprised. Our ability to achieve profitability depends on attracting and retaining customers for our current products and building brand loyalty for our pharmaceuticals and consumer health product offerings. To successfully perform sales, marketing, distribution and customer support functions, we will face a number of risks, including:

- our ability to attract and retain skilled support team, marketing staff and sales force necessary to increase the market for our approved products and to maintain market acceptance for our product candidates;
- the ability of our sales and marketing team to identify and penetrate the potential customer base; and
- the difficulty of establishing brand recognition and loyalty for our products.

In addition, we may seek to enlist one or more third parties to assist with sales, distribution and customer support globally or in certain regions of the world. If we do seek to enter into these arrangements, we may not be successful in attracting desirable sales and distribution partners, or we may not be able to enter into these arrangements on favorable terms, or at all. If our sales and marketing efforts, or those of any third-party sales and distribution partners, are not successful, our currently approved products may not achieve increased market acceptance and our product candidates may not gain market acceptance, which would materially impact our business and operations.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We face significant existing competition in the United States and, if approved, would face significant competition in markets outside the United States, from major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs.

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.

If our competitors market products that are more effective, safer or less expensive than our products or that reach the market sooner than our products we may enter the market too late in the cycle and may not achieve commercial success, or we may have to reduce our price, which would impact our ability to generate revenue and obtain profitability. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

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 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 Laboratories FL, Inc. ("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 Pharmaceuticals USA, Inc. ("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.

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 in connection with 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 attention deficit/hyperactivity disorder ("ADHD") products, generic Tussionex, Tuzistra XR and ZolpiMist is a regulated drug product and subject to the U.S. Drug Enforcement Administration ("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, at any time following approval of a product for sale, 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 or the relevant regulatory authority may require 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. As a result, our business, financial condition and results of operations may be materially harmed.

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 approved products may not be accepted by physicians, patients, healthcare payors, health technology assessment bodies or the medical community in general.

Even if the medical community accepts a product as safe and efficacious for its indicated use, physicians may choose to restrict the use of the product if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to any existing medicines or treatments. We cannot predict the degree of market acceptance of any of our approved products, which will depend on a number of factors, including, but not limited to:

- the efficacy and safety of the product;
- changes in the standard of care for the targeted indication for any therapeutic candidate;
- the approved labeling for the product and any required warnings;
- the advantages and disadvantages of the product compared to alternative treatments;
- our and any collaborator's ability to educate the medical community about the safety and effectiveness of the product;
- the reimbursement policies of government and third-party payors pertaining to the product;
- the prevalence and severity of adverse events or publicity;
- the ability to manufacture our product in sufficient quantities and yields;
- potential product liability claims; and
- the market price of our product relative to competing treatments.

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.

Our pharmaceutical, device and consumer health products may prove to be difficult to effectively commercialize as planned.

Various commercial, regulatory, and manufacturing factors may impact our ability to maintain or grow revenues from sales of our pharmaceutical, device and consumer health product offerings. Specifically, we may encounter difficulty by virtue of:

- our inability to adequately market and increase sales of any of these products;
- our inability to secure continuing prescribing of any of these products by current or previous users of the product;
- our inability to effectively transfer and scale manufacturing as needed to maintain an adequate commercial supply of these products;
- reimbursement and medical policy changes that may adversely affect the pricing, profitability or commercial appeal of pharmaceutical products; and

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

We cannot be certain that we will be able to obtain regulatory approval for, or successfully commercialize, our product candidates.

We may not be able to develop our current or any future product candidates. Our product candidates will require substantial additional clinical development, testing, and regulatory approval before we are permitted to commence commercialization. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through pre-clinical testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years and may include post-marketing studies and surveillance, which will require the expenditure of substantial resources. Of the large number of drugs in development in the U.S., only a small percentage successfully completes the FDA regulatory approval process and is commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development and clinical programs, we cannot assure you that any of our product candidates will be successfully developed or commercialized.

For our more strictly regulated pharmaceutical products, such as our Rx Portfolio product offerings, we are not permitted to market a pharmaceutical product in the U.S. until we receive approval of a New Drug Application, or an NDA, for that product from the FDA, or in any foreign countries until we receive the requisite approval from such countries. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA may delay, limit or deny approval of any product candidate for many reasons, including, among others:

- we may not be able to demonstrate that a product candidate is safe and effective to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may require that we conduct additional clinical trials;
- the FDA may not approve the formulation, labeling or specifications of any product candidate;
- the clinical research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- the FDA may find the data from pre-clinical studies and clinical trials insufficient to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks, such as the risk of drug abuse by patients or the public in general;
- the FDA may disagree with our interpretation of data from our pre-clinical studies and clinical trials;
- the FDA may not accept data generated at our clinical trial sites;
- if an NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval,

additional pre-clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions;

- the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- the FDA may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the FDA may change its approval policies or adopt new regulations.

These same risks apply to applicable foreign regulatory agencies from which we may seek approval for any of our product candidates.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market any product candidate. Moreover, because a substantial portion of our business is or may be dependent upon our product candidates, any such setback in our pursuit of initial or additional regulatory approval would have a material adverse effect on our business and prospects.

Even if we in the future successfully complete clinical trials of our product candidates, those product candidates may not be commercialized successfully for other reasons.

Even if we successfully complete clinical trials for one or more of our product candidates, those candidates may not be commercialized for other reasons, including:

- failure to receive regulatory clearances required to market them as drugs;
- being subject to proprietary rights held by others;
- being difficult or expensive to manufacture on a commercial scale;
- having adverse side effects that make their use less desirable; or
- failing to compete effectively with products or treatments commercialized by competitors.

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. 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.

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. 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.

Manufacturing risks and inefficiencies may adversely affect our ability to produce our products.

We expect to engage third parties to manufacture all of our products, at the very least, in the near future. For any future product, we expect to use third-party manufacturers because we 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 our third-party manufacturing. We may not be able to meet the demand for our products if one or more of any third-party manufacturers is unable to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers for any of our products or product candidates in a timely manner and on terms acceptable to us.

If we fail to manufacture our ADHD 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 our customers' demands 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 result in our being unable to effectively commercialize 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.

Our Grand Prairie facility was formerly operated by PharmaFab, Inc., or PharmaFab, the predecessor of Neos. In April 2007, the FDA announced entry of a Consent Decree of Permanent Injunction, or the Consent Decree, against PharmaFab, one of its subsidiaries and two of its officials. The Consent Decree arose out of several perceived cGMP deficiencies related to the manufacture of unapproved drugs or Drug Efficacy Study Implementation drugs that we no longer manufacture. In July 2019, Neos filed a motion with the U.S. District Court of North Texas to vacate the Consent Decree, which was unopposed by the Department of Justice and the FDA and was granted by the court on July 11, 2019. While the Consent Decree has been vacated, there can be no assurance that we will not become subject to similar orders in the future, which may result in us continuing to expend resources and attention to observe its terms, and there can be no assurance that we will be in compliance with its requirements.

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 or our generic Tussionex 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 and our generic Tussionex 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.

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 or our generic Tussionex 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.

The outsourcing of the manufacturing of our ADHD products to third parties, may negatively impact our business.

We plan to outsource the manufacturing of our ADHD products to third-party manufacturers to produce commercial quantities of our ADHD products. Manufacturing partner requirements may require us to fund capital improvements, perhaps on behalf of third parties, to support the scale-up of manufacturing and related activities. If our third-party manufacturers are unable to provide commercial quantities of our ADHD products or on acceptable terms, we will have to successfully transfer manufacturing technology to a different manufacturer which may impact our financial performance. Engaging a new manufacturer for our ADHD products will require us to conduct comparative studies or utilize other means to determine bioequivalence of the new and prior manufacturers' products, which could negatively impact our financial performance. If our third-party manufacturers are unable or unwilling to increase their manufacturing capacity or if we are unable to establish alternative arrangements on a timely basis or on acceptable terms, the revenue that we might receive from our ADHD products may be delayed or there may be a shortage in supply. Any inability to manufacture our ADHD products in sufficient quantities when needed could seriously harm our business and our financial results.

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.

If we fail to successfully acquire new products, we may lose market position.

Acquiring new products is an important factor in our planned sales growth, including products that already have been developed and found market acceptance. If we fail to identify existing or emerging prescription or consumer health markets and trends and to acquire new products, we will not develop a strong revenue source to help pay for our development activities as well as possible acquisitions. This failure would delay implementation of our business plan, which could have a negative adverse effect on our business and prospects.

If we do not secure collaborations with strategic partners to test, commercialize and manufacture product candidates, we may not be able to successfully develop products and generate meaningful revenues.

We may enter into collaborations with third parties to conduct clinical testing, as well as to commercialize and manufacture our products and product candidates. If we are able to identify and reach an agreement with one or more collaborators, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. Further, the economic environment at any given time may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our product candidates.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize our products or product candidates. Collaborations involving our product candidates pose a number of risks, including the following:

- collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others;
- collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement;
- collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals;
- collaborators may delay the development or commercialization of our product candidates in favor of developing or commercializing their own or another party's product candidate; or
- collaborators may decide to terminate or not to renew the collaboration for these or other reasons.

As a result, collaboration agreements may not lead to development or commercialization of our product candidates in the most efficient manner or at all.

Collaboration agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product candidate. We also face competition in seeking out collaborators. If we are unable to secure collaborations that achieve the collaborator's objectives and meet our expectations, we may be unable to advance our products or product candidates and may not generate meaningful revenues.

We or our strategic partners may choose not to continue an existing product or choose not to develop a product candidate at any time during development, which would reduce or eliminate our potential return on investment for that product.

At any time and for any reason, we or our strategic partners may decide to discontinue the commercialization or development of a product or product candidate. If we terminate a program in which we have invested significant resources, we will reduce the return, or not receive any return, on our investment and we will have missed the opportunity to have allocated those resources to potentially more productive uses. If one of our strategic partners terminates a program, we will not receive any future milestone payments or royalties relating to that program under our agreement with that party. As an example, we sold Primsol in March 2017, and abandoned Fiera and ProstaScint in June 2018.

We may never realize the expected benefits from the divestiture of Natesto.

The divestiture of Natesto is part of a strategy to transform ourselves into a high growth, specialty pharmaceutical company. If we are unable to achieve our growth and profitability objectives due to competition, lack of acceptance of our products, failure to generate favorable clinical data or gain regulatory approvals, or other risks as described in this section, or due to other events, we will not be successful in transforming our business and may not see the appropriate market valuation. Moreover, Natesto generated substantial revenue historically which we may not be able to replace. While over time we expect to replace this revenue by investing in, acquiring and accelerating other

revenue streams, there is a risk we will be unable to replace the revenue that Natesto generated, or that the cost of such will be higher than expected. In addition, we may not ultimately receive the full benefits from the divestiture over the term as expected. If we are unable to achieve our growth objectives, such failure will be exacerbated by the loss of revenue generated by Natesto, and could materially impact our financial position and results of operations, resulting in a decline in our stock price.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of our product candidates may be delayed, and our business will be harmed.

We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the initiation or completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval, or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of such milestones are based on a variety of assumptions which may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators, and our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals from the FDA and other regulatory agencies and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of compounds used in the manufacture of our product candidates;
- our efforts, or those efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we announce and expect, the commercialization of our product candidates may be delayed and our business, prospects and results of operations may be harmed.

Any third-party manufacturers we engage are subject to various governmental regulations, and we may incur significant expenses to comply with, and experience delays in, our product commercialization as a result of these regulations.

The manufacturing processes and facilities of third-party manufacturers we have engaged for our current approved products are, and any future third-party manufacturer will be, required to comply with the federal Quality System Regulation, or QSR, which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of devices. The FDA enforces the QSR through periodic unannounced inspections of manufacturing facilities. Any inspection by the FDA could lead to additional compliance requests that could cause delays in our product commercialization. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with the manufacturing processes and

facilities of third-party manufacturers we engage, including the failure to take satisfactory corrective actions in response to an adverse QSR inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties;
- recall or seizure of the product in question;
- total or partial suspension of production or distribution;
- the FDA's refusal to grant pending future clearance or pre-market approval;
- withdrawal or suspension of marketing clearances or approvals;
- clinical holds;
- warning letters;
- refusal to permit the export of the product in question; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from marketing, distributing or selling our products, and would likely harm our business.

In addition, a product defect or regulatory violation could lead to a government-mandated or voluntary recall by us. We believe the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall drugs or devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert our management attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers.

We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us.

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

- expand the market for our approved products, especially our pharmaceutical and devices regulated by the FDA;
- successfully commercialize our product candidates alone or with commercial partners;
- discover and develop product candidates that are superior to other products in the market;

- obtain required regulatory approvals;
- attract and retain qualified personnel; and
- obtain patent and/or other proprietary protection for our product candidates.

Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our products and product candidates obsolete. Our competitors may obtain patent protection, receive FDA approval, and commercialize medicines before us. Other companies are or may become engaged in the discovery of compounds that may compete with the product candidates we are developing.

For our approved products, we compete with companies that design, manufacture and market treatments that compete with our products.

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

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

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

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

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

The 2010 enactments of the Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act, or the Health Care Reconciliation Act, significantly impacted the provision of, and payment for, health care in the U.S. Various provisions of these laws are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre-existing conditions, establish health insurance exchanges, and provide additional support for medical research. Amendments to the PPACA and/or the Health Care Reconciliation Act, as well as new legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the U.S., could influence the purchase of medicines and medical devices and reduce demand and prices for our products and product candidates, if approved. This could harm our or our collaborators' ability to market any approved products and generate revenues. As we expect to receive significant revenues from reimbursement 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 European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. A member state may require that physicians prescribe the generic version of a drug instead of our approved branded product. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products or product candidates. Historically, pharmaceutical products launched in the European Union do not follow price structures of the U.S. and generally tend to have significantly lower prices.

Our financial results will depend on the acceptance among clinicians, hospitals, third-party payors and the medical community of our products and product candidates.

Our future success depends on the acceptance by our target customers, third-party payors and the medical community that our products and product candidates are reliable, safe and cost-effective. Many factors may affect the market acceptance and commercial success of our products and product candidates, including:

- our ability to convince our potential customers of the advantages and economic value our products and product candidates over existing technologies and products;
- the relative convenience and ease of our products and product candidates over existing technologies and products;
- the introduction of new technologies and competing products that may make our products and product candidates less attractive for our target customers;
- our success in training medical personnel on the proper use of our products and product candidates;
- the willingness of third-party payors to reimburse our target customers that adopt our products and product candidates;
- the acceptance in the medical community of our products and product candidates;
- the extent and success of our marketing and sales efforts; and
- general economic conditions.

If third-party payors do not reimburse our customers for the products we sell or if reimbursement levels are set too low for us to sell one or more of our products at a profit, our ability to sell those products and our results of operations will be harmed.

While 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.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our products and product candidates in foreign markets for which we intend to primarily rely on collaboration with third parties. If we commercialize our products or product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;

- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to our products;
- foreign currency exchange rate fluctuations;
- our customers' ability to obtain reimbursement for our products in foreign markets; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our products or product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

RISKS RELATED TO PRODUCT DEVELOPMENT AND REGULATORY APPROVAL

Our pre-commercial product candidates are expected to 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. If clinical trials of our product candidates fail to satisfactorily demonstrate safety and efficacy to the FDA and other regulators, we or our collaborators may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of these product candidates.

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. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre-clinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Interim results of clinical trials do not necessarily predict final results, and success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major set-back for that product candidate and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business, prospects and financial condition and on the value of our common stock.

In connection with clinical testing and trials, we face a number of risks, including:

- a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects;
- patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested;
- the results may not confirm the positive results of earlier testing or trials; and

- the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to establish the safety and efficacy of the product candidate.

If we do not successfully complete pre-clinical and clinical development, we will be unable to market and sell products derived from our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Although there are a large number of drugs in development in the U.S. and other countries, only a small percentage result in the submission of an NDA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business, prospects and financial condition will be materially harmed.

Delays, suspensions and terminations in any clinical trial we undertake could result in increased costs to us and delay or prevent our ability to generate revenues.

Human clinical trials are very expensive, time-consuming, and difficult to design, implement and complete. The completion of trials for any product candidates, which as planned could take years to complete, may be delayed for a variety of reasons, including delays in:

- demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- validating test methods to support quality testing of the drug substance and drug product;
- obtaining sufficient quantities of the drug substance or device parts;
- manufacturing sufficient quantities of a product candidate;
- obtaining approval of an IND from the FDA;
- obtaining institutional review board approval to conduct a clinical trial at a prospective clinical trial site; and
- determining dosing and clinical design and making related adjustments.

Identifying and qualifying patients to participate in our clinical trials will be critical to our success. Patient enrollment depends on many factors, including:

- the size of the patient population required for analysis of the trial’s primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the therapeutic candidate under study;
- the willingness or availability of patients to participate in our trials, including due to the perceived risks and benefits, stigma or other side effects of use of a controlled substance;

- perceived risks and benefits of our approach to treatment of indication;
- the proximity of patients to clinical sites;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient informed consents.

Even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials.

In addition, any negative results we may report in clinical trials may make it difficult or impossible to recruit and retain patients in other clinical trials of that same therapeutic candidate. Delays in the enrollment for any clinical trial will likely increase our costs, slow down the approval process and delay or potentially jeopardize our ability to commence sales of our future therapeutic candidates and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of any future therapeutic candidates.

The commencement and completion of clinical trials for our product candidates may be delayed, suspended or terminated due to a number of factors, including:

- lack of effectiveness of product candidates during clinical trials;
- adverse events, safety issues or side effects relating to the product candidates or their formulation or design;
- inability to raise additional capital in sufficient amounts to continue clinical trials or development programs, which are very expensive;
- the need to sequence clinical trials as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into collaborations relating to the development and commercialization of our product candidates;
- failure by us or our collaborators to conduct clinical trials in accordance with regulatory requirements;
- our inability or the inability of our collaborators to manufacture or obtain from third parties materials sufficient for use in pre-clinical studies and clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines, including mandated changes in the scope or design of clinical trials or requests for supplemental information with respect to clinical trial results;
- failure of our collaborators to advance our product candidates through clinical development;

- delays in patient enrollment, variability in the number and types of patients available for clinical trials, and lower-than anticipated retention rates for patients in clinical trials;
- difficulty in patient monitoring and data collection due to failure of patients to maintain contact after treatment;
- a regional disturbance where we or our collaborative partners are enrolling patients in our clinical trials, such as a pandemic, terrorist activities or war or a natural disaster; and
- varying interpretations of our data, and regulatory commitments and requirements by the FDA and similar foreign regulatory agencies.

Many of these factors may also ultimately lead to denial of an NDA for a product candidate. If we experience delays, suspensions or terminations in a clinical trial, the commercial prospects for the related product candidate will be harmed, and our ability to generate product revenues will be delayed.

In addition, we may encounter delays or product candidate rejections based on new governmental regulations, future legislative or administrative actions, or changes in FDA policy or interpretation during the period of product development. If we obtain required regulatory approvals, such approvals may later be withdrawn. Delays or failures in obtaining regulatory approvals may result in:

- varying interpretations of data and commitments by the FDA and similar foreign regulatory agencies; and
- diminishment of any competitive advantages that such product candidates may have or attain.

Furthermore, if we fail to comply with applicable FDA and other regulatory requirements at any stage during this regulatory process, we may encounter or be subject to:

- diminishment of any competitive advantages that such product candidates may have or attain;
- delays or termination in clinical trials or commercialization;
- refusal by the FDA or similar foreign regulatory agencies to review pending applications or supplements to approved applications;
- product recalls or seizures;
- suspension of manufacturing;
- withdrawals of previously approved marketing applications; and
- fines, civil penalties, and criminal prosecutions.

The medical device regulatory clearance or approval process is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from broadly commercializing the Healight Platforms for clinical 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.

The approval process for pharmaceutical and medical device products outside the U.S. varies among countries and may limit our ability to develop, manufacture and sell our products internationally. Failure to obtain marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union and many other jurisdictions, we, and our collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. We may conduct clinical trials for, and seek regulatory approval to market, our product candidates in countries other than the U.S. Depending on the results of clinical trials and the process for obtaining regulatory approvals in other countries, we may decide to first seek regulatory approvals of a product candidate in countries other than the U.S., or we may simultaneously seek regulatory approvals in the U.S. and other countries. If we or our collaborators seek marketing approval for a product candidate outside the U.S., we will be subject to the regulatory requirements of health authorities in each country in which we seek approval. With respect to marketing authorizations in Europe, we will be required to submit a European Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval.

Obtaining regulatory approvals from health authorities in countries outside the U.S. is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA.

Even if we, or our collaborators, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our products may limit how we or they market our products, which could materially impair our ability to generate revenue.

Even if we receive regulatory approval for a product candidate, this approval may carry conditions that limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, a regulatory approval may limit the indicated uses for which we can market a product or the patient population that may utilize the product, or may be required to carry a warning in its labeling and on its packaging. Products with black box warnings are subject to more restrictive advertising regulations than products without such warnings. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators expect to continue to expend time, money and effort in all areas of regulatory compliance.

If the FDA or a comparable foreign regulatory authority approves any of our future therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the therapy and underlying therapeutic substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice (“cGMP”) and with good clinical practice (“GCP”) for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such therapies. Later discovery of previously unknown problems with any approved

therapeutic 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, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of our future therapeutic candidates, withdrawal of the product from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- 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;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that we receive for our future therapeutic candidates may also be subject to limitations on the approved indicated uses for which the therapy may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of such therapeutic candidates.

If there are changes in the application of legislation, regulations or regulatory policies or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the therapeutic or its manufacture and requiring us to recall or remove the therapeutic from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our therapeutic labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such therapy may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

Any of our products and product candidates for which we, or our collaborators, obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market and we, and our collaborators, may be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our products following approval.

Any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval, as well as the manufacturing processes, post approval studies and measures, labeling, advertising and promotional activities for such products, among other things, are or will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the FDA requirement to implement a REMS to ensure that the benefits of a drug outweigh its risks.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws.

We are subject to various regulations pertaining to the marketing of our approved products.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products, including inducements to potential patients to request our products and services. Additionally, any product promotion educational activities, support of continuing medical education programs, and other interactions with health-care professionals must be conducted in a manner consistent with the FDA regulations and the Anti-Kickback Statute. The Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Violations of the Anti-Kickback Statute can also carry potential federal False Claims Act liability. Additionally, many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. These and any new regulations or requirements may be difficult and expensive for us to comply with, may adversely impact the marketing of our existing products or delay introduction of our product candidates, which may have a material adverse effect on our business, operating results and financial condition.

Our products and product candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities.

Further, if a product candidate receives marketing approval and we or others identify undesirable side effects caused by the product after the approval, or if drug abuse is determined to be a significant problem with an approved product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as a "Black Box warning" or a contraindication;
- we may be required to change the way the product is distributed or administered, conduct additional clinical trials or change the labeling of the product;
- we may decide to remove the product from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking the product; and

- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate and could substantially increase the costs of commercializing an affected product or product candidates and significantly impact our ability to successfully commercialize or maintain sales of our product or product candidates and generate revenues.

Certain of our products contain, and future other product candidates may contain, controlled substances, the manufacture, use, sale, importation, exportation, prescribing and distribution of which are subject to regulation by the DEA.

Certain of our products, such as, Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT, Tuzistra XR, ZolpiMist and our generic Tussionex (collectively, our "Controlled Substance Products") which are approved by the FDA, are regulated by the DEA as Schedule II, III or Schedule IV controlled substances. Before any commercialization of any product candidate that contains a controlled substance, the DEA will need to determine the controlled substance schedule, taking into account the recommendation of the FDA. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible. 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.

ZolpiMist is regulated by the DEA as a Schedule IV controlled substance. Consequently, the manufacturing, shipping, storing, selling and using of the products are subject to a high degree of regulation. Also, distribution, prescribing and dispensing of these drugs are highly regulated.

Amphetamine, methylphenidate and hydrocodone, which are the active ingredients in our Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT and generic Tussionex 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 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.

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

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

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 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.

Inadequate funding for the FDA, and other government agencies could prevent our new products, services and product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which could adversely affect our business. Any government shutdown or other disruption of normal activities at these regulatory agencies, such as the FDA, could lead to a delay or stop in critical activities. If a prolonged government shutdown were to occur, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We rely on third parties to conduct our clinical trials and perform data collection and analysis, which may result in costs and delays that prevent us from successfully commercializing product candidates.

We rely, and will rely in the future, on medical institutions, clinical investigators, contract research organizations, contract laboratories, and collaborators to perform data collection and analysis and others to carry out our clinical trials. Our development activities or clinical trials conducted in reliance on third parties may be delayed, suspended, or terminated if:

- the third parties do not successfully carry out their contractual duties or fail to meet regulatory obligations or expected deadlines;
- we replace a third party; or
- the quality or accuracy of the data obtained by third parties is compromised due to their failure to adhere to clinical protocols, regulatory requirements, or for other reasons.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our product candidates. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs.

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

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

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

The development of Healight faces uncertainties related to testing.

The development of Healight is based on scientific hypotheses and experimental approaches that may not lead to desired results. It is possible that the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic, and collaborator constraints. Success in one stage of testing is not necessarily an indication that the Healight program will succeed in later stages of testing and development. The discovery 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.

Our Enzastaurin product candidate is being developed for other indications by other sponsors. Any undesirable adverse events that occur in relation to the activities by other sponsors could delay or prevent our regulatory approval, limit the commercial profile of Enzastaurin, or result in significant negative consequences following any regulatory approval.

Undesirable adverse events that occur in relation to the activities by other sponsors related to our Enzastaurin 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 Enzastaurin by other sponsors could also harm our reputation, business, financial condition and business prospects.

Additionally, if Enzastaurin receives regulatory approval, and we or others later identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including but not limited to:

- suspending the marketing of the drug;
- having regulatory authorities withdraw approvals of the drug;
- adding warnings on the label;

- conducting post-marketing studies;
- being sued and held liable for harm caused to subjects or patients; and
- damage to our reputation.

Any of these events could prevent us from achieving or maintaining market acceptance of Enzastaurin, if approved, and could significantly harm our business, results of operations and prospects.

We may 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 may 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.

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 will not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under these license agreements, we will not be able to commercialize certain products subject to patent or patent application or trademark or trademark application, and our business, results of operations, financial condition and prospects would be materially adversely affected.

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

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

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

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

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

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

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

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

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

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

The patent positions of pharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering pharmaceutical compositions may be uncertain and difficult to determine and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the U.S. Patent and Trademark Office, or USPTO, are sometimes uncertain and could change in the future. Consequently, the issuance and scope of patents cannot be predicted with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to interference proceedings, and U.S. patents may be subject to re-examination proceedings, post-grant review and/or inter partes review in the USPTO. Foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, re-examination, post-grant review, inter partes review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the U.S. and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products and product candidates without providing any compensation to us or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection of our products and product candidates, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

Developments in patent law could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability and any such changes could have a negative impact on our business.

In addition, the Leahy-Smith America Invents Act, or the America Invents Act, which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes the way issued patents are challenged, and changes the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of discovery and development of therapies and medical devices, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific and commercial collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We may not be able to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U.S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and medical devices. This could make it difficult for us to stop the infringement of some of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-

country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U.S. and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have or expect to have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We might employ individuals who were previously employed at universities or other biopharmaceutical or medical device companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the pharmaceutical and medical device industries regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our products or product candidates infringe the intellectual property rights of others. If our development and commercialization activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs, compositions or devices. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior

affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- we or our collaborators having to enter into license arrangements that may not be available on commercially acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, prospects and financial condition. As a result, we could be prevented from commercializing our products and product candidates.

RISKS RELATED TO OUR ORGANIZATION, STRUCTURE AND OPERATION

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

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

We intend to acquire, through mergers, asset purchases or in-licensing, businesses or products, or form strategic alliances, in the future, and we may not realize the intended benefits of such acquisitions or alliances.

We intend to acquire, through mergers, asset purchases or in-licensing, additional businesses or products, form strategic alliances and/or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses or assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses or assets if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition or alliance, we will achieve the expected synergies to justify the transaction. These risks apply to our acquisition of ZolpiMist in June 2018 and Tuzistra XR in November 2018, our acquisition of the Pediatric Portfolio in November 2019, the merger with Innovus

Pharmaceuticals, Inc. in February 2020, and the merger with Neos Therapeutics, Inc. in March 2021. As an example, we acquired Primsol in October 2015 and Natesto in 2016, but sold those assets in March 2017 and March 2021, respectively. Depending on the success or lack thereof of any of our existing or future acquired products and product candidates, we might seek to out-license, sell or otherwise dispose of any of those products or product candidates, which could adversely impact our operations if the dispositions triggers a loss, accounting charge or other negative impact.

The combined company's ability to successfully manage this expanded business will depend, in part, upon management's ability to implement an effective integration of the two companies and its ability to manage a combined business with significantly larger size and scope with the associated increased costs and complexity. There can be no assurances that the management of the combined company will be successful or that the combined company will realize the expected operating efficiencies, cost savings and other benefits currently anticipated from the merger.

We may fail to realize the anticipated benefits and cost savings of the Neos merger, which could adversely affect the value of shares of our common stock.

The success of the Neos merger will depend, in part, on our ability to realize the anticipated benefits and cost savings from combining the businesses. Our ability to realize these anticipated benefits and cost savings is subject to certain risks, including, among others:

- our ability to successfully combine the businesses of Aytu and Neos;
- the risk that the combined businesses will not perform as expected;
- the extent to which Aytu will be able to realize the expected synergies, which include potential savings from re-assessing priority assets and aligning investments, eliminating duplication and redundancy, adopting an optimized operating model between both companies and leveraging scale, and value creation resulting from the combination of the businesses of Aytu and Neos;
- the possibility that Aytu paid more for Neos than the value it will derive from the merger;
- the assumption of known and unknown liabilities of Neos;
- the possibility that significant unanticipated costs may be incurred in the course of coordinating the merged businesses; and
- the possibility of costly litigation challenging the merger.

If we is not able to successfully combine the businesses of Aytu and Neos within the anticipated time frame, or at all, the anticipated cost savings and other benefits of the merger may not be realized fully or may take longer to realize than expected, the combined businesses may not perform as expected and the value of the shares of Aytu common stock may be adversely affected.

Aytu and Neos have operated independently, and there can be no assurances that their businesses can be integrated successfully. It is possible that the integration process could result in the loss of key Aytu or Neos employees, the disruption of either company's or both companies' ongoing businesses or in unexpected integration issues, higher than expected integration costs and an overall post-completion integration process that takes longer than originally anticipated. Specifically, issues that must be addressed in integrating the operations of Neos and Aytu in order to realize the anticipated benefits of the merger so the combined business performs as expected include, among others:

- integrating the companies' technologies, products and services;
- identifying and eliminating redundant and underperforming operations and assets;

- harmonizing the companies' operating practices, employee development, compensation and benefit programs, internal controls and other policies, procedures and processes;
- addressing possible differences in corporate cultures and management philosophies;
- maintaining employee morale and retaining key management and other employees;
- attracting and recruiting prospective employees;
- consolidating the companies' corporate, administrative and information technology infrastructure;
- managing the movement of certain businesses and positions to different locations;
- coordinating geographically dispersed organizations; and
- effecting potential actions that may be required in connection with obtaining regulatory approvals.

In addition, at times, the attention of certain members of each company's management and each company's resources may be focused on the integration of the businesses of the two companies and diverted from day-to-day business operations, which may disrupt each company's ongoing business and the business of the combined company.

Following the merger, a significant amount of the combined company's total assets will be related to acquired intangible assets and goodwill, which are subject to annual impairment reviews, or more frequent reviews if events or circumstances indicate that the carrying value may not be recoverable. Because of the significance of these assets, any charges for impairment as well as amortization of intangible assets could have a material adverse effect on the combined company's results of operations and financial condition.

In fiscal 2021, 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, 2021 and 2020. During the years ended June 30, 2021 and 2020, three customers accounted for 54% and 46% 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.

We are also subject to credit risk from our accounts receivable related to our product sales. As of June 30, 2021, three customers accounted for 85% of gross accounts receivable. As of June 30, 2020, four customers accounted for 60% of gross accounts receivable.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of June 30, 2021, we had 175 full-time employees, and in connection with the expansion of our commercial product portfolio and our internal drug candidate development programs, we expect to continue to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the planned expanded commercialization of our approved products and the development of

our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to expand the market for our approved products and develop our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We depend on key personnel and attracting qualified management personnel and our business could be harmed if we lose personnel and cannot attract new personnel.

Our success depends to a significant degree upon the technical and management skills of our directors, officers and key personnel. Any of our directors could resign from our board at any time and for any reason. Although our executive officers Joshua Disbrow and Richard Eisenstadt 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.

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

To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may, as we have in the past, sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors may be further diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

Pursuant to our Aytu 2015 Stock Plan, our Board of Directors is currently authorized to award up to a total of 5.0 million shares of common stock or options to purchase shares of common stock to our officers, directors, employees and non-employee consultants. Stockholders will experience dilution in the event that additional shares of common stock are issued under our Aytu 2015 Stock Plan, or options issued under our Aytu 2015 Stock Plan are exercised, or any warrants are exercised for shares of our common stock.

Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the products or product candidates we acquire for commercialization;
- the products and product candidates we seek to pursue, and our ability to obtain rights to develop, commercialize and market those product candidates;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- actual or anticipated adverse results or delays in our clinical trials;
- our failure to expand the market for our currently approved products or commercialize our product candidates, if approved;
- unanticipated serious safety concerns related to the use of any of our product candidates;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the healthcare, biotechnology and pharmaceutical industries;
- introduction of new products offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;

- issuances of debt or equity securities;
- sales of our common stock by us or our stockholders in the future, or the perception that such sales could occur;
- trading volume of our common stock;
- ineffectiveness of our internal control over financial reporting or disclosure controls and procedures;
- general political and economic conditions;
- effects of natural or man-made catastrophic events;
- other events or factors, many of which are beyond our control;
- adverse regulatory decisions;
- additions or departures of key scientific or management personnel;
- changes in laws or regulations applicable to our product candidates, including without limitation clinical trial requirements for approvals;
- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our product candidates;
- our dependence on third parties, including CROs and scientific and medical advisors;
- failure to meet or exceed any financial guidance or expectations regarding development milestones that we may provide to the public;
- actual or anticipated variations in quarterly operating results; and
- failure to meet or exceed the estimates and projections of the investment community.

In addition, the stock market in general, and the stocks of small-cap healthcare, biotechnology and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and any trading volume could decline.

Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. We have a limited number of securities and industry analysts who publish research on us or our business and additional securities and industry analysts may never publish research on us or our business. If we do not broaden the coverage of our company from securities or industry analysts, the trading price for our stock could be negatively affected. If securities or industry analysts initiate coverage, and one or more of those analysts downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and any trading volume to decline.

Our reverse stock split of 1-for-10 effected on December 8, 2020 may not achieve one or more of our objectives.

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

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

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

We could need significant additional capital in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities in more than one transaction, investors in a prior transaction may be materially diluted by subsequent sales. Additionally, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. Any future grants of options, warrants or other securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and applicable Delaware law may discourage an acquisition of us by others, even if the acquisition may be beneficial to some of our stockholders.

Provisions in our Certificate of Incorporation and Amended and Restated Bylaws, as well as certain provisions of Delaware law, could make it more difficult for a third-party to acquire us, even if doing so may benefit some of our stockholders. These provisions include:

- the authorization of 50.0 million shares of “blank check” preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval;
- limiting the removal of directors by the stockholders;
- allowing for the creation of a staggered board of directors;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by or beneficial to our stockholders.

Any provision of our Certificate of Incorporation or Bylaws or of Delaware law that is applicable to us that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock in the event that a potentially beneficial acquisition is discouraged, and could also affect the price that some investors are willing to pay for our common stock.

The elimination of personal liability against our directors and officers under Delaware law and the existence of indemnification rights held by our directors, officers and employees may result in substantial expenses.

Our Certificate of Incorporation and our Bylaws eliminate the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty as a director or officer to the extent permissible under Delaware law. Further, our Certificate of Incorporation and our Bylaws and individual indemnification agreements we have entered with each of our directors and executive officers provide that we are obligated to indemnify each of our directors or officers to the fullest extent authorized by the Delaware law and, subject to certain conditions, advance the expenses incurred by any director or officer in defending any action, suit or proceeding prior to its final disposition. Those indemnification obligations could expose us to substantial expenditures to cover the cost of settlement or damage awards against our directors or officers, which we may be unable to afford. Further, those provisions and resulting costs may discourage us or our stockholders from bringing a lawsuit against any of our current or former directors or officers for breaches of their fiduciary duties, even if such actions might otherwise benefit our stockholders.

We do not intend to pay cash dividends on our capital stock in the foreseeable future.

We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any 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 in the operations of third-party manufacturers (“CMOs” and contract research organizations (“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 and CMOs as well as to perform third-party logistics functions. 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, 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 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 mid-June and our offices reponed 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.

Legislative or regulatory reform of the health care system in the United States may adversely impact our business, operations or financial results.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively the “Affordable Care Act” or “ACA”), was signed into law. This legislation changes the current system of healthcare insurance and benefits intended to broaden coverage and control costs. The law also contains provisions that will affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following:

- mandatory rebates for drugs sold into the Medicaid program have been increased, and the rebate requirement has been extended to drugs used in risk based Medicaid managed care plans.

- the 340B Drug Pricing Program under the Public Health Service Act has been extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities.

- pharmaceutical companies are required to offer discounts on branded drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the “Donut Hole."

- pharmaceutical companies are required to pay an annual non tax deductible fee to the federal government based on each company’s market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense.

Despite initiatives to invalidate the ACA, the U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the “individual mandate.” However, as a result of tax reform legislation passed in December 2017, the individual mandate was eliminated effective January 1, 2019. On December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The Trump administration and CMS have both stated that the ruling would have no immediate effect, and on December 30, 2018, the same judge issued an order staying the judgment pending appeal. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. Pending review, it is unclear what effect the latest ruling will have on the status of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance

mandated by the ACA. Further, the Trump administration has concluded that cost sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it would discontinue these payments immediately until such appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017 and again on July 18, 2018. Furthermore, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in Moda Health Plan, Inc. v. United States, which will determine whether the government must make risk corridor payments. On April 27, 2020, the U.S. Supreme Court decided that ACA requires the federal government to compensate insurers for significant losses their health plans incurred during the first three years of the Act's marketplaces, and that insurers can sue for nonpayment in the Court of Federal Claims. The effects of a potential future gap in reimbursement on third party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment.

Moreover, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices; however, on December 20, 2019, President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repeals the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

In 2021, Congress may consider other legislation to repeal and replace elements of the ACA, and litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. Changes to the ACA or other existing health care regulations could significantly impact our business and the pharmaceutical industry. Although it is too early to determine the effect of legal challenges, pending legislation, and executive action on the ACA, the law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Additionally, other federal health reform measures have been proposed and adopted in the United States since the ACA was enacted:

- the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional Congressional action is taken.

- the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Right to Try Act of 2018 provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer should develop an internal policy and respond to patient requests according to that policy.

Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. In addition, the United States government, state legislatures, and foreign governments have shown significant interest in implementing cost containment programs, including price-controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs to limit the growth of government paid health care costs. Individual states in the United States have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the federal level, the Trump Administration's budget proposal for fiscal year 2020 contained further drug price control measures that could be enacted during the 2020 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, the Trump Administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. Additionally, in December 2019, the FDA issued a draft guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country. The regulatory and market implications of the draft guidance, if finalized, is unknown at this time. Proponents of drug reimportation may attempt to pass legislation that would directly allow reimportation under certain circumstances. Legislation or regulations allowing the reimportation of drugs, if enacted, could decrease the price we receive for any products that we may develop and adversely affect our future revenues and prospects for profitability. Further, Congress and the Trump Administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. For example, on September 25, 2019, the Senate Finance Committee introduced the Prescription Drug Pricing Reduction Act of 2019, a bill intended to reduce Medicare and Medicaid prescription drug prices. The proposed legislation would restructure the Part D benefit, modify payment methodologies for certain drugs, and impose an inflation cap on drug price increases. An even more restrictive bill, the Lower Drug Costs Now Act of 2019, was introduced in the House of Representatives on September 19, 2019, and would require the Department of Health and Human Services (HHS) to directly negotiate drug prices with manufacturers. The Lower Drugs Costs Now Act of 2019 has passed out of the House and was delivered to the Senate on December 16, 2019. However, it is unclear whether either of these bills will make it through both chambers and be signed into law, and if either is enacted, what effect it would have on our business. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, have been designed to encourage importation from other countries and bulk purchasing. We anticipate pricing scrutiny will continue and escalate, including on a global basis. As a result, our business and reputation may be harmed, our stock price may be adversely impacted and experience periods of volatility, and our results of operations may be adversely impacted.

CMS may also develop new payment and delivery models, such as bundled payment models. CMS finalized regulations that give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Additionally, CMS finalized a rule that amends the Medicare Advantage and Medicare Part D prescription drug benefit regulations to reduce out of pocket costs for plan enrollees and allow Medicare plans to negotiate lower rates for certain drugs. In May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. CMS is still considering proposed changes to the definition of "negotiated prices" in the regulations. It is unclear what effect such changes will have on our business and ability to receive adequate reimbursement for our products.

In addition, in September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted giving the FDA enhanced post-marketing authority including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information and compliance with REMS approved by the FDA. The FDA's exercise of this authority could result in delays or increased costs during product development, clinical trials and regulatory review, increased

costs to ensure compliance with post-approval regulatory requirements and potential restrictions on the sale and/or distribution of approved products.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

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, 2021.

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

Item 3. Legal Proceedings

Harris and Walker County. On March 7, 2018 and April 18, 2019, Neos received citations advising Neos 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 Neos 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.

Merger Action. Between January 27, 2021 and February 25, 2021, nine lawsuits were filed related to the Neos Merger; on January 27, 2021, *Wang v. Neos Therapeutics, Inc., et al*., 1:21-cv-00095, was filed by purported Neos stockholder Elaine Wang against Neos and its directors in the U.S. District Court for the District of Delaware; on January 29, 2021, *Dupree v. Neos Therapeutics, Inc., et al*., 1:121-cv-00124, was filed by purported Neos stockholder Michael Dupree against Neos, its directors, the Merger Sub, and Aytu in the U.S. District Court for the District of Delaware; on February 1, 2021, *London v. Neos Therapeutics, Inc., et al*., 1:21-cv-00874, was filed by purported Neos stockholder Jack London against Neos and its directors in the U.S. District Court for the Southern District of New York; on February 3, 2021, *Kates v. Neos Therapeutics, Inc., et al*., 1:21-cv-00953, was filed by purported Neos stockholder Erin Kates against Neos and its directors in the U.S. District Court for the Southern District of New York; on February 3, 2021, *Smith v. Neos Therapeutics, Inc., et al*., 1:21-cv-00940, was filed by purported Neos stockholder Hayley Smith against Neos, its directors, the Merger Sub, and Aytu in the U.S. District Court for the Southern District of New York; on February 9, 2021, *Tkatch v. Neos Therapeutics, Inc., et al*., 1:21-cv-01187, was filed by purported Neos stockholder Natalia Tkatch against Neos and its directors, the Merger Sub, and Aytu in the U.S. District Court for the Southern District of New York; on February 16, 2021, *Bushansky v. Neos Therapeutics, Inc., et al*., 1:121-cv-00208, was filed by purported Neos stockholder Stephen Bushansky against Neos and its directors in the U.S. District Court for the District of Delaware; on February 16, 2021, *Wheeler v. Neos Therapeutics, Inc., et al*., 1:121-cv-00213, was filed by purported Neos stockholder Jacob Wheeler against Neos and its directors in the U.S. District Court for the District of Delaware; on February 25, 2021, *Hein v. Neos Therapeutics, Inc., et al*., 1:121-cv-00287, was filed by purported Neos stockholder Matthew Hein against Neos and its directors in the U.S. District Court for the District of Delaware. All of the cases have subsequently been dismissed and the merger actions are considered to be closed.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Data

Our common stock has been listed on the NASDAQ Capital Market under the symbol "AYTU" since October 20, 2017. The following table sets forth the range of high and low sales prices on the NASDAQ Capital Market, as applicable, for the periods shown.

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

Fiscal Year ended June 30, 2021	High	Low
First Quarter (ended September 30, 2020)	$ 15.50	$ 9.00
Second Quarter (ended December 31, 2020)	$ 14.00	$ 5.86
Third Quarter (ended March 31, 2021)	$ 11.76	$ 5.89
Fourth Quarter (ended June 30, 2021)	$ 7.71	$ 4.73

On December 8, 2020, we effected a reverse stock split in which each common stockholder received one share of common stock for every 10 shares held (herein referred to collectively as the "Reverse Stock Split"). All share and per share amounts in this report have been adjusted to reflect the effect of the Reverse Stock Split.

On September 10, 2021, the closing price as reported on the NASDAQ of our common stock was $3.29. As of September 10, 2021, there were 1,092 holders of record of our common stock.

Equity Compensation Plan Information

In June 2015, our shareholders approved the adoption of a stock and option award plan (the "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 stockholder 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, 2021 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	2,062,290	$ 23.54	2,937,710
Equity compensation plans not approved by security holders[2]	81,042	$ 6.36	1,271,657
Total	2,143,332	$ 14.52	4,209,367

(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 13 - Equity Incentive Plan).

(2) It reflects the equity plan we assumed pursuant to the Neos Merger and restricted stock previously issued outside of the Aytu 2015 Plan (see Note 13 - 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 Deerfield Private Design Fund III, L.P. and Deerfield Special Situations Fund, L.P. 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 6. Reserved

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, 2021 and our financial condition as of June 30, 2021. The MD&A is provided as a supplement to, and should be read in conjunction with, our financial statements and notes. The MD&A is organized in the following sections:

- **Overview**

- **Significant Developments.** We discuss (i) impact of COVID-19 on our operations and (ii) material acquisitions and divestitures.

- **Liquidity and Capital Resources.** We discuss (i) sources of our liquidity, (ii) cash flows, (iii) obligations due on our debt obligations and (iv) expected payments under contractual obligations, commitments and contingencies.

- **Results of Operations.** We discuss year-over-year changes in our statements of operations line items, including the major drivers of these changes for fiscal year 2021, as compared with 2020.

- **Critical Accounting Estimates.** We discuss the critical accounting policies and estimates that require significant management judgment.

Overview

We are commercial-stage specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products. We operate through two business segments: Aytu BioPharma segment, consisting of various prescription pharmaceutical products sold through third party wholesalers, and Aytu 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 develop and manufacture our ADHD products at our manufacturing facilities, and use third party manufacturers for our other prescription and consumer health products.

We have incurred significant losses in each year since inception. Our net losses were $58.3 million and $13.6 million for the years ended June 30, 2021 and 2020, respectively. As of June 30, 2021 and 2020, we had an accumulated deficit of approximately $178.3 million and $120.0 million, respectively. We expect to continue to incur significant expenses in connection with our ongoing activities, including the successful integration of our acquisitions.

Significant Developments

Below are significant developments in our business and other factors affecting our business during the fiscal year 2021.

COVID-19

The ongoing COVID-19 pandemic continues to impact the global economy and create economic uncertainties during fiscal years 2020 and 2021. The federal government and states imposed restrictions on travel and business operations and placed limitations on the size of public and private gatherings. However, beginning the third quarter of fiscal 2021, with the introduction of vaccines under emergency use authorizations, these restriction began to wind down and business operating environments have improved.

We believe COVID-19 has negatively impacted the overall market for prescription products. 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 rollbacked 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.

Acquisitions and Divestitures

On April 12, 2021, we closed on an asset purchase agreement with Rumpus Therapeutics, LLC through an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (together with Rumpus VEDS, LLC and Rumpus Therapeutics LLC, "Rumpus"), pursuant to which we acquired certain rights and other assets, including key commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin (now referred to as AR101), which is a pivotal study-ready therapeutic being studied for the treatment of vascular Ehlers-Danlos Syndrome or vEDS. This asset was acquired for $1.5 million in cash, payment of aggregated fees of $0.6 million and, 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 our common stock, generally at our option.

On March 31, 2021, we terminated the Natesto license agreement previously entered into on July 1, 2016 as amended on July 29, 2019. With the acquisition of Neos Therapeutics, Inc. ("Neos"), we believe that this divestiture will not have significant impact on our financials, and will also allow us to focus on and further develop our prescription pharmaceutical products ("Rx Portfolio").

On March 19, 2021, we acquired Neos (the "Neos Merger"), a commercial-stage pharmaceutical company developing, manufacturing and commercializing Adzenys XR-ODT, Cotempla XR-ODT and Adzenys ER in the U.S. using Neos' internal commercial organization. These commercial products are extended-release ("XR") medications in patient-friendly, orally disintegrating tablet ("ODT") or oral suspension dosage forms that utilize our microparticle modified-release drug delivery technology platform. Neos received approval from the U.S. Food and Drug Administration ("FDA") for these three products. In addition, Neos manufactures and sells generic Tussionex, an extended-release oral suspension for the treatment of cough and upper respiratory symptoms of a cold.

We incurred restructuring costs as a result of our merger and acquisitions. These costs are primarily related to severance payments to employees affected by the change in business structure. During the year ended June 30, 2021, we incurred $4.9 million in severance cost, all of which was paid during the year ended June 30, 2021.

Results of Operations

Comparison of the years ended June 30, 2021 and 2020.

	Year Ended June 30,			
	2021	2020	Change	Change
	(In thousands)			
Product revenue, net	$ 65,632	$ 27,632	$ 38,000	138 %
Cost of sales	36,432	8,281	28,151	340 %
Gross profit	29,200	19,351	9,849	50.90 %
Operating expenses				
Research and development	5,623	1,722	3,901	227 %
Advertising and direct marketing	20,568	6,396	14,172	222 %
Other selling and marketing	9,740	5,007	4,733	95 %
General and administrative	25,500	19,657	5,843	30 %
Acquisition related costs	2,919	2,348	571	24 %
Restructuring costs	4,886	667	4,219	633 %
Impairment of intangible assets	12,825	195	12,630	6,477 %
Amortization of intangible assets	6,009	4,490	1,519	34 %
Total operating expenses	88,070	40,482	47,588	118 %
Loss from operations	(58,870)	(21,131)	(37,739)	179 %
Other (expense) income				
Other (expense), net	(2,050)	(2,606)	556	(21)%
Gain / (Loss) from contingent consideration	4,459	10,430	(5,971)	(57)%
Gain (Loss) on extinguishment of debt	(1,569)	(316)	(1,253)	397 %
Gain from warrant derivative liability	—	2	(2)	(100)%
Total other (expense) income	840	7,510	(6,670)	(89)%
Loss before income tax	(58,030)	(13,621)	(44,409)	326 %
Income tax expense	259	—	259	—
Net loss	$ (58,289)	$ (13,621)	$ (44,668)	328 %

Product revenue. Total net product revenue was $65.6 million during the year ended June 30, 2021, an increase of approximately $38.0 million, or 138%, compared to $27.6 million during the year ended June 30, 2020. The increase was primarily driven by the full year contributions from our fiscal year 2020 acquisitions and the partial year revenue generated from the ADHD product portfolio of Neos, which was acquired on March 19, 2021, as well as additional revenues from COVID-19 test kit sales. Due to our entry into a termination and transition agreement with Acerus Pharmaceuticals Corporation, on March 31, 2021, terminating the License and Supply Agreement related to Natesto, we will no longer recognize revenue related to Natesto as of April 1, 2021.

Cost of sales. Total cost of sales was $36.4 million during the year ended June 30, 2021, an increase of $28.1 million, or 340%, compared to $8.3 million during the year ended June 30, 2020. The increase was primarily driven by the full year operations of our fiscal year 2020 acquisitions and the partial year costs incurred for the production and sale of ADHD product portfolio of Neos, which was acquired on March 19, 2021. In addition, we recognized approximately $7.3 million in write-downs for slow moving inventory during the year ended June 30, 2021. Neos manufactures the ADHD products at its Grand Prairie, Texas facilities, and as such, allocates a significant portion of its intangible assets amortization and fixed assets depreciation into cost of sales.

Research and development. Total research and development expense was $5.6 million during the year ended June 30, 2021, an increase of $3.9 million, or 192%, compared to $1.7 million during the year ended June 30, 2020. The increase was due primarily to $2.9 million in costs related to the acquisition of in-process research and development that we determined to have no alternative future use at the time of purchase and was expensed as incurred, and costs associated with our Healight Platform license and initial research and development costs, as well as the acquisition of

Neos on March 19, 2021, which incurs costs related to product development and FDA-required post-marketing clinical trials.

Advertising and direct marketing. Advertising and direct marketing expenses include direct-to-consumer marketing, advertising, sales and customer support and processing fees related to our consumer health segment. Total advertising and direct marketing expense was $20.6 million for the year ended June 30, 2021, an increase of $14.2 million, or 222%, compared to $6.4 million during the year ended June 30, 2020. The increase was primarily driven by the inclusion of full year operations of the consumer health segment, which was acquired on February 14, 2020.

Other selling and marketing. Total other selling and marketing expense was $9.7 million during the year ended June 30, 2021, an increase of $4.7 million, or 95%, compared to $5.0 million during the year ended June 30, 2020. The increase was primarily driven by the partial year commercialization of the ADHD product portfolio of Neos, which was acquired on March 19, 2021.

General and administrative. Total general and administrative expense was $25.5 million during the year ended June 30, 2021, an increase of $5.8 million, or 30%, compared to $19.7 million during the year ended June 30, 2020. The increase was primarily driven by the full year operations of our fiscal year 2020 acquisitions and the partial year expenses of Neos, which was acquired on March 19, 2021.

Acquisition related costs. Acquisition related costs was $2.9 million during the year ended June 30, 2021, an increase of $0.6 million, or 24%, compared to $2.3 million during the year ended June 30, 2020. The increase was due primarily to the Neos Merger on March 19, 2021. Such costs include legal fees, due diligence expenses and financial advisory fees.

Restructuring costs. Restructuring costs was $4.9 million during the year ended June 30, 2021, an increase of $4.2 million, compared to $0.7 million during the year ended June 30, 2020. The increase was due primarily to the Neos Merger on March 19, 2021. Such costs primarily consisted of severance payments for terminated employees.

Impairment of intangible assets. Total impairment expense of intangible assets was $12.8 million during the year ended June 30, 2021, and increase of $12.6 million, compared to $0.2 million for the year ended June 30, 2020. The increase was due primarily to the $8.5 million write-off of the licensed intangible asset related to Tuzistra as a result of the impact of COVID-19 and other factors negatively impacting product sales, and $4.3 million write-off of licensed intangible asset related to the March 30, 2021 Natesto divestiture.

Amortization of intangible assets. Total amortization expense of intangible assets was $6.0 million during the year ended June 30, 2021, an increase of $1.5 million, or 34%, compared to $4.5 million for the year ended June 30, 2020. The increase was due primarily to the full year amortization of intangible assets related to our fiscal year 2020 acquisitions and the partial year expense for Neos, which was acquired on March 19, 2021.

Other (expense) income, net. Total other (expense) income, net during the year ended June 30, 2021 was expense of approximately $2.1 million, a decrease of $0.5 million, or 21%, compared to other expense of $2.6 million during the year ended June 30, 2020. The decrease was primarily due to an increase in other income of $0.8 million from partial proceeds from the Natesto divestiture, partially offset by an increase in interest expense from the increase in debt as a result of the Neos Merger on March 19, 2021.

Gain (Loss) from contingent consideration. Gain from contingent considerations during the year ended June 30, 2021 was $4.5 million, a decrease of $5.9 million, or 57%, compared to $10.4 million during the year ended June 30, 2020. Of the $4.5 million gain during the year ended June 30, 2021, $1.3 million gain was attributable to change in change in the fair value of the ZolpiMist and Tuzistra contingent consideration liabilities and $3.2 million gain was attributable to change in fair value of the contingent value rights ("CVR's") liability related to the Innovus Merger (see Note 10 – Fair Value Considerations).

Loss on debt extinguishment. During the year ended June 30, 2021, we recognized $1.3 million loss from modification of our obligations under Fixed Payment Arrangement and $0.3 million loss from conversion of outstanding debt to our shares of common stock.

Income tax expense. Our provision for income taxes during the year ended June 30, 2021 was $0.3 million at effective tax rate of 0.45%, primarily comprised of deferred taxes.

Liquidity and Capital Resources

Sources of Liquidity

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

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. Since initiated in June 2020 through June 30, 2021, we issued a total of 3,093,539 shares of common stock for aggregate proceeds of $23.1 million before estimated offering costs of $2.6 million.

We entered into three separate registered direct stock offerings on March 10, 2020, March 12, 2020 and March 19, 2020 (the “March Offerings”) in which we issued a combination of common stock and warrants. In July 2020, we issued 92,302 warrants to purchase 92,302 shares of our common stock with a weighted-average exercise price of $15.99 to an investment bank. The warrants have a term of one year from the issuance date. These warrants had at issuance a fair value of approximately $0.4 million and were valued using a Black-Scholes model.

In December 2020, we entered into an underwriting agreement with H.C. Wainwright & Co., LLC (“Wainwright”) (as amended and restated, the “Underwriting Agreement”), pursuant to which the underwriter exercised its over-allotment option in full and purchased 4,791,667 shares of our common stock for total proceeds of $28.8 million before estimated offering costs of $2.6 million. Effective June 2, 2021, we terminated the Underwriting Agreement with Wainwright, and pursuant to such termination, there will be no future sales of our common stock under the agreement.

On June 2, 2021, we terminated our “at-the-market” sales agreement with Jefferies LLC. On June 4, 2021, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Cantor Sales Agreement”) with Cantor Fitzgerald & Co. (“Cantor”), 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.

In October 2019, our Neos subsidiary entered into a senior secured credit agreement with Encina Business Credit, LLC (“Encina”) as agent for the lenders (the “Loan Agreement”). Under the Loan Agreement, Encina will extend up to $25.0 million in secured revolving loans to us (the “Revolving Loans”), of which up to $2.5 million may be available for short-term swingline loans, against 85% of eligible accounts receivable (see Note 18).

Cash Flows

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

	Year Ended June 30,		Increase (Decrease)
	2021	2020	
		(In thousands)	
Net cash used in operating activities	$ (25,964)	$ (28,374)	$ 2,410
Net cash used in investing activities	$ (2,782)	$ (5,656)	$ 2,874
Net cash provided by financing activities	$ 30,314	$ 71,069	$ (40,755)

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 inventory write-down, changes in fair values of various liabilities, stock-based compensation expense, depreciation, amortization and accretion and other charges.

During fiscal 2021, net operating cash outflows 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.

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

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 $2.8 million during the year ended June 30, 2021 was primarily due to $15.5 million principally for the paydown of debt of Neos as part of the Neos Merger, $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 Merger.

Net cash used in investing activities of $5.7 million during the year ended June 30, 2020 was primarily due to $1.4 million cash paid for the Innovus merger, $4.5 million for the acquisition of the Pediatric Portfolio from Cerecor, and $0.2 million payment of contingent consideration, partially offset by $0.4 million cash acquired due to the Innovus merger.

Net Cash from Financing Activities

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 2020, 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.

Net cash provided by financing activities of $71.1 million during the year ended June 30, 2020. This was primarily related to the (i) October 2019 Offering for gross proceeds of $10.0 million, offset by the offering cost of $0.7 million which was paid in cash; (ii) $49.0 million raised in the March 2020 Offerings, offset by offering costs of approximately $4.5 million, (iii) $27.0 million raised as the result of warrant exercises in March 2020, and (iv) gross proceeds of $6.8 million from the at-the-market offering program in June 2020, offset by offering costs of $0.2 million.

Capital Resources

We have obligations related to our loan and credit facilities, contingent considerations related to our acquisitions, milestone payments and purchase commitments.

Loan and Credit

Upon closing of the Neos Merger, we indirectly assumed $15.6 million principal and $1.0 million in exit fee obligation under Neos' credit facility with Deerfield. As of June 30, 2021, outstanding under the Deerfield facility, including the exit fee was $16.0 million. Interest is due quarterly at a rate of 12.95% per year. Payment on the Deerfield facility, including the exit fee and any unpaid interest, is due on May 11, 2022. If all or any of the principal is prepaid or required to be prepaid prior to December 31, 2021, then we shall pay, in addition to such prepayment and accrued interest thereon, a prepayment premium equal to 6.25% of the amount of principal prepaid.

Our Neos subsidiary's Loan Agreement with Encina, provide us with up to $25.0 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 bear variable interest through maturity at the one-month London Interbank Offered Rate, plus an applicable margin of 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 facility amount during the immediately preceding month. Interest is payable monthly in arrears, upon a prepayment of a loan and on the maturity date. The maturity date under the Loan Agreement is May 11, 2022.

We may permanently terminate the Loan Agreement by prepaying all outstanding principal amounts and accrued interest at any time, subject to at least five (5) business days prior notice to the lender and the payment of a prepayment fee equal to (i) 1.0% of the aggregate principal amount prepaid if such prepayment occurs after October 2, 2020 but on or before October 2, 2021, and (ii) 0.5% of the aggregate principal amount prepaid if such prepayment occurs after October 2, 2021 but before May 11, 2022.

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 milestone payments (see Note 16 – Commitments and Contingencies for additional information).

Upon closing of the Pediatric Portfolio acquisition in October 2019, we assumed fixed payment obligations that required us to make a payment of $4.1 million in the fiscal year 2022, $3.1 million in fiscal year 2023 and annual payments of $2.1 million in each of the fiscal years 2024 and 2025. In addition, in fiscal year 2022, upon occurrence of certain events, we may be required to pay approximately $3.0 million in milestone payments.

In February 2020, upon closing of our Innovus Merger, all of Innovus 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. Depending on satisfaction of these conditions, we may be required to pay $2.0 million in fiscal year 2022 and additional $5.0 million in each of the fiscal years 2023 and 2024.

Our Innovus subsidiary is also contractually obliged for inventory purchase commitments, for which we are expected to pay approximately $0.7 million in July 2021 and $0.7 million in fiscal year 2022.

In February 2015, Innovus acquired Novalere, which included the rights associated with distributing FlutiCare. As part of the Novalere acquisition, Innovus is obligated to make five payments of $0.5 million, between fiscal year 2026 through fiscal year 2033, when certain levels of FlutiCare sales are achieved.

In connection with our acquisition of the Rumpus assets, as discussed above under the section "Acquisitions and Divestitures", we are required to make a payment of $0.6 for an option license fee in April 2022.

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 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 Aytu BioPharma segment and Aytu Consumer Health Segment. We recognize revenue when all of the following criteria are satisfied: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) as each performance obligation is individually satisfied.

Revenue from our Aytu BioPharma segment involves significant judgment and estimates of the net sales price, including estimates of variable consideration (e.g., savings offers, prompt payment discounts, product returns, wholesaler (distributor) fees, wholesaler chargebacks and estimated rebates) to be incurred on the respective product sales, and we recognize the estimated amount as revenue when control of the product is transferred to our customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint requires the use of significant management judgment and other market data. We provide for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. We analyze recent product return history to determine a reliable return rate. Additionally, management analyzes historical savings offers and rebate payments based on patient prescriptions and information obtained from third party providers to determine these respective variable considerations.

Savings offers

We offer savings programs for our patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. The amount of redeemed savings offers is recorded based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustments at the time revenue is recognized. Historical trends of savings offers will be regularly monitored, which may result in adjustments to such estimates in the future.

Prompt payment discounts

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustments at the time revenue is recognized.

Wholesale distribution fees

Wholesale distribution fees are based on definitive contractual agreements for the management of our products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

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 information from third-party providers. Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized. Historical trends of estimated rebates will be regularly monitored, which may result in adjustments to such estimates in the future.

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. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. We analyzed return data available from sales since inception date to determine a reliable return rate.

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 us. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustment at the time revenue is recognized based on information provided by third parties.

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. Unsaleable items will be written-down to net realizable value in the period identified.

Stock-based compensation expense

Stock-based compensation awards, including grants of stock options, restricted stock and restricted stock units, and modifications to existing awards, are recognized in the statement of operations based on their fair values on the date of grant. Stock option grants are valued on the grant date using the Black-Scholes option pricing model and compensation costs are recognized ratably over the period of service using the graded method. 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 ratable over the requisite service period. Forfeitures are adjusted for as they occur.

We calculated 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. We have not paid and do not anticipate paying cash dividends. Therefore, the expected dividend rate is assumed to be 0%. The expected stock price volatility for stock option awards is based on our stock price volatility in the valuation model. The risk-free rate was based on the U.S. Treasury yield curve in effect commensurate with the expected life assumption. The average expected life of stock options was determined according to the "simplified method" as described in SAB Topic 110, which is the midpoint

between the vesting date and the end of the contractual term. The risk-free interest rate was determined by reference to implied yields available from U.S. Treasury securities with a remaining term equal to the expected life assumed at the date of grant. 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, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee stock-based awards is determined using an option pricing model, such a model value may not be indicative of the fair value that would be observed in a market transaction between a willing buyer and willing seller. 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.

Impairment of Long-lived Assets

We assess impairment of long-lived assets 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) 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 the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value.

Contingent considerations

We classify contingent consideration liabilities related to business acquisitions within Level 3 as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity. We estimate the fair value of contingent consideration liabilities 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 remeasured 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.

Fixed payment arrangements are comprised of minimum product payment obligations relating to either make whole payments or fixed minimum royalties arising from a business acquisition. The fixed payment arrangements were recognized at their amortized cost basis using a market appropriate discount rate and are accreted up to their ultimate face value over time. The liabilities related to fixed payment arrangements are not remeasured at each reporting period, unless we determine the circumstances have changed such that the fair value of these fixed payment obligations would have changed due to changes in company specific circumstances or interest rate environments.

Warrants

We account 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 were recorded as derivative income or expense for the warrants and reported as a component of cash flows from operations.

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, 2021, our principal executive officer and principal financial officer concluded that, as a result of the material weakness in our internal control over financial reporting as described below and in Part I Item 1A. of the Annual Report on Form 10-K, our disclosure controls and procedures were not effective as of the end of the period covered by this Report. Notwithstanding the material weakness, our management believes that the financial statements included elsewhere in this report present fairly, in all material respects, our financial position, results of operations, changes in stockholders' equity (deficit) and cash flows in conformity with GAAP.

In connection with the preparation of our financial statements for the period ended June 30, 2021, 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 intangibles and accounting for the impairment of long-lived assets. As a result, we have sought and received technical guidance from a third-party provider. This deficiency did not result in a revision of any of our previously issued financial statements. However, if not addressed, the deficiency could result in a material misstatement in the future. 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 our controls are now designed properly and operating effectively.

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, 2021. 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, 2021, 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

Other than the material weakness discussed above, there were no changes in our internal controls over financial reporting, known to the Chief Executive Officer or the Chief Financial Officer that occurred during the period covered by this Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

The Company's assessment over changes in our internal controls over financial reporting excluded those processes or controls that exist at our Neos subsidiary, which we acquired from the March 19, 2021 Neos Merger. Neos' last annual report for the year ended December 31, 2020 has been audited without any qualifications. Since the merger, there has been no significant change to its internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors and Executive Officers, and Corporate Governance

The following table sets forth the names and ages of all of our directors and executive officers as of August 31, 2021. 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	46	Chairman and Chief Executive Officer
Richard Eisenstadt	62	Chief Financial Officer, Secretary, and Treasurer
Michael E. Macaluso	69	Director
Carl C. Dockery	58	Director
John A. Donofrio, Jr.	53	Director
Gary V. Cantrell	66	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

Joshua R. 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 with 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 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, which he joined as the company’s second employee and oversaw the launch and subsequent growth of the company’s commercial operations. Mr. Disbrow led the launch of the company’s first product, subsequently launching numerous products and scaling the commercial organization across sales, marketing, managed care, sales training and national accounts. In less than five years, Arbor grew from a company from the pre-commercialization stage to product sales of over $250 million. 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 currently serves on the Board of Zynex Medical, Inc. 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.

Gary V. Cantrell – Director

Gary 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. As Principal of 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 plc.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 Health Inc., Yasoo Health Limited and Flexible Stenting Solutions, Inc., a leading developer of next generation peripheral arterial, venous, neurovascular and biliary stents, which was sold to Cordis, while a Division of Johnson & Johnson in March 2013. Mr. Cantrell served as a director of Vyrix 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

Carl 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. Mr. Dockery served as a director of CytoDyn Inc. (OTCQB: CYDY), a biotechnology company, from September 2014 until September 2019. 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. – Director

John Donofrio joined our Board of Directors in July 2016. He is a senior pharmaceutical executive with 28 years of experience in industry including a broad range of areas in finance, including consolidated financial reporting, international accounting and internal controls, financial systems development and implementation, cost accounting, inventory management, supply chain, transfer pricing, budget and forecast planning, integration of mergers and acquisitions and business development. Since March 2019, he has served as the President of EPI Health, a privately-held specialty pharmaceutical company commercializing products in the dermatology market. He previously served as Chief Financial Officer 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, internal controls, business development and strategic business planning and analysis for the finance organization in North America. Prior to joining Merz, Mr. Donofrio served as Vice President, Stiefel Global Finance, U.S. Specialty Business and Puerto Rico for Stiefel, a GlaxoSmithKline plc company from July 2009 to July 2013. In that role, Mr. Donofrio was responsible for the financial strategy, management reporting, and overall control framework for the Global Dermatology Business Unit. He was also the Senior Finance Partner accountable for the U.S. Specialty Business Units of GlaxoSmithKline plc. Mr. Donofrio served as a director of Vyrix from February 2014 to April 2015. Mr. Donofrio holds a degree in Accounting from North Carolina State University. Mr. Donofrio's financial expertise and experience in the pharmaceutical industry led to the conclusion that he should serve as a member of our Board of Directors.

Michael E. Macaluso – Director

Michael Macaluso joined our Board of Directors in April 2015. Mr. Macaluso is also the Chairman and Chief Executive Officer of Ampio. Mr. Macaluso has been a member of Ampio's board of directors since March 2010 and Ampio's Chief Executive Officer since January 2012. Mr. Macaluso served in the roles of President and Chief Executive Officer of Isolagen, Inc. (AMEX: ILE) from June 2001 until September 2004. Mr. Macaluso also served on the Board of Directors of Isolagen from June 2001 until April 2005. From October 1998 until June 2001, Mr. Macaluso was the owner of Page International Communications, a manufacturing business. Mr. Macaluso was a founder and principal of International Printing and Publishing, a position Mr. Macaluso held from 1989 until 1997, when he sold that business to a private equity firm. Mr. Macaluso's experience in executive management 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.

Richard Eisenstadt – Chief Financial Officer, Secretary, and Treasurer

Richard Eisenstadt has served as our Chief Financial Officer, Secretary and Treasurer since March 31, 2021. Prior to joining us, Mr. Eisenstadt served as Chief Financial Officer from May 2014 to March 2021 of Neos Therapeutics, Inc. Mr. Eisenstadt served as Chief Financial Officer of ArborGen Inc. from January 2013 to May 2014, and as Vice President of Finance and Chief Financial Officer of Tranzyme, Inc., now part of Mallinckrodt Pharmaceuticals (NYSE: MNK) from June 2003 to December 2012. He previously held financial leadership positions at Cogent Neuroscience, Inc. and Nimbus CD International, Inc. Mr. Eisenstadt received his M.B.A. from James Madison University and his B.A. in Economics from the University of North Carolina, Chapel Hill.

Family Relationships

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

Involvement in Certain Legal Proceedings

None of our directors or executive officers has been involved in any legal proceeding in the past 10 years that would require disclosure under Item 401(f) of Regulation S-K promulgated under the Securities Act.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act requires our officers and directors and persons who own more than 10% of our outstanding common stock to file reports of ownership and changes in ownership with the Securities and Exchange Commission. These officers, directors and stockholders are required by regulations under the Securities Exchange Act to furnish us with copies of all forms they file under Section 16(a).

Based solely on our review of the copies of forms we have received, we believe that all such required reports have been timely filed.

Code of Ethics

The information required by this Item regarding our Code of Ethics is found in Part I, Item 1, under the caption “Code of Ethics.”

Board Committees

Our Board has established an Audit Committee, Compensation Committee and a Nominating and Governance Committee. Our Audit Committee consists of Mr. Donofrio (Chair), Mr. Macaluso and Mr. Dockery. Our Compensation Committee consists of Mr. Macaluso (Chair), Mr. Cantrell, Mr. Dockery and Mr. Donofrio. Our Nominating and Governance Committee consists of Mr. Dockery (Chair), Mr. Cantrell and Mr. Donofrio. The independence of our directors is discussed in Part III, Item 13 under the caption “Director Independence.”

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

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

Stockholder Proposals

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

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

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

Item 11. Executive Compensation

Executive Compensation

In accordance with Item 402 of Regulation S-K promulgated by the SEC, we are required to disclose certain information regarding the makeup of and compensation for our company's directors and named executive officers.

In establishing executive compensation, our Board is guided by the following goals:

- compensation should consist of a combination of cash and equity awards that are designed to fairly pay the executive officers and directors for work required for a company of our size and scope;
- compensation should align the executive officers' and directors' interests with the long-term interests of stockholders; and
- compensation should assist with attracting and retaining qualified executive officers and directors.

Compensation of Directors

Our current compensation package for non-employee directors, effective July 1, 2020, consists of: an annual cash retainer of $70,000 for each non-executive Board chair, $40,000 for each other director, $20,000 for the committee chair of the Audit and Compensation Committees, $10,000 for each other member of the Audit and Compensation Committees, $10,000 for the committee chair of the Nominating and Governance committee, and $5,000 for each other member of the Nominating and Governance committee; a grant of 6,500 restricted shares of stock 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, 2021.

Name	Fees Earned or Paid in Cash	All Other Compensation (1)	Total
Gary V. Cantrell (2)(3)	$ 55,000	$ 1,218,848	$ 1,273,848
Carl C. Dockery (2)(3)	$ 70,000	$ 1,218,848	$ 1,288,848
John A. Donofrio Jr. (2)(3)	$ 75,000	$ 1,218,848	$ 1,293,848
Michael E. Macaluso (2)(3)	$ 70,000	$ 1,218,848	$ 1,288,848
Steven J. Boyd (2)(3)(4)	$ —	$ —	$ —

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

(2) As of June 30, 2021, 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.

(3) As of June 30, 2021, 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.

(4) Steven J. Boyd resigned as a member of the board of directors effective August 30, 2021.

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, 2021 and 2020 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	2021	$545,000	$462,203	$5,192,000	$ —	—	—	—	$6,199,203
since December 2012	2020	$607,620	$185,000	$ 652,500	$140,330	$ —	$ —	$ —	$1,585,450
Richard Eisenstadt (1)									
Chief Financial Officer, Secretary	2021	$151,934	$175,000	$ 455,947	$ —	$ —	$ —	$ —	$ 782,881
and Treasurer since April 2021									
David A. Green (2)									
Former Chief Financial Officer, Secretary	2021	$345,192	$430,463	$ —	$ —	$ —	$ —	$ 500,000	$1,275,655
and Treasurer	2020	$400,046	$150,000	$ 362,500	$140,330	$ —	$ —	$ —	$1,052,876

(1) Option awards are reported at fair value at the date of grant. See Item 15 of Part IV, “Notes to the Financial Statements — Note 10 — Fair Value Considerations.”
(2) Mr. Eisenstadt was appointed to Chief Financial Officer, Secretary and Treasurer effective March 31, 2021.
(3) Mr. Green ceased to be employed as Chief Financial Officer, Secretary and Treasurer effective March 31, 2021.

Our executive officers are reimbursed by us for any out-of-pocket expenses incurred in connection with activities conducted on our behalf. Executives are reimbursed for business expenses directly related to Aytu business activities, such as travel, primarily for business development as we grow and expand our product lines. On average, each executive incurs between $1,000 to $3,000 of out-of-pocket business expenses each month. The executive management team meets weekly and determines which activities they will work on based upon what we determine will be most beneficial to our company and our shareholders. No interest is paid on amounts reimbursed to the executives.

Outstanding Equity Awards at Fiscal Year-End 2021

The following table contains certain information concerning unexercised options for the Named Executive Officers as of June 30, 2021.

	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	2,500	7,500	—	$ 14.50	6/8/2030	—	$ —	—	$ —
Chief Executive Officer	13	—	—	3,280.00	11/11/2025	—	—	—	—
	15	—	—	3,280.00	7/7/2026	—	—	—	—
	—	—	—	—	—	750	3,758	—	—
	—	—	—	—	—	44,550	223,196	—	—
	—	—	—	—	—	800,000	4,008,000	—	—
	—	—	—	—	—	33,750	169,088	—	—
	—	—	—	—	—	48	240	—	—
Total	**2,528**	**7,500**	**—**	**$**		**879,098**	**$ 4,404,281**	**—**	**$ —**
Richard Eisenstadt	—	—	—	$ —	—	510	$ 2,555	—	$ —
Chief Financial Officer	—	—	—	—	—	5,440	27,254	—	—
	—	—	—	—	—	55,000	275,550	—	—
Total	**—**	**—**	**—**	**$**		**60,950**	**$ 305,359**	**—**	**$ —**
David A. Green	10,000	—	—	$ 14.50	6/8/2030	—	$ —	—	$ —
Former Chief Financial Officer									

(1) Based on $5.01 per share which was the closing price of our common stock on NASDAQ on June 30, 2021, the last trading day of that fiscal year.

Employment Agreements

We entered into an employment agreement with Joshua Disbrow in connection with his employment as our Chief Executive Officer. The agreement is for a term of 24 months beginning on April 16, 2015, subject to termination by us with or without Cause or as a result of officer's disability, or by the officer with or without Good Reason (as defined below). Mr. Disbrow is entitled to receive $330,000 in annual salary, plus a discretionary performance bonus with a target of 125% of his base salary. Mr. Disbrow is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans. On April 7, 2021, we extended this agreement for another 24 months.

We entered into an employment agreement with Richard Eisenstadt, effective March 31, 2021, to serve as our Chief Financial Officer. The agreement is subject to termination by us with or without Cause (as defined below) or as a result of Mr. Eisenstadt's disability, or by Mr. Eisenstadt with or without Good Reason (as defined below). Mr. Eisenstadt is entitled to receive $400,000 in annual salary, plus a discretionary performance bonus with a target of 40% of his base salary, based on his individual achievements and company performance objectives established by the board or the compensation committee in consultation with Mr. Eisenstadt. Mr. Eisenstadt is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans.

We entered into an employment agreement with David A. Green, effective December 18, 2017, to serve as our Chief Financial Officer. The agreement is subject to termination by us with or without Cause (as defined below) or as a result of Mr. Green's disability, or by Mr. Green with or without Good Reason (as defined below). Mr. Green is entitled to receive $250,000 in annual salary, plus a discretionary performance bonus with a target of 50% of his base salary, based on his individual achievements and company performance objectives established by the board or the compensation committee in consultation with Mr. Green. Mr. Green is also eligible to participate in the benefit plans maintained by us from time to time, subject to the terms and conditions of such plans. Effective March 31, 2021, Mr. Green resigned from his position with the Company.

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

CEO Amendment

- Effective June 1, 2020, increase base salary to $500,000 and lower annual bonus % target from 100% to 60% of base salary
- Effective January 1, 2021, increase base salary to $590,000
- Granted 100,000 options on terms set forth in a separate option agreement
- Granted 450,000 shares of restricted stock on the terms set forth in a separate restricted stock agreement.
- Granted 800,000 shares of restricted stock on the terms set forth in a separate restricted stock agreement.

Former CFO Amendment

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

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

Payments Provided Upon Termination for Good Reason or Without Cause

Pursuant to the employment agreements, in the event employment is terminated without Cause by us or the officer terminates his employment with Good Reason, we will be obligated to pay him any accrued compensation and a lump sum payment equal to two times his base salary in effect at the date of termination, as well as continued participation in the health and welfare plans for up to two years. All vested stock options shall remain exercisable from the date of termination until the expiration date of the applicable award. So long as a Change in Control is not in effect, then all options which are unvested at the date of termination Without Cause or for Good Reason shall be accelerated as of the date of termination such that the number of option shares equal to 1/24th the number of option shares multiplied by the number of full months of such officer's employment shall be deemed vested and immediately exercisable by the officer. Any unvested options over and above the foregoing shall be cancelled and of no further force or effect and shall not be exercisable by such officer.

"Good Reason" means, without the officer's written consent, there is:

- a material reduction in the officer's overall responsibilities or authority, or scope of duties (it being understood that the occurrence of a Change in Control shall not, by itself, necessarily constitute a reduction in the officer's responsibilities or authority);
- a material reduction of the level of the officer's compensation (excluding any bonuses) (except where there is a general reduction applicable to the management team generally, provided, however, that in no case may the base salary be reduced below certain specified amounts); or
- a material change in the principal geographic location at which the officer must perform his services.

"Cause", means:

- conviction of, or entry of a plea of guilty to, or entry of a plea of nolo contendere with respect to, any crime, other than a traffic violation or a misdemeanor;
- willful malfeasance or willful misconduct by the officer in connection with his employment;
- gross negligence in performing any of his duties;
- willful and deliberate violation of any of our policies;
- unintended but material breach of any written policy applicable to all employees adopted by us which is not cured to the reasonable satisfaction of the board;
- unauthorized use or disclosure of any proprietary information or trade secrets of us or any other party as to which the officer owes an obligation of nondisclosure as a result of the officer's relationship with us;
- willful and deliberate breach of his obligations under the employment agreement; or
- any other material breach by officer of any of his obligations which is not cured to the reasonable satisfaction of the board.

Payments Provided Upon a Change in Control

In the event of a Change in Control of us, all stock options, restricted stock and other stock-based grants granted or may be granted in the future by us to the officers will immediately vest and become exercisable.

"Change in Control" means: the occurrence of any of the following events:

- the acquisition by any individual, entity, or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Exchange Act) (the "Acquiring Person"), other than us, or any of our Subsidiaries, of beneficial ownership (within the meaning of Rule 13d-3- promulgated under the Exchange Act) of 50% or more of the combined voting power or economic interests of the then outstanding voting securities of us entitled to vote generally in the election of directors (excluding any issuance of securities by us in a transaction or series of transactions made principally for bona fide equity financing purposes); or

- the acquisition of us by another entity by means of any transaction or series of related transactions to which we are party (including, without limitation, any stock acquisition, reorganization, merger or consolidation but excluding any issuance of securities by us in a transaction or series of transactions made principally for bona fide equity financing purposes) other than a transaction or series of related transactions in which the holders of the voting securities of us outstanding immediately prior to such transaction or series of related transactions retain, immediately after such transaction or series of related transactions, as a result of shares in us held by such holders prior to such transaction or series of related transactions, at least a majority of the total voting power represented by the outstanding voting securities of us or such other surviving or resulting entity (or if we or such other surviving or resulting entity is a wholly-owned subsidiary immediately following such acquisition, its parent); or

- the sale or other disposition of all or substantially all of the assets of us in one transaction or series of related transactions.

Our only obligation to Joshua Disbrow and Richard Eisenstadt had a Change in Control occurred as of June 30, 2021, would be the acceleration of the vesting of all equity securities held by them at that date. On June 30, 2021, 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, 2021 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, 2021. The percentage ownership information shown in the table is based upon 27,551,912 shares of common stock outstanding as of August 31, 2021.

Except as otherwise indicated, all of the shares reflected in the table are shares of common stock and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to

applicable community property laws. The information is not necessarily indicative of beneficial ownership for any other purpose.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, we deemed outstanding shares of common stock subject to options and warrants held by that person that are immediately exercisable or exercisable within 60 days of August 31, 2020. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. Beneficial ownership representing less than 1% is denoted with an asterisk (*). The information in the tables below are based on information known to us or ascertained by us from public filings made by the stockholders. Except as otherwise indicated in the table below, addresses of the director, executive officers and named beneficial owners are in care of Aytu BioPharma, Inc., 373 Inverness Parkway, Suite 206, Englewood, Colorado 80112.

	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Stonepine Capital Management, LLC and related entities[1]	1,398,776	5.1 %
Non-employee Directors		
Macaluso, Michael[2]	212,091	*
Cantrell, Gary[3]	206,093	*
Dockery, Carl[4]	208,077	*
Donofrio, John[5]	207,075	*
Named Officers		
Disbrow, Joshua[6]	902,318	3.3 %
Richard Eisenstadt[7]	7,784	*
All directors and executive officers as a group, including those named above (six persons)	1,743,438	6.3 %

* Represents beneficial ownership of less than 1%.

(1) Based on a Schedule 13G/A filed with the SEC on December 31, 2021, Stonepine Capital Management ("SCM") is the general partner and investment advisor of investment funds, including Stonepine Capital, L.P. ("Capital"). Jon M. Plexico ("Plexico") and Thomas P. Lynch ("Lynch") are the control persons of SCM. Each of SCM, Capital, Plexico, and Lynch have sole voting and dispositive power with respect to 1,398,776 shares and may be deemed to be the beneficial owner of such shares. The principal business address of the beneficial owners is 919 NW Bond Street, Suite 204, Bend, OR 97703.

(2) Consists of (i) 8 shares of common stock, (ii) 208,071 restricted shares, and (iii) 4,012 shares of common stock issuable upon the exercise of vested options.

(3) Consists of (i) 1,018 shares of common stock, (ii) 203,071 restricted shares, and (iii) 2,004 shares of common stock issuable upon the exercise of vested options.

(4) Consists of (i) 1,001 shares of common stock, (ii) 203,071 restricted shares, (iii) 4,005 shares of common stock issuable upon the exercise of vested options, and 2,094 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.

(5) Consists of (i) 203,071 restricted shares, and (iii) 4,004 shares of common stock issuable upon the exercise of vested options.
.

(6) Consists of (i) 18,408 shares of common stock, (ii) 879,098 restricted shares, (iii) 2,556 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.

(7) Consists of 7,784 shares of common stock.

Item 13. Certain Relationships, Related Transactions, and Director Independence

Related Party Transactions

We describe below all transactions and series of similar transactions, other than compensation arrangements, during the last 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.

Tris Pharmaceutical, Inc.

On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tris License Agreement"). On November 1, 2019, the Company acquired the rights to Karbinal as a result of the acquisition of the Pediatric Portfolio from Cerecor, Inc. (See Notes 4 and 16). Mr. Ketan Mehta serves as a Director on the Board of Directors of the Company, and is also the Chief Executive Officer of Tris Pharma, Inc. ("Tris"). During the years ended June 30, 2021 and 2020, the Company paid Tris approximately $3.2 and $1.3 million, respectively for a combination of royalty payments, inventory purchases and other payments as contractually required. The Company's liabilities, including accrued royalties, contingent consideration and fixed payment obligations were $19.7 million and $22.9 million as of June 30, 2021 and 2020, respectively. In October 2020, the Company paid Tris approximately $1.6 million related to its Karbinal fixed payment obligation. On March 19, 2021, Mr. Ketan Mehta resigned as a Director on the Board of the Company, and Tris will no longer be considered a related party in the future.

Review, Approval or Ratification of Transactions with Related Persons

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

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

Director Independence

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

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

Item 14. Principal Accountant Fees and Services

Plante Moran, PLLC, or Plante Moran, (formerly known as EKS&H LLLP) has served as our independent auditor since April 2015 and has been appointed by our Audit Committee to continue as our independent auditor for the fiscal year ending June 30, 2021.

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,	
	2021	2020
	(In thousands)	
Audit fees	$ 216	$ 226
Audit related fees*	63	68
Total fees	$ 279	$ 294

* Audit-related fees for both fiscal year 2021 and 2020 were comprised of fees related to registration statements, including S-3, S-4 and S-8 filings, our March 2020 and December 2020 registered offerings and June 2020 and June 2021 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, 2021 and 2020
- Consolidated Statements of Operations for the years ended June 30, 2021 and 2020
- Consolidated Statements of Stockholders' Equity (Deficit) for the years ended June 30, 2021 and 2020
- Consolidated Statements of Cash Flows for the years ended June 30, 2021 and 2020
- 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
1.1	Controlled Equity OfferingSM Sales Agreement, dated June 4, 2021, by and between the registrant and Cantor Fitzgerald & Co.	8-K	06/04/21	1.1	
1.2	Amended and Restated Underwriting Agreement, dated December 10, 2020, between Aytu BioScience, Inc. and H.C. Wainwright & Co., LLC	8-K	12/14/20	1.1	
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.	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.	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 Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, filed on August 11, 2017.	8-K	08/16/17	3.1	
3.5	Certificate of Amendment of Certificate of Incorporation, effective August 25, 2017.	8-K	08/29/17	3.1	
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock filed on March 2, 2018.	S-1/A	02/27/18	3.6	
3.7	Certificate of Amendment to the Restated of Certificate of Incorporation, effective August 10, 2018.	8-K	08/10/18	3.1	
3.8	Amended and Restated Bylaws.	8-K	06/09/15	3.2	
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock.	10-Q	02/07/19	10.4	
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series F Convertible Preferred Stock.	8-K	10/15/19	3.1	
3.11	Certificate of Designation of Preferences, Rights and Limitations of Series G Convertible Preferred Stock.	8-K	110/4/19	3.1	
3.12	Certificate of Amendment to the Restated Certificate of Incorporation, effective December 7, 2020.	8-K	12/08/20	3.1	
3.13	Certificate of Amendment of Certificate of Incorporation of Aytu Bioscience, Inc., effective March 19, 2021.	8-K	03/22/21	3.1	
4.1	Form of Placement Agent Warrant issued in 2015 Convertible Note Financing.	8-K	07/24/15	4.2	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
4.2	Warrant Agent Agreement, dated May 6, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC.	8-K	05/06/16	4.1	
4.3	First Amendment to May 6, 2016 Warrant Agent Agreement between Aytu BioScience, Inc. and VStock Transfer LLC.	S-1	09/21/16	4.5	
4.4	Warrant Agent Agreement, dated November 2, 2016 by and between Aytu BioScience, Inc. and VStock Transfer, LLC.	8-K	11/2/16	4.1	
4.5	Form of Amended and Restated Underwriters' Warrant (May 2016 Financing).	8-K	03/1/17	4.1	
4.6	Form of Amended and Restated Underwriters' Warrant (October 2016 Financing).	8-K	03/1/17	4.2	
4.7	Form of Common Stock Purchase Warrant issued on August 15, 2017.	8-K	08/16/17	4.1	
4.8	Form of Common Stock Purchase Warrant for March 2018 Offering.	S-1	02/27/18	4.8	
4.9	Form of Pre-Funded Purchase Warrant.	8-K	03/13/20	4.1	
4.10	Form of Placement Agents Warrant.	8-K	03/13/20	4.2	
4.11	Form of Warrant.	8-K	03/13/20	4.1	
4.12	Form of Placement Agents Warrant.	8-K	03/13/20	4.2	
4.13	Form of Warrant.	8-K	03/20/20	4.1	
4.14	Form of Placement Warrant.	8-K	03/20/20	4.2	
4.15	Form of Wainwright Warrant.	8-K	07/02/20	4.1	
4.16	Form of Underwriter's Warrant.	8-K	12/14/20	4.1	
10.1#	Asset Purchase Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Valeant International (Barbados) SRL, effective as of December 2, 2011.	8-K/A	06/08/15	10.4	
10.2#	Manufacturing and Supply Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Ethypharm S.A., dated September 10, 2012.	8-K/A	06/08/15	10.5	
10.3	License, Development and Commercialization Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Daewoong Pharmaceuticals Co., Ltd., effective as of August 23, 2011 (incorporated by reference to Exhibit 10.1 of Ampio Pharmaceuticals Form 8-K/A filed October 5, 2011; File No. 001-25182).				
10.4#	Distribution Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and FBM Industria Farmaceutica, Ltda., dated as of March 1, 2012.	8-K/A	06/08/15	10.7	
10.5#	Distribution and License Agreement between the Registrant (as assigned to it by Ampio/Vyrix) and Endo Ventures Limited, dated April 9, 2014.	8-K/A	06/08/15	10.8	
10.6#	Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated September 1, 2009.	8-K/A	06/08/15	10.9	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.7#	Addendum No. 4 to Sponsored Research Agreement between the Registrant (as assigned to it by Ampio/Luoxis) and Trauma Research LLC, dated March 17, 2014.	8-K	05/27/15	10.14	
10.8	Promissory Note issued by Ampio to the Registrant on April 16, 2015.	8-K	04/22/15	10.11	
10.9	Subscription Agreement between the Registrant and Ampio, dated April 16, 2015.	8-K	04/22/15	10.12	
10.10	Voting Agreement between the Registrant and Ampio, dated April 21, 2015 (incorporated by reference to Exhibit 10.1 to Ampio's Form 8-K filed April 22, 2015; File No. 001-35182).				
10.11	Asset Purchase Agreement between Jazz Pharmaceuticals, Inc. and Rosewind Corporation, dated May 20, 2015.	8-K	05/27/15	10.14	
10.12	Form of Note Purchase Agreement for 2015 Convertible Note Financing.	8-K	07/24/15	10.1	
10.13	Asset Purchase Agreement, dated October 5, 2015, between Aytu BioScience, Inc. and FSC Laboratories, Inc.	8-K	10/07/15	10.18	
10.14	Master Services Agreement between Biovest International, Inc. and Aytu BioScience, Inc., entered into on October 8, 2015, and effective October 5, 2015.	8-K	10/13/15	10.19	
10.15	Form of Subscription Agreement for January 2016 common stock purchases.	8-K	01/20/16	10.1	
10.16	License and Supply Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016.	8-K	04/25/16	10.1	
10.17	Subscription Agreement between the Registrant and Acerus Pharmaceuticals Corporation, dated April 22, 2016.	8-K	04/25/16	10.2	
10.18	Purchase Agreement, dated July 27, 2016, by and between Aytu BioScience, Inc. and Lincoln Park Capital Fund, LLC.	8-K	07/28/16	10.1	
10.19	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	
10.20†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Joshua R. Disbrow.	8-K	04/18/17	10.1	
10.21†	Employment Agreement, effective as of April 16, 2017, between Aytu BioScience, Inc. and Jarrett T. Disbrow.	8-K	04/18/17	10.2	
10.22	Asset Purchase Agreement, dated March 31, 2017, between Allegis Holdings, LLC and Aytu BioScience, Inc.	10-Q	05/11/17	10.1	
10.23#	Merger Agreement, dated May 3, 2017, between Nuelle, Inc. and Aytu BioScience, Inc.	10-K	08/31/17	10.25	
10.24†	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	07/27/17	10.1	
10.25	Securities Purchase Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	08/16/17	10.1	
10.26	Registration Rights Agreement, dated August 11, 2017, between Aytu BioScience, Inc. and the investors named therein.	8-K	08/16/17	10.2	
10.27†	Employment Agreement, effective as of December 18, 2017, between Aytu BioScience, Inc. and David A. Green.	8-K	12/19/17	10.1	
10.28	Warrant Exercise Agreement dated March 23, 2018.	8-K	03/28/18	10.1	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.29	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	
10.30	Promissory Note, dated November 29, 2018, between Aytu BioScience, Inc. and Armistice Capital Master Fund Ltd.	8-K	11/29/18	10.1	
10.31	Waiver of Blocker.	10-Q	02/07/19	10.6	
10.32	Common Stock Purchase Warrant.	10-Q	02/07/19	10.5	
10.33	Exchange Agreement, dated February 5, 2019.	10-Q	02/07/19	10.3	
10.34	License, Development, Manufacturing and Supply Agreement, dated November 2, 2018.	10-Q	02/07/19	10.2	
10.35	Amendment No.1 to Securities Purchase Agreement.	8-K	04/26/19	10.1	
10.36	Independent Contractor Services Agreement.	8-K	05/02/19	10.1	
10.37	Second Amendment to Lease Agreement, dated April 4, 2019.	10-Q	05/14/19	10.3	
10.38†	Employment Agreement with Jarret T. Disbrow, dated April 16, 2019.	10-Q	05/14/19	10.2	
10.39†	Employment Agreement with Joshua R. Disbrow, dated April 16, 2019.	10-Q	05/14/19	10.1	
10.40	Amended and restated License and Supply Agreement with Acerus Pharmaceuticals, dated July 29, 2019.	8-K	08/02/19	10.1	
10.41	Form of Contingent Value Rights Agreement.	8-K	09/18/19	10.1	
10.42	Registration Rights Agreement, dated October 11, 2019.	8-K	10/15/19	10.3	
10.43	Securities Purchase Agreement, dated October 15, 2019.	8-K	10/15/19	10.2	
10.44	Placement Agency Agreement with Ladenburg Thalmann & Co. Inc., dated October 15, 2019.	8-K	10/15/19	10.1	
10.45	First Amendment to Asset Purchase Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.1	
10.46	Registration Rights Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.2	
10.47	Form of Cerecor Voting Agreement, dated November 1, 2019.	8-K	11/04/19	10.3	
10.48	Form of Security Holder Voting Agreement, dated November 1, 2019.	8-K	11/04/19	10.4	
10.49	Form of Officer Voting Agreement, dated November 1, 2019	8-K	11/04/19	10.5	
10.50	Transition Services Agreement, dated November 1, 2019.	8-K	11/04/19	10.7	
10.51	Consent and Limited Waiver Agreement, dated November 1, 2019.	8-K/A	11/04/19	10.6	
10.52	Consent and Limited Waiver Agreement, dated November 1, 2019.	8-K/A	11/07/19	10.6	
10.53	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	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.54	Form of Securities Purchase Agreement, dated March 10, 2020.	8-K	03/13/20	10.1	
10.55	Form of Securities Purchase Agreement, dated March 12, 2020	8-K	03/13/20	10.1	
10.56	Form of Securities Purchase Agreement, dated March 19, 2020.	8-K	03/20/20	10.1	
10.57	Early Payment Agreement, dated May 29, 2020.	8-K	06/01/20	10.1	
10.58	Form of Restricted Stock Cancelation and Exchange Agreement.	8-K	07/02/20	10.1	
10.59†	Amended Employment Agreement with Joshua R. Disbrow dated July 1, 2020.	10-K	10/06/20	10.62	
10.60†	Amended Employment Agreement with David A. Green dated July 1, 2020.	10-K	10/06/20	10.63	
10.61	License Agreement with Avrio Genetics, LLC, dated January 20, 2020.	10-Q	02/11/21	10.1	
10.62	Consent, Waiver and Sixth Amendment to Facility Agreement, by and among Aytu BioScience, Inc., Neos Therapeutics, Inc., Neos Therapeutics Brands, LLC, Neos Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, LLC, Deerfield Private Design Fund III L.P., Deerfield Partners, L.P. and Deerfield Mgmt, L.P., dated March 19, 2021.	8-K	03/22/21	10.1	
10.63	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 Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, and Encina Business Credit, LLC, dated March 19, 2021.	8-K	03/22/21	10.2	
10.64†	Employment Agreement between Aytu BioPharma, Inc. and Richard Eisenstadt, dated March 31, 2021.	8-K	4/05/21	10.1	
10.65	Indemnification Agreement between Aytu BioPharma, Inc. and Gerald McLaughlin, dated March 19, 2021.	10-Q	05/17/21	10.7	
10.66	Indemnification Agreement between Aytu BioPharma, Inc. and Beth P. Hecht, dated March 19, 2021	10-Q	05/17/21	10.8	
10.67	Termination and Transition Agreement between Aytu BioPharma, Inc. and Acerus Pharmaceuticals Corporation, dated March 31, 2021.	10-Q	05/17/21	10.9	
10.68†	Separation Agreement between Aytu BioPharma, Inc. and David A. Green, dated March 31, 2021.	10-Q	05/17/21	10.10	
10.69†	Second Amendment to Employment Agreement with Joshua R. Disbrow dated April 7, 2021.	10-Q	05/17/21	10.11	
10.70†	Employment Agreement between Aytu BioPharma, Inc. and Nathaniel Massari, dated April 12, 2021.	10-Q	05/17/21	10.12	
10.71	Employment Agreement between Aytu BioPharma, Inc. and Christopher Brooke, dated April 12, 2021	10-Q	05/17/21	10.13	
10.72	Option and Exclusive License Agreement between Rumpus VEDS, LLC and Denovo Biopharma LLC, dated December 21, 2019.	10-Q	05/17/21	10.14	

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
10.73	Exclusive License Agreement between Rumpus VEDS, LLC and Johns Hopkins University, dated December 20, 2019.	10-Q	05/17/21	10.15	
10.74	Commitment Letter between Aytu BioScience, Inc. and Neos Therapeutics, Inc.	8-K	12/10/20	10.1	
10.75	Deerfield Consent Letter, dated as of December 10, 2020, by and among Aytu BioScience, Inc., Neos Therapeutics, Inc. and the lenders party thereto.	8-K	12/10/20	10.2	
10.76	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	
10.77	Form of Aytu Stockholder Voting Agreement	8-K	12/10/20	10.4	
10.78	Form of Neos Stockholder Voting Agreement	8-K	12/10/20	10.5	
10.79	Asset Purchase Agreement, dated July 1, 2021 by and between Aytu BioPharma, Inc. and UAB "Caerus Biotechnologies'				X
10.80	Termination Agreement, dated June 29, 2021 by and between Aytu BioPharma, Inc. and Avrio Genetics, LLC				X
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 28, 2021

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 Richard Eisenstadt, 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 28, 2021.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chairman and Chief Executive Officer *(Principal Executive Officer)*
/s/ Richard I. Eisenstadt Richard I. Eisenstadt	Chief Financial Officer *(Principal Financial and Accounting Officer)*
Michael E. Macaluso	Director
/s/ Carl C. Dockery Carl C. Dockery	Director
/s/ John A. Donofrio, Jr. John A. Donofrio, Jr.	Director
/s/ Gary V. Cantrell Gary V. Cantrell	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. and Subsidiaries (the "Company") as of June 30, 2021 and 2020; the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended; and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of June 30, 2021 and 2020, and the results of its operations and its cash flows for each of the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were 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, Aytu BioPharma Reporting Unit – 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. The determination of the estimated fair value requires management to make significant estimates and assumptions related to the valuation of the reporting unit. Changes in these assumptions could have a significant impact on either the fair value of the reporting unit, the amount of any goodwill impairment charge, or both. The Company's consolidated goodwill balance was $65.8 million as of June 30, 2021, of which $57.2 million was

allocated to the Aytu BioPharma unit, which is the reporting unit that exhibits significant sensitivity to changes in estimates and assumptions given the limited cushion between the carrying value and estimated fair value. As of June 30, 2021, the estimated fair value of the Aytu BioPharma reporting unit exceeded its carrying value by more than 12%.

We identified the valuation of goodwill for the Aytu BioPharma reporting unit as a critical audit matter because of the significant estimates and assumptions management to estimate its fair value. These assumptions included revenue growth rates, forecasted margins, and the selection of a discount rate. 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 fair value of the Aytu BioPharma reporting unit 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 reporting units and estimate the fair value of its reporting units 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 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 as well as information included the in Company press releases.
- 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 earnings multiples. 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.

Business Combination – Refer to Notes 2 and 4 to the consolidated financial statements

Critical Audit Matter Description

On March 19, 2021, the Company completed the merger with Neos Therapeutics, Inc. ("Neos) for total consideration of $69.1 million. The Company accounted for the merger under the acquisition method of accounting for business combinations. Accordingly, the purchase price was allocated to the assets acquired and liabilities assumed based on their respective fair values, resulting in developed technology rights of $30.2 million, developed products technology of $22.7 million, other identifiable intangible assets of $3.6 million, and goodwill of $37.7 million. Management estimated the fair value of the intangible assets using discounted cash flow analyses, which were based on the Company's best estimates of future sales, earnings and cash flows after considering such factors as general market conditions, product lifecycles, long term business plans and recent operating performance. Determining the fair value of the intangible assets acquired required significant judgment, including the amount and timing of expected future cash flows and the selected discount rates.

We identified the assumptions related to estimating the amount and timing of expected future cash flows and discount rates to be a critical audit matter given the inherent judgment involved in estimating these amounts. Performing audit procedures to evaluate the reasonableness of these estimates and assumptions required a high degree of auditor judgment and an increased extent of 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 Neos business combination included the following, among others:

- We obtained an understanding of management's process to estimate the fair value of the acquired assets and assumed liabilities and ensure the accuracy of key data used in their fair value calculations. We also evaluated the design of key controls used by management to develop their fair value estimate.

- We assessed the reasonableness of management's forecasts of future cash flows by performing inquiries of appropriate individuals outside of the finance organization, comparing the projections to historical results, contractual agreements, and internal communications to management and board of directors.
- With the assistance of our fair value specialists, we evaluated the reasonableness of (1) the valuation methodology and (2) the discount rates utilized, including testing the source information underlying the determination of the discount rates, testing the mathematical accuracy of the calculation, and developing a range of independent estimates and comparing those to the discount rates selected by management.
- We evaluated whether the estimated future cash flows were consistent with evidence obtained in other areas of the audit.

/s/ Plante & Moran, PLLC
Denver, Colorado

September 28, 2021

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

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

	June 30, 2021	June 30, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 49,649	$ 48,082
Restricted cash	252	251
Accounts receivable, net	28,176	5,633
Inventory, net	16,339	9,999
Prepaid expenses	9,780	5,715
Other current assets	1,038	5,742
Total current assets	105,234	75,422
Property and equipment, net	5,140	259
Operating lease right-of-use asset	3,563	634
Intangible assets, net	85,464	48,855
Goodwill	65,802	28,090
Other long-term assets	465	33
Total long-term assets	160,434	77,871
Total assets	$ 265,668	$ 153,293
Liabilities		
Current liabilities		
Accounts payable and other	$ 19,255	$ 11,640
Accrued liabilities	51,295	8,831
Accrued compensation	5,939	3,117
Short-term line of credit	7,934	—
Current portion of debt	16,668	982
Current portion of operating lease liabilities	940	300
Current portion of fixed payment arrangements	3,134	2,340
Current portion of CVR liabilities	218	840
Current portion of contingent consideration	4,055	713
Total current liabilities	109,438	28,763
Long-term debt, net of current portion	180	—
Long-term operating lease liability, net of current portion	2,624	725
Long-term fixed payment arrangements, net of current portion	6,324	11,172
Long-term CVR liabilities, net of current portion	1,177	4,732
Long-term contingent consideration, net of current portion	8,002	12,875
Other long-term liabilities	355	11
Total liabilities	128,100	58,278
Commitments and contingencies		
Stockholders' equity		
Preferred Stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding as of June 30, 2021 and 2020	—	—
Common Stock, par value $.0001; 200,000,000 shares authorized; shares issued and outstanding 27,490,412 and 12,583,736, respectively, as of June 30, 2021 and 2020	3	1
Additional paid-in capital	315,864	215,024
Accumulated deficit	(178,299)	(120,010)
Total stockholders' equity	137,568	95,015
Total liabilities and stockholders' equity	$ 265,668	$ 153,293

See the accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended June 30,	
	2021	2020
Product revenue, net	$ 65,632	$ 27,632
Cost of sales	36,432	8,281
Gross profit	29,200	19,351
Operating expenses		
Research and development	5,623	1,722
Selling and marketing	30,308	11,403
General and administrative	25,500	19,657
Acquisition related costs	2,919	2,348
Restructuring costs	4,886	667
Impairment of intangible assets	12,825	195
Amortization of intangible assets	6,009	4,490
Total operating expenses	88,070	40,482
Loss from operations	(58,870)	(21,131)
Other (expense) income		
Other (expense), net	(2,050)	(2,606)
Gain / (Loss) from contingent consideration	4,459	10,430
Gain (Loss) on extinguishment of debt	(1,569)	(316)
Gain from warrant derivative liability	—	2
Total other (expense) income	840	7,510
Loss before income tax	(58,030)	(13,621)
Income tax expense	259	—
Net loss	$ (58,289)	$ (13,621)
Weighted average number of common shares outstanding	16,746,679	4,519,201
Basic and diluted net loss per common share	$ (3.48)	$ (3.01)

See the accompanying Notes to the Consolidated Financial Statements.

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

	Year Ended June 30,			
	2021		2020	
	Shares	Amount	Shares	Amount
Preferred Stock				
Balance beginning of period	—	$ —	3,594,981	$ —
Issuance of stock for business acquisition, net of issuance costs	—	—	11,803,747	1
Issuance of preferred stock in private placement, net of $742 issuance costs	—	—	10,000	—
Preferred converted into common stock	—	—	(15,408,728)	(1)
Balance end of period	—	—	—	—
Common Stock				
Balance beginning of period	12,583,736	1	1,753,808	—
Stock-based compensation	1,722,125	—	195,291	—
Issuance of stock for business acquisition, net of issuance costs	5,471,804	1	380,971	—
Issuance of common stock from March 2020 offerings, net of $4,524 issuance costs	—	—	3,636,527	1
Issuance of common stock from 2020 Shelf, net of $731 and $1,860 issuance costs in 2021 and 2020, respectively	2,663,312	1	430,227	—
Preferred converted into common stock	—	—	2,539,873	—
Issuance of common stock related to debt conversion	130,081	—	184,205	—
Warrants exercised	—	—	3,310,276	—
Issuance of common stock from December 2020 offering, net of $2,640 issuance costs	4,816,164	—	—	—
Issuance of common stock to consultants	—	—	16,500	—
Issuance of common stock related to settlement	—	—	12,238	—
Issuance of common stock for CVRs payout	103,190	—	123,820	—
Balance end of period	27,490,412	3	12,583,736	1
Additional Paid-In Capital				
Balance beginning of period	—	215,024	—	113,477
Stock-based compensation	—	3,574	—	1,079
Issuance of stock for business acquisition, net of issuance costs	—	53,102	—	9,965
Issuance of preferred stock in private placement, net of $742 issuance costs	—	—	—	5,250
Warrants issued in private placement	—	—	—	4,009
Issuance of common stock from March 2020 offerings, net of $4,524 issuance costs	—	—	—	33,278
Warrants issued from March 2020 offerings	—	—	—	11,182
Issuance of common stock from 2020 Shelf, net of $731 and $1,860 issuance costs in 2021 and 2020, respectively	—	15,569	—	4,983
Preferred converted into common stock	—	—	—	94
Issuance of common stock related to debt conversion	—	1,058	—	2,579
Issuance of common stock from December 2020 offering, net of $2,640 issuance costs	—	26,110	—	—
Warrants exercised	—	—	—	26,990
Issuance of common stock to consultants	—	—	—	231
Issuance of common stock related to settlement	—	—	—	174
Tax withholding for stock-based compensation	—	(5)	—	—
Estimated fair value of replacement equity awards	—	432	—	—
Issuance of common stock for CVRs payout	—	1,000	—	1,733
Balance end of period	—	315,864	—	215,024
Accumulated Deficit				
Balance beginning of period	—	(120,010)	—	(106,389)
Net loss	—	(58,289)	—	(13,621)
Balance end of period	—	(178,299)	—	(120,010)
Total stockholders' equity	27,490,412	$ 137,568	12,583,736	$ 95,015

See the accompanying Notes to the Consolidated Financial Statements

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

	Year Ended June 30,	
	2021	**2020**
Operating Activities		
Net loss	$ (58,289)	$ (13,621)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	9,201	5,714
Impairment of intangible assets	12,825	195
Stock-based compensation expense	3,574	1,079
Loss (gain) from contingent considerations	(4,459)	(10,430)
Inventory write-down	7,332	1,265
Changes in allowance for bad debt	608	405
Loss on debt extinguishment	1,569	316
Amortization of senior debt discount (premium)	(44)	532
Other noncash adjustments	38	46
Changes in operating assets and liabilities:		
Accounts receivable	1,544	(3,561)
Inventory	2,786	(8,216)
Prepaid expenses and other current assets	157	(6,066)
Accounts payable and other	(3,245)	(1,377)
Accrued liabilities	771	5,345
Other operating assets and liabilities, net	(332)	—
Net cash used in operating activities	(25,964)	(28,374)
Investing Activities		
Contingent consideration payment	(683)	(203)
Cash received from acquisition	15,722	391
Cash payment for business acquisition	(15,520)	(5,850)
Cash payment for asset acquisition	(2,341)	—
Other investing activities	40	6
Net cash used in investing activities	(2,782)	(5,656)
Financing Activities		
Proceeds from issuance of stock	45,051	65,730
Payment of stock issuance costs	(4,903)	(5,404)
Warrant exercises	—	26,992
Payment made to fix payment arrangement	(6,088)	—
Payments made to borrowings	(54,947)	(19,437)
Proceeds from borrowings	51,206	3,188
Other financing activities	(5)	—
Net cash provided by financing activities	30,314	71,069
Net change in cash, restricted cash and cash equivalents	1,568	37,039
Cash, cash equivalents and restricted cash at beginning of period	48,333	11,294
Cash, cash equivalents and restricted cash at end of period	$ 49,901	$ 48,333
Reconciliation of cash, cash equivalents, and restricted cash to the consolidated balance sheets		
Cash and cash equivalents	$ 49,649	$ 48,082
Restricted cash	252	251
Total cash, cash equivalents and restricted cash	$ 49,901	$ 48,333
Supplemental cash flow data		
Cash paid for interest	$ 1,249	$ 1,040
Non-cash investing and financing activities:		
Contingent value rights payout	$ 1,000	$ 2,000
Issuance of common stock for note conversion	$ 1,058	$ 2,579
Estimated fair value of replacement equity awards	$ 432	$ —
Fair value of liabilities assumed	$ 88,700	$ —
Fair value of non-cash assets acquired	$ 104,322	$ —
Issuance cost related to S-3	$ —	$ 1,531
Issuance of stock for business acquisition	$ 53,104	$ 18,365
Other noncash investing and financing activities	$ —	$ 1,607
Warrants issued	$ 1,628	$ —

See accompanying Notes to Consolidated Financial Statements

AYTU BIOPHARMA, INC. AND SUBSIDIARY
Notes to the Financial Statements

1. Nature of Business and Financial Condition

Aytu BioPharma, Inc. (“Aytu”, the “Company” or “we”), is a commercial-stage specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products. The Company currently operates the Aytu BioPharma business, consisting of the prescription pharmaceutical products (the “Rx Portfolio”), and Aytu consumer healthcare products business (the “Consumer Health Portfolio”). The Rx Portfolio is focused on commercializing prescription pharmaceutical products for the treatment of attention deficit hyperactivity disorder ("ADHD"), allergies, insomnia and various pediatric conditions. The Aytu consumer health business is focused on commercializing consumer healthcare products. The Company was incorporated as Rosewind Corporation on August 9, 2002 in the State of Colorado and was re-incorporated in the state of Delaware on June 8, 2015.

The Rx Portfolio consists of (i) Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets, Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets and Adzenys ER (amphetamine) extended-release oral suspension for the treatment of 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, (iii) Karbinal ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, (iv) ZolpiMist, the only FDA-approved oral spray prescription sleep aid, (v) Tuzistra XR, the only FDA-approved 12-hour codeine-based antitussive syrup and (vi) a generic Tussionex (hydrocodone and chlorpheniramine) (“generic Tussionex”), extended-release oral suspension for the treatment of cough and upper respiratory symptoms of a cold.

The Consumer Health Portfolio consists of over thirty consumer health products competing in large healthcare categories, including diabetes management (with a concentration on neuropathy), pain management, digestive health, sexual and urological health and general wellness for men and women, commercialized through direct-to-consumer marketing channels utilizing the Company's proprietary Beyond Human marketing and sales platform and on e-commerce platforms.

On April 12, 2021, the Company entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, Christopher Brooke and Nathaniel Massari pursuant to which the Company acquired certain rights and other assets, including key commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin (now referred to as AR101), which is a pivotal study-ready therapeutic being studied for the treatment of vascular Ehlers-Danlos Syndrome (“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, up to $67.5 million in earn-out payments, which are payable in cash or shares of the Company’s common stock, generally at the Company’s option. AR101 (enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways.

On March 31, 2021, the Company and Acerus Pharmaceuticals Corporation (“Acerus”) entered into a termination and transition agreement (the “Termination Agreement”) to terminate the License and Supply Agreement previously entered into on July 29, 2019 related to Natesto®. Pursuant to the Termination Agreement, the Company ceased all sales, marketing and promotion of Natesto, and Acerus agreed to pay the Company an aggregate amount of $7.5 million, payable in equal monthly installment payments of $250,000 for a period of 30 consecutive months.

On March 19, 2021, the Company acquired Neos Therapeutics, Inc. (“Neos”), a commercial-stage pharmaceutical company developing and manufacturing central nervous system-focused products (the “Neos Merger”). Neos commercializes Adzenys XR-ODT, Cotempla XR-ODT and Adzenys-ER in the United States using Neos’ internal commercial organization. These commercial products are extended-release (“XR”) medications in patient-friendly, orally disintegrating tablet (“ODT”) or oral suspension dosage forms that utilize Neos' microparticle modified-release drug delivery technology platform. Neos received approval from the U.S. Food and Drug Administration (“FDA”) for these three products. In addition, Neos manufactures and sells a generic Tussionex.

On December 8, 2020, the Company effected a reverse stock split in which each common stockholder received one share of common stock for every 10 shares held (herein referred to collectively as the “Reverse Stock Split”). All share and per share amounts in this report have been adjusted to reflect the effect of the Reverse Stock Split.

The Company incurred $4.9 million and $0.7 million merger and acquisitions related restructuring costs during the years ended June 30, 2021 and 2020, respectively, all of which was paid during the year ended June 30, 2021. These costs are primarily related to severance payments to employees affected by the change in business structure.

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 de-risked, late-stage pipeline focused on pediatric-onset conditions and difficult-to-treat diseases.

As of June 30, 2021, the Company had approximately $49.9 million of cash, cash equivalents and restricted cash. The Company’s operations have historically consumed cash and are expected to continue to consume cash. The Company incurred a net loss of approximately $58.3 million and $13.6 million during the years ended June 30, 2021 and 2020, respectively. The Company had an accumulated deficit of approximately $178.3 million and $120.0 million as of June 30, 2021 and 2020, respectively. Cash used in operations was approximately $26.0 million and $28.4 million during the years ended June 30, 2021 and 2020, respectively.

Management plans to focus on raising additional capital in order to meet its obligations and execute its business plan or otherwise reduce its expenses or renegotiate its debt facilities. Management believes that the Company has access to capital resources through possible public or private equity offerings, debt financings, or other means; however, the Company cannot provide any assurance that it will be able to raise additional capital 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.

As of the date of this Report, the Company expects its costs for operations to increase as the Company integrates the Neos acquisition, invests in new product development, continues to focus on revenue growth through increasing product sales and additional acquisitions. The Company’s current assets totaling approximately $105.2 million as of June 30, 2021 and the proceeds expected from ongoing product sales will be used to fund existing operations. The Company may continue to access the capital markets from time-to-time when market conditions are favorable. The timing and amount of capital that may be raised is dependent on the terms and conditions upon which investors would require to provide such capital. There is no guarantee that capital will be available on terms favorable to the Company and its stockholders, or at all. Upon closing of the Neos merger, on March 19, 2021, the Company paid down $15.4 million of Neos' senior secured long-term debt, including accrued interest and $5.5 million of merger costs incurred by Neos.

Since the Company has sufficient cash on-hand as of June 30, 2021 to cover potential net cash outflows for the twelve months following the filing date of this Annual Report, the Company reports that there exists no substantial doubt about its ability to continue as a going concern.

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

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 estimate. The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for doubtful accounts, determination of variable consideration for accruals of chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

Prior Period Reclassification. Certain prior year amounts in the consolidated balance sheets, statements of earnings and statements of cashflows have been reclassified to conform to the current year presentation, including a reclassification made in the presentation of FDA fees for commercialized product. This was previously included in general and administrative expenses and now is recorded as a component of cost of sales on the consolidated statements of earnings. These reclassifications did not affect operating earnings or other consolidated financial statements for the years ended June 30, 2021 and 2020.

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 primarily of amounts held in a certificate of deposit to maintain certain business credit cards. As of June 30, 2021 and 2020, cash, cash equivalents and restricted cash was $49.9 million and $48.3 million, respectively.

Accounts Receivable. Accounts receivables are reported on the consolidated balance sheets at outstanding amounts due from customers, less an allowance for doubtful accounts, discounts and pricing chargebacks. The Company extends credit without requiring collateral and typically does not charge interest on past due accounts but reserves the right to do so. As of June 30, 2021, reserve for discounts and chargebacks were $1.1 million and $1.0 million, respectively, and were $0.3 million and negligible amount as of June 30, 2020.

The Company writes off uncollectible receivables when the likelihood of collection is remote. The Company evaluates the collectability of accounts receivable on a quarterly basis. An allowance, when needed, is based upon various factors, including: the financial condition and payment history of customers; an overall review of collections experience on other accounts; and, economic factors or events expected to affect future collections experience. Allowance for doubtful accounts was $1.0 million and $0.4 million as of June 30, 2021 and 2020, respectively.

Inventories. Inventories consist of raw materials, work in process and finished goods and are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. 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 capitalized into inventory.

The Company periodically reviews the composition of its inventories in order to identify obsolete, slow-moving, excess or otherwise unsaleable items. Unsaleable items will be written- down to net realizable value in the period identified. The reserve for slow moving inventories was $2.5 million and $1.3 million as of June 30, 2021 and 2020, respectively.

Going Concern Determination. The Company periodically performs an evaluation for going concern accounting if the Company has experienced negative financial trends. The evaluation should be 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 and amortization. Depreciation is computed using the straight-line method over the assets' estimated useful lives. Leasehold improvements are amortized over the term of the lease agreement or the service lives of the improvements, whichever is shorter. The Company begins depreciating assets when they placed into service. When property and equipment is disposed, the associated cost and accumulated depreciation is removed from the consolidated balance sheets and any resulting gain or loss included in the consolidated statements of operations. Maintenance and repairs are expenses as incurred. Useful lives of property and equipment by each asset category is summarized below:

	Estimated Useful Lives in years
Manufacturing equipment	2 - 7
Leasehold improvements	3
Office equipment, furniture and other	2 - 7
Lab equipment	3 - 7

Leases. At the inception of an arrangement, the Company determines if an arrangement is, or contains, a lease based on the unique facts and circumstances present in such arrangement. Lease classification, recognition and measurement are then determined at the lease commencement date. For arrangements that contain a lease, the Company will (i) identify lease and non-lease components, (ii) determine the consideration in the contract, (iii) determine whether the lease is an operating or financing lease, and (iv) recognize lease right-of-use ("ROU") assets and liabilities. Lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected lease term. When determining the lease term, the Company includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. 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 in determining the present value of the lease payments.

Fixed lease payments are recognized over the expected term of the lease using the effective interest method. Variable lease expenses that are not considered fixed, or in substance fixed, are expensed as incurred. Fixed and variable lease expense 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 the short-term lease exemption and recognizes a short-term lease expense over lease terms of 12 months or less.

Operating leases are included in operating lease ROU assets, current portion of operating lease liabilities and operating lease 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.

Cash, cash equivalents and restricted cash, accounts receivable and accounts payable. The carrying amounts of financial instruments, including cash and cash equivalents, restricted cash, accounts receivable and accounts payable approximate their fair value due to their short maturities.

Contingent consideration. The Company classifies contingent consideration liabilities related to business acquisitions within Level 3 as factors used to develop the estimated fair value are unobservable inputs that

are not supported by market activity. The Company estimates the fair value of contingent consideration liabilities using a Monte Carlo models. Changes in the fair value of contingent liabilities in subsequent periods are recorded as a loss (gain) in the statements of operations.

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.

Contingent value rights. The Company classifies contingent value rights liabilities related to business acquisitions within Level 3 as factors used to develop the estimated fair value are unobservable inputs that are not supported by market activity. The Company estimates the fair value of contingent value rights liabilities using a Monte Carlo model. Changes in the fair value of contingent liabilities in subsequent periods are recorded as a loss (gain) in the statements of operations.

Fixed Payment Arrangements. Fixed payment arrangements are comprised of minimum product payment obligations relating to either make whole payments or fixed minimum royalties. The fixed payment arrangements were recognized at their amortized cost basis using a market appropriate discount rate and are accreted up to their ultimate face value over time. The liabilities related to fixed payment arrangements are not remeasured at each reporting period unless there is an occurrence of a modification or extinguishment of these obligations.

Revenue Recognition. The Company generates revenue from product sales through its prescription pharmaceutical products segment ("Aytu BioPharma Segment") and its consumer healthcare products segment ("Aytu Consumer Health Segment"). The Company recognizes revenue when all of the following criteria are satisfied: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) as each performance obligation is individually satisfied.

Aytu BioPharma Segment

Net product sales 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. International sales are made primarily to specialty distributors, as well as to hospitals, laboratories, and clinics, some of which are government owned or supported (collectively, its "Customers"). Products are generally shipped "free-on-board" destination when shipped domestically within the United States, and "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 (e.g., savings offers, prompt payment discounts, product returns, wholesaler (distributor) fees, wholesaler chargebacks and estimated rebates) to be incurred on the respective product sales, and recognizes the estimated amount as revenue when control of the product is transferred to its customers (e.g., upon delivery). Variable consideration is determined using either an expected value or a most likely amount method. The estimate of variable consideration is also subject to a constraint such that some or all of the estimated amount of variable consideration will only be included in the transaction price to the extent that it is probable that a significant reversal of revenue (in the context of the contract) will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Estimating variable consideration and the related constraint requires the use of significant management judgment and other market data. The Company provides for prompt payment discounts, wholesaler fees and wholesaler chargebacks based on customer contractual stipulations. The Company analyzes recent product return history to determine a reliable return rate. Additionally, management analyzes historical savings offers and rebate payments based on patient prescriptions and information obtained from third party providers to determine these respective variable considerations.

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. The amount of redeemed savings offers is recorded based on information from third-party providers against the estimated discount recorded as accrued expenses. The estimated discount is recorded as a gross to net sales adjustment at the time revenue is recognized. Historical trends of estimated savings offers will be regularly monitored, which may result in adjustments to such estimates in the future.

Prompt payment discounts

Prompt payment discounts are based on standard programs with wholesalers and are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustment at the time revenue is recognized.

Wholesale distribution fees

Wholesale distribution fees are based on definitive contractual agreements for the management of the Company’s products by wholesalers and are recorded as accrued expenses and as a gross to net sales adjustment at the time revenue is recognized.

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 information from third-party providers. Estimated rebates are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. Historical trends of estimated rebates will be regularly monitored, which may result in adjustments to such estimates in the future.

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. Estimated returns are recorded as accrued expenses and as a gross to net sales adjustments at the time revenue is recognized. The Company analyzed return data available from sales since inception date to determine a reliable return rate.

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. Estimated chargebacks are recorded as a discount allowance against accounts receivable and as a gross to net sales adjustment at the time revenue is recognized based on information provided by third parties.

Aytu Consumer Health Segment

The Aytu Consumer Health Portfolio 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 has elected to adopt the practical expedient on expensing the incremental costs to obtain a contract, given the expectation that any amounts attributable to obtaining such a contract would be satisfied within one year.

Credit Risk and Customer Concentrations. Financial instruments that potentially subject the Company to credit risk concentrations consist of cash, cash equivalents and accounts receivable. The counterparties are various corporations, governmental institutions and financial institutions of high credit standing.

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

The Company's customers, sometimes referred to as partners or customers, are primarily large wholesale distributors that resell the Company's products to retailers. As such, 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 is also subject to credit risk from accounts receivable related to product sales. Historically, the Company has not experienced significant credit losses on its accounts receivable and does not expect to have write-offs or adjustments to accounts receivable which would have a material adverse effect on the Company's financial position, liquidity or results of operations. The following table presents certain customers that contributed more than 10% of gross revenue and accounts receivable*:*

	Percentage of gross revenue		Percentage of accounts receivable	
	June 30,			
	2021	2020	2021	2020
Customer A	25 %	16 %	35 %	19 %
Customer B	15 %	16 %	29 %	16 %
Customer C	14 %	14 %	22 %	14 %
Customer D	— %	— %	— %	12 %

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, FDA fees for commercialized products and cost of royalties. In addition, distribution, shipping and handling costs invoiced by the Company's third party logistics companies are included in cost of sales.

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

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

Intangible Assets and Goodwill. The Company records intangible assets based on fair value on the date of acquisition. Intangible assets include licensed asset, product technology rights, developed technology right, distribution rights, commercial technology, tradename, trademarks and customer lists and in-process research and development ("IPR&D"). The finite-lived intangible assets are recorded at cost and amortized on a straight-line basis over the estimated lives of the assets. The indefinite-lived intangible assets are not subject to amortization.

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. Goodwill and other intangible assets are 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. Useful lives of finite-lived intangible assets by each asset category is summarized below:

	Estimated Useful Lives in years
Licensed asset	7
Product technology rights	10 - 17
Developed technology	17
Product distribution rights	5 - 10
Commercial technology	2
Tradename	1
Customer list	1.5

Impairment of Long-lived Assets. The Company assesses impairment of long-lived assets 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) 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 the carrying value, a write-down would be recorded to reduce the related asset to its estimated fair value.

The Company evaluated its long-lived assets for impairment as of June 30, 2021 and 2020 respectively, and recorded an impairment of $12.8 million for the Natesto and Tuzistra licensed asset and $0.2 million for the MiOXSYS patent portfolio.

Advertising Costs. Advertising costs consist of the direct marketing activities related to the Aytu Consumer Health segment. The Company expenses all advertising costs as incurred. The Company incurred $15.2 million and $4.7 million for the years ended June 30, 2021 and 2020, 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.

The Company reviews its deferred tax assets for recoverability and establishes a valuation allowance based on historical taxable income, projected future taxable income, remaining carryforward periods, applicable tax strategies and the expected timing of the reversals of existing temporary differences. A valuation allowance is provided when it is more likely than not (likelihood of greater than 50%) that some portion or all of the deferred tax assets will not be realized.

The Company considers many factors when evaluating and estimating its tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes. Tax positions are recognized only when it is more likely than not (likelihood of greater than 50%), based on technical merits, that the positions will be sustained upon examination. Tax positions that meet the more-likely-than-not threshold are measured using a probability weighted approach as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement.

Whether the more-likely-than-not recognition threshold is met for a tax position is a matter of judgment based on the individual facts and circumstances of that position evaluated in light of all available evidence.

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

As of June 30, 2021, the Company had $0.2 million deferred tax liabilities included in other long-term liabilities in the consolidated balance sheet. There was no such liabilities as of June 30, 2020.

Debt issuance costs, discounts (premium). Debt issuance costs reflect fees paid to lenders as compensation for services beyond their role as a creditor, and third parties whose costs are directly related to issuing debt and that otherwise would not be incurred. Amounts paid to the lender as a reduction in the proceeds received are considered a component of the discount on the issuance and not an issuance cost. Debt issuance costs, discounts (premium) related to term loans are reported as a direct deduction (increase) 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 accounted for in accordance with ASU 2015-15, Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of-Credit Arrangements, in which the Company elects to defer and present debt issuance costs as an asset and are recorded at cost and subsequently amortized over the term of the line of credit as additional interest expense.

As of the Neos merger date of March 19, 2021, the Company recorded a $0.8 million premium on the Deerfield debt (see Note 18) with a balance remaining of $0.6 million as of June 30, 2021.

Segment information. The Company determines its reportable segments in accordance with ASC 280—Segment Reporting. 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. Operating results for the operating segments are 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 primarily on product lines. The reporting segments have different lines of management responsibility as each business requires different marketing strategies and management expertise. The Company has two reportable segments: Aytu BioPharma (Rx division) and Aytu Consumer Health. The Company uses operating income (loss) to compare and evaluate its financial performance (see Note 17).

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 Aytu. For all periods presented, there is no difference in the number of shares used to compute basic and diluted shares outstanding due to the Company's net loss position. Restricted stock is considered legally issued and outstanding on the grant date, while RSUs are not considered legally issued and outstanding until the RSUs vest. Once the RSUs vest, equivalent common shares will be issued or issuable to the grantee and therefore the RSUs are not considered for inclusion in total common shares issued and outstanding until vested.

The following table sets-forth securities that could be potentially dilutive, but as of the years ended June 30, 2021 and 2020 are anti-dilutive, and therefore are excluded from the calculation of diluted earnings per share.

		June 30,	
		2021	2020
Warrants to purchase common stock - liability classified	(Note 14)	24,105	24,105
Warrant to purchase common stock - equity classified	(Note 14)	1,254,952	2,288,454
Employee stock options	(Note 13)	109,588	76,594
Employee unvested restricted stock	(Note 13)	1,955,426	418,606
Employee unvested restricted stock units	(Note 13)	78,318	—
		3,422,389	2,807,759

Recent Accounting Pronouncements

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

The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The Company adopted this as of July 1, 2020, the beginning of the Company's fiscal year-ended June 30, 2021. The most relevant component of ASU 2018-13 to the Company's financial statements relates to the need to disclose the range and weighted-average of significant unobservable inputs used in Level 3 fair value measurements. However, the Company discloses on a discrete basis all significant inputs for all Level 3 Fair Value measurements.

Financial Instruments – Credit Losses ("ASU 2016-13"). In June 2016, the FASB issued ASU 2016-13, "Financial Instruments – Credit Losses" to require the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of this ASU is to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date.

The standard was originally effective for interim and annual reporting periods beginning after December 15, 2019 and early adoption was permitted for interim and annual reporting periods beginning after December 15, 2018. However, in November 2019, the Financial Accounting Standard Board (FASB) issued ASU 2019-10, *Financial Instruments—Credit Losses, (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842) — Effective Dates* ("*ASU 2019-10*"). ASU 2019-10 deferred the adoption date for (i) public business entities that meet the definition of an SEC filer, excluding entities eligible to be "smaller reporting companies" as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and (2) all other entities for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. As of June 30, 2020, the Company qualified as a smaller reporting companies as defined by the SEC. The Company is currently assessing the impact that ASU 2016-13 will have on its consolidated financial statements but does not anticipate there to be a material impact.

3. Revenues from Contracts with Customers

Contract Balances: Contract assets primarily relate to the Company's right to consideration in exchange for products transferred to a customer in which that right to consideration is dependent upon the customer selling these products. As of June 30, 2021, contract assets of $21,000 was included in other current assets in the consolidated balance sheet. There was no contract asset as of June 30, 2020. Contract liabilities primarily relate to advances or deposits received from the Company's customers before revenue is recognized. As of June 30, 2021 and 2020, contract liabilities of $0.2 million and $0.3 million, respectively, were included in accrued liabilities in the consolidated balance sheets.

Revenues by Product Portfolio: Net revenue disaggregated by significant product portfolio for the years ended June 30, 2021 and 2020 were as follows.

	Year Ended June 30,	
	June 30, 2021	June 30, 2020
	(In thousands)	
Primary care and devices portfolio	$ 8,250	$ 7,957
Pediatric portfolio	24,428	9,292
Consumer Health portfolio	32,954	10,383
Consolidated revenue	$ 65,632	$ 27,632

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,	
	2021	2020
	(In thousands)	
U.S.	$ 60,687	$ 24,980
International	4,945	2,652
Total net revenue	$ 65,632	$ 27,632

4. Acquisitions

Fiscal Year 2020 acquisitions

On October 10, 2019, the Company entered into the Purchase Agreement with Cerecor, Inc. ("Cerecor") to acquire a line of prescription pediatric products, (the "Pediatric Portfolio"), which closed on November 1, 2019. At closing, the Pediatric Portfolio consisted of four prescription products (i) Cefaclor™ for Oral Suspension, (ii) Karbinal® ER, (iii) Poly-Vi-Flor® and (iv) Tri-Vi-Flor™. Total consideration transferred to Cerecor consisted of $4.5 million in cash and approximately 9.8 million shares of Series G Convertible Preferred Stock.

On February 14, 2020, the Company completed the merger with Innovus Pharmaceuticals, Inc. ("Innovus") after approval by the stockholders of both companies on February 13, 2020 (the "Innovus Merger"). Upon the effectiveness of the Innovus Merger, a subsidiary of the Company merged with and into Innovus, and all outstanding Innovus common stock was exchanged for approximately 380,000 shares of the Company's common stock and up to $16.0 million of Contingent Value Rights ("CVRs"). The outstanding Innovus warrants at the time of merger with 'cash out' rights were exchanged for approximately 2,000,000 shares of Series H Convertible Preferred stock of the Company over a period of time covering February 26, 2020 through March 10, 2020. The remaining Innovus warrants outstanding at the time of the merger, those without 'cash out' rights at the time of the Innovus Merger, remain outstanding, and upon exercise, retain the right to the merger consideration offered to Innovus stockholders, including any remaining claims represented by CVRs at the time of exercise. Innovus is now a 100% wholly-owned subsidiary of the Company, ("Aytu Consumer Health").

Neos Merger

On March 19, 2021, the Company completed the Neos Merger with Neos Therapeutics, Inc. after approval by the stockholders of Neos on March 18, 2021 and the approval of the consideration to be delivered by the Company in connection with the merger by the shareholders of Aytu, also on March 18, 2021. Upon the effectiveness of the Neos Merger, a subsidiary of the Company merged with and into Neos, and all outstanding Neos common stock was exchanged for approximately 5.5 million shares of the Company's common stock. Neos is now a 100% wholly-owned subsidiary of the Company. The Company pursued the acquisition of Neos in order to gain scale in the industry, expand its product portfolio and as an opportunity to potentially accelerate the pathway to breakeven. The Company incurred in relation to the Neos Merger (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 summarized the preliminary fair value of assets acquired and liabilities assumed at the date of acquisition. These estimates are preliminary, pending final evaluation of certain assets and liabilities, and therefore, are subject to revisions that may result in adjustments to the values presented below;

	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
Estimated fair value per share of Aytu common stock	$	9.73
Estimated 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 intangible assets were determined using variations of the cost approach, excess earnings method and the relief-from-royalties method. The fair value of 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 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, which is a developed technology for the Neos-sponsored patient support program that offers affordable and predictable copays to all commercially insured patients, was determined using cost to recreate method. The finite-lived intangible assets are being amortized over a range of between 1 to 17 years.

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

Pro Forma Impact due to Business Combinations

The following supplemental unaudited proforma financial information presents the Company's results as if the following acquisitions had occurred on July 1, 2019:

- Acquisition of the Pediatric Portfolio, effective November 1, 2019.
- Merger with Innovus effective February 14, 2020.
- Merger with Neos, effective March 19, 2021.

	Year ended June 30,	
	2021	2020
	Pro forma Unaudited	Pro forma Unaudited (aa)
	(In thousands)	
Total revenues, net	$ 98,064	$ 97,561
Net (loss)	$ (74,710)	$ (35,321)

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

Since the acquisition of Neos on March 19, 2021, Neos has contributed approximately $11.5 million in net revenues and $8.0 million to net loss.

Other acquisitions

On April 12, 2021, the Company acquired substantially all the assets of Rumpus Therapeutics, LLC through an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (together with Rumpus VEDS, LLC and Rumpus Therapeutics LLC, "Rumpus"). 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, 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. AR101 (enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways.

5. Inventories

Inventory balances consist of the following:

	June 30,	
	2021	2020
	(In thousands)	
Raw materials	$ 2,269	$ 397
Work in process	3,346	—
Finished goods	10,724	9,602
Inventory, net	$ 16,339	$ 9,999

The Company wrote down $7.3 million and $1.3 million of inventory during the years ended June 30, 2021 and 2020, respectively, primarily as a result of changing market conditions for the Company's COVID-19 test kits.

6. Property and Equipment

Property and equipment, net consist of the following:

	June 30,	
	2021	2020
	(In thousands)	
Manufacturing equipment	$ 3,070	$ 112
Leasehold improvements	959	229
Office equipment, furniture and other	1,093	312
Lab equipment	832	90
Assets under construction	198	—
Less accumulated depreciation and amortization	(1,012)	(484)
Property and equipment, net	$ 5,140	$ 259

Depreciation expense was $0.6 million and $0.1 million for the years ended June 30, 2021 and 2020, respectively. During the year ended June 30, 2021, the Company recognized a loss of $0.1 million on sale of equipment primarily due to termination of leases. There was no such loss during the year ended June 30, 2020.

7. Leases

The Company has entered into various operating lease agreements for certain of its offices, manufacturing facilities and equipment, and finance lease agreements for certain equipment. These leases have original lease periods expiring between 2022 and 2024. Most leases include one or more options to renew and the exercise of a lease renewal option typically occurs at the discretion of both parties. Certain leases also include options to purchase the leased property. For purposes of calculating operating lease liabilities, lease terms are deemed not to include options to extend the lease termination until it is reasonably certain that the Company will exercise that option. The Company’s lease agreements generally do not contain any material residual value guarantees or material restrictive covenants.

Upon the closing of the Neos Merger on March 19, 2021, pursuant to the guidance under ASC 805, Neos recognized 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 its office space and manufacturing facilities at Grand Prairie, Texas. As the lease agreement does not provide an implicit rate, Neos used its borrowing rate of 6.7% to determine the present value of future lease payments. Furthermore, as of the acquisition date, no assets or liabilities of the operating

leases that have a remaining lease term of less than twelve months were recognized. The finance leases are related to Neos equipment finance leases with fixed contract terms and an implicit interest rate of approximately 5.9%.

The components of lease expenses are as follows;

	Year Ended June 30,		
	2021	2020	Statement of Operations Classification
	(In thousands)		
Lease cost:			
Operating lease cost	$ 476	$ 199	Operating expenses
Short-term lease cost	109	9	Operating expenses
Finance lease cost:			
Amortization of leased assets	21	—	Cost of sales
Interest on lease liabilities	6	—	Other (expense), net
Total net lease cost	$ 612	$ 208	

Supplemental balance sheet information related to leases is as follows:

	June 30,		Balance Sheet Classification
	2021	2020	
	(In thousands)		
Assets:			
Operating lease assets	$ 3,563	$ 634	Operating lease right-of-use asset
Finance lease assets	329	—	Fixed assets, net
Total leased assets	$ 3,892	$ 634	
Liabilities:			
Current:			
Operating leases	$ 940	$ 300	Current operating lease liabilities
Finance leases	102	—	Current portion of debt
Long-term			
Operating leases	2,624	725	Long-term operating lease liabilities
Finance leases	180	—	Long-term debt
Total lease liabilities	$ 3,846	$ 1,025	

Remaining lease terms and discount rates used are as follows;

	June 30,	
	2021	2020
Weighted-Average Remaining Lease Term (years)		
Operating lease assets	3.42	2.96
Finance lease assets	2.72	—
Weighted-Average Discount Rate		
Operating lease assets	6.62 %	10.02 %
Finance lease assets	6.41 %	—

Supplemental cash flow information related to leases is as follows:

	Year Ended June 30,	
	2021	2020
	(In thousands)	
Cash flow classification of lease payments:		
Operating cash flows from operating leases	$ 467	$ 199
Operating cash flows from finance leases	$ 5	$ —
Financing cash flows from finance leases	$ 25	$ —

As of June 30, 2021, maturities of lease liabilities are as follows:

	Operating	Finance
	(In thousands)	
2022	$ 1,154	$ 117
2023	1,182	104
2024	1,117	88
2025	556	—
Total lease payments	4,009	309
Less: Imputed interest	(445)	(27)
Lease liabilities	$ 3,564	$ 282

8. Goodwill and Other Intangible Assets

During the year ended June 30, 2021, the Company completed the Neos Merger, which resulted in goodwill of $37.7 million (see Note 4).

As of June 30, 2021, based on forecast models, there was no impairment of the Company's net asset value. However, the Company's market capitalization has been below the carrying value of its assets, which could be indicative of a future impairment of assets. Management will continue to assess those relative valuations.

The change in carrying amount of goodwill by reportable segment is as follows;.

	Aytu BioPharma	Aytu Consumer Health	Consolidated
		(In thousands)	
Balance as of June 30, 2019	$ —	$ —	$ —
Goodwill acquired	19,453	8,637	28,090
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

The Company currently holds the following intangible asset portfolios as of June 30, 2021: (i) Licensed asset, which consist of pharmaceutical product assets that were acquired prior to July 1, 2020; (ii) Product technology rights, acquired from the November 1, 2019 acquisition of the Pediatric Portfolio from Cerecor and the Neos Merger on March 19, 2021, (iii) Proprietary modified-release drug delivery technology right as a result of the Neos Merger, (iv) Acquired product distribution rights and commercial technology consisting of RxConnect and trade names as a result of the Neos

Merger, and patents, trade names and the acquired customer lists from the Innovus Merger, (v) Acquired in-process R&D from the Neos Merger related to the NT0502 product candidate for sialorrhea.

The following table provides the summary of the Company's intangible assets as of June 30, 2021 and June 30, 2020, respectively.

	June 30, 2021			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life (in years)
	(In thousands)			
Licensed asset	$ 3,246	$ (1,430)	$ 1,816	3.92
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
Acquired in-process R&D	2,600	—	2,600	Indefinite-lived
Acquired commercial technology	630	(178)	452	0.75
Acquired trade name	400	(56)	344	1.75
Acquired customer lists	390	(358)	32	0.01
Total	$ 94,220	$ (8,756)	$ 85,464	13.47

	June 30, 2020				
	Gross Carrying Amount	Accumulated Amortization	Impairment	Net Carrying Amount	Weighted-Average Remaining Life (in years)
	(In thousands)				
Licensed assets	$ 23,649	$ (7,062)	$ —	$ 16,587	11.88
MiOXSYS Patent	380	(185)	(195)	—	—
Acquired product technology right	22,700	(1,513)	—	21,187	9.34
Acquired product distribution rights	11,354	(565)	—	10,789	7.78
Acquired customer lists	390	(98)	—	292	1.12
Total	$ 58,473	$ (9,423)	$ (195)	$ 48,855	9.11

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

	June 30,
	(In thousands)
2022	$ 8,038
2023	7,489
2024	7,333
2025	7,099
2026	6,331
Thereafter	46,574
Total future amortization expense	$ 82,864

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 $7.1 million and $4.5 million during the years ended June 30, 2021 and 2020, respectively.

On March 31, 2021, the Company terminated the Acerus agreement previously entered into on July 29, 2019. Pursuant to the Termination Agreement, the Company ceased all sales, marketing and promotions of Natesto, and Acerus agreed to pay the Company an aggregate amount of $7.5 million, payable in equal monthly installment payments for a period of 30 consecutive months. At the March 31, 2021 termination date, the Company determined that none of the $7.5 million future cash payments could be recognized as of that date, and therefore the remaining $4.3 million carrying value of the licensed intangible asset related to Natesto was impaired. There was no remaining value as of June 30, 2021.

On April 12, 2021, the Company acquired substantially all the assets of Rumpus Therapeutics, LLC through an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (together with Rumpus VEDS, LLC and Rumpus Therapeutics LLC, "Rumpus"). This in-process research and development (IPR&D) asset was acquired for an up-front fee of $1.5 million in cash and payment of aggregated fees of $0.6 million. The Company determined that the IPR&D asset has no alternative future use at the time of purchase and was recorded as research and development expense in the statements of operations.

Licensed Assets

ZolpiMist. In June 2018, the Company signed an exclusive license agreement for ZolpiMist™ (zolpidem tartrate oral spray) from Magna Pharmaceuticals, Inc., ("Magna"). This agreement allows for the Company's exclusive commercialization of ZolpiMist in the U.S. and Canada. The ZolpiMist license agreement was valued at $3.2 million and is being amortized on a straight-line over the life of the license agreement up to seven years.

Tuzistra XR. On November 2, 2018, the Company entered into a License, Development, Manufacturing and Supply Agreement (the "Tuzistra License Agreement") with Tris Pharma, Inc. ("Tris"). Pursuant to the Tris License Agreement, Tris granted the Company an exclusive license in the United States to commercialize Tuzistra XR. On June 30, 2021, the Company recognized an impairment of approximately $8.5 million related to the remaining net carrying value of the licensed intangible asset related to Tuzistra as a result of the impact of COVID-19 and other factors negatively impacting product sales.

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 Merger in March 2021. The aggregate acquisition date fair value of the acquired Product Technology Rights was $45.4 million and is being amortized on a straight-line over the lives of these rights.

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.

Cefaclor (cefaclor oral suspension). The Company acquired the License, Supply and Distribution Agreement for rights to promote and commercialize Cefaclor within the United States, but does not own or license any patents covering this product.

ADHD Portfolio. As part of the Neos Merger, the Company acquired developed product technology for the production and sale of Adzenys XR-ODT, Adzenys ER, Cotempla XR-ODT and generic Tussionex. 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 Merger, 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. The acquisition date fair value of the Developed Technology Right was $30.2 million and is being amortized on a straight-line over the estimated useful life of 17 years.

Product distribution rights and customer list

In connection with the Innovus Merger, the Company obtained 35 products with a combination of over 300 registered trademarks and/or patent rights and customer lists. The acquisition date fair values of these trademarks and/or patent rights was $11.4 million, which is being amortized, on a straight-line, over the estimated life ranging 3 to 10 years. The acquired customer list had an acquisition date fair value of $0.4 million, which is being amortized on a straight-line over the estimated useful life of 1.5 years.

In-Process R&D

IPR&D – NT0502. As part of the Neos Merger, the Company acquired in-process research and development associated with NT0502, a new chemical entity that is being developed by the Company for the treatment of sialorrhea, which is excessive salivation or drooling. The acquisition date fair value of the In-Process R&D was $2.6 million. As this is an indefinite-lived intangible asset, it is not subject to amortization at that time. 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.

Commercial Technology and Tradename

RxConnect. As part of the Neos Merger, the Company acquired a commercial program, which is a Company-sponsored network of patient support program that offers affordable and predictable copays to all commercially insured patients. The acquisition date fair value was $0.6 million and is being amortized on a straight-line over the estimated useful life of 1 year. In addition, the Company acquired the Neos tradename with an acquisition date fair value of $0.4 million, and is being amortized on a straight-line over the estimated useful life of 2 years.

9. Accrued liabilities

Accrued liabilities consist of the following:

	June 30,	
	2021	2020
	(In thousands)	
Accrued settlement expense	$ —	$ 315
Accrued program liabilities	8,689	959
Accrued product-related fees	2,501	2,471
Accrued savings offers	20,148	—
Accrued distributor fees	2,710	457
Accrued liabilities for trade partners	6,021	185
Medicaid liabilities	1,714	1,842
Return reserve	6,367	1,329
Other accrued liabilities*	3,145	1,273
Total accrued liabilities	$ 51,295	$ 8,831

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

10. Fair Value Considerations

The Company's asset and liability classified financial instruments include cash and cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, warrant derivative liability and contingent consideration. The carrying amounts of 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. The fair value of acquisition-related contingent consideration is based on a Monte Carlo models. The valuation policies are determined by management, and the Company's Board of Directors is informed of any policy change.

Authoritative guidance defines fair value as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. The guidance establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions of what market participants would use in pricing the asset or liability developed based on the best information available in the circumstances. The hierarchy is broken down into three levels based on reliability of the inputs as follows:

Level 1: Inputs that reflect unadjusted quoted prices in active markets that are accessible to Aytu for identical assets or liabilities;

Level 2: Inputs include quoted prices for similar assets and liabilities in active or inactive markets or that are observable for the asset or liability either directly or indirectly; and

Level 3: Unobservable inputs that are supported by little or no market activity.

The Company's assets and liabilities which are measured at fair value on a recurring basis are classified in their entirety based on the lowest level of input that is significant to their fair value measurement. The Company'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. The Company has consistently applied the valuation techniques discussed below in all periods presented.

The following table presents Company's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2021 and 2020, by level within the fair value hierarchy:

		Fair Value Measurements at June 30, 2021		
	Fair Value at June 30, 2021	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Recurring:				
Contingent consideration	$ 12,057	$ —	$ —	$ 12,057
CVR liability	1,395	—	—	1,395
Total	$ 13,452	$ —	$ —	$ 13,452

		Fair Value Measurements at June 30, 2020		
	Fair Value at June 30, 2020	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Recurring:				
Contingent consideration	$ 13,588	$ —	$ —	$ 13,588
CVR liability	5,572	—	—	5,572
Total	$ 19,160	$ —	$ —	$ 19,160

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

Tuzistra XR. The contingent consideration related to Tuzistra XR was valued at $8.8 million using a Monte Carlo simulation as of November 2, 2018. As of June 30, 2021, the contingent consideration was revalued at $11.0 million using a Scenario-Based model. As of June 30, 2020, the contingent consideration was revalued at $13.2 million using the Discounted Cash Flow method. The Company's policy is to value contingent consideration liabilities using a Monte Carlo model. However, the Monte Carlo model could not be used for the valuation of Tuzistra XR contingent consideration given management's revenue forecast for the product; therefore, the Company used a Scenario-Based model instead. The contingent consideration accretion expense for the years ended June 30, 2021 and June 30, 2020 was $0.2 million, and $0.4 million, respectively. As of June 30, 2021, none of the milestones had been achieved, and therefore, no milestone payment was made. However, approximately $3.0 million is expected to be paid in November 2021, as this milestone will be satisfied.

ZolpiMist. The contingent consideration related to the ZolpiMist royalty payments was valued at $2.6 million using a Monte Carlo simulation, as of June 11, 2018. As of June 30, 2021, the contingent consideration was revalued at $0.7 million using the Monte Carlo model. As of June 30, 2020, the contingent consideration was revalued at $0.2 million using the Discounted Cash Flow method. The contingent consideration accretion expense for the years ended June 30, 2021 and June 30, 2020 was $0.1 million, and $0.2 million, respectively As of June 30, 2021, none of the milestones had been achieved, and therefore, no milestone payment was made.

On February 14, 2020, the Company recognized approximately $0.2 million in product related contingent consideration as a result of the Innovus Merger. 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 would be achieved. As of June 30, 2021 and June 30, 2020, the contingent consideration was $0.3 million and $0.2 million, respectively. The contingent consideration accretion expense for the year ended June 30, 2021 was $0.1 million and was negligible during the year ended June 30, 2020.

In June 2017, Innovus entered into Exclusive License Agreement ("the Agreement") with University of Iowa Research Foundation ("UIRD") for the use of patent and technology know-how. Pursuant to the 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 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 The discounted value as of June 30, 2021, was approximately $0.1 million.

Contingent value rights. Contingent value rights ("CVRs") represent contingent additional consideration of up to $16.0 million payable to satisfy future performance milestones related to the Innovus Merger. 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. The fair value of the contingent value rights was based on a Monte Carlo model which takes into account current interest rates and expected sales potential. On March 31, 2020, the Company issued to the CVR holders 123,820 shares of the Company's common stock to satisfy the first $2.0 million milestone, which related to the Innovus achievement of $24.0 million in revenues during the 2019 calendar year. On March 20, 2021, the Company issued to the CVR holders 103,190 shares of the Company's common stock to satisfy one of two $1.0 million 2020 milestones, which relates to the Innovus achievement of $30.0 million in revenues during the 2020 calendar year. The $1.0 million 2020 milestone for achieving profitability was not met. As of June 30, 2021 and June 30, 2020, the CVRs were revalued at $1.4 million and $5.6 million, respectively, using the same Monte Carlo simulation methodology.

Non-Recurring Fair Value Measurement

Fixed payment arrangements. As part of the Cerecor transaction, the Company assumed obligations due to an investor 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 2020. 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 2020, 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 the next six quarters, beginning September 30, 2021. The Company accounted the Waiver, Release and Consent as a debt modification in accordance with ASC 470. Such a modification to the original terms required us to remeasure the related liabilities as of June 30, 2021 using discounted cash flow model. As of June 30, 2021, the fair value of the fixed payment arrangements was $9.5 million. The Company recognized a $1.3 million loss on extinguishment of the fixed obligation for the year ended June 30, 2021.

The following able represents Company's financial liabilities that were accounted for at fair value on a non-recurring basis as of June 30, 2021 and 2020, by level within the fair value hierarchy:

		Fair Value Measurements at June 30, 2021		
	Fair Value at June 30, 2021	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Non-recurring				
Fixed payment arrangements	$ 9,458	$ —	$ —	$ 9,458
	$ 9,458	$ —	$ —	$ 9,458

		Fair Value Measurements at June 30, 2020		
	Fair Value at June 30, 2020	Quoted Priced in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(In thousands)		
Non-recurring				
Fixed payment arrangements	$ 13,512	$ —	$ —	$ 13,512
Total	$ 13,512	$ —	$ —	$ 13,512

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, 2021:

	CVR Liability	Contingent Consideration	Fixed Payment Arrangements
	(In thousands)		
Balance as of June 30, 2019	$ —	$ 23,326	$ —
Included in earnings	523	(9,741)	1,452
Purchases, issues, sales and settlements:			
Purchases	7,049	183	—
Issues	—	—	29,838
Settlements	(2,000)	(180)	(17,778)
Balance as of June 30, 2020	5,572	13,588	13,512
Included in earnings	(3,177)	(848)	2,795
Purchases, issues, sales and settlements:			
Settlements	(1,000)	(683)	(6,849)
Balance as of June 30, 2021	$ 1,395	$ 12,057	$ 9,458

Significant Assumptions

Significant assumptions used in valuing the contingent consideration were as follows:

	June 30,	
	2021	2020
Tuzistra		
Valuation model	Scenario-Based	Discounted Cash Flow
Leveraged Beta	0.68	0.36
Market risk premium	6.00 %	6.00 %
Risk-free interest rate	1.90 %	3.00 %
Discount	15.30 %	5.20 %
Company specific discount	15.00 %	15.00 %

	June 30,	
	2021	2020
ZolpiMist		
Valuation method	Monte Carlo	Discounted Cash Flow
Leveraged Beta	1.09	1.17
Market risk premium	6.00 %	6.00 %
Risk-free interest rate	0.70 %	3.00 %
Discount	10.30 %	5.20 %
Company specific discount	15.00 %	5.00 %

Significant assumptions used in valuing the CVRs were as follows:

	June 30,	
	2021	2020
Contingent Value Rights		
Valuation method	Monte Carlo	Monte Carlo
Leveraged Beta	0.91	0.88
Market risk premium	6.00 %	6.17 %
Risk-free interest rate	0.36 %	1.15 %
Discount	13.00 %	30.00 %
Company specific discount	5.00 %	20.00 %

Significant assumptions used in valuing the Fixed Payment Arrangements were as follows:

	June 30,	
	2021	2020
Fixed Payment Obligations		
Valuation method	Discounted Cash Flow	Discounted Cash Flow
Discount rate - minimum	10.0 %	1.8 %
Discount rate - maximum	12.4 %	12.4 %

11. Income Taxes

The provision for income taxes consisted of the following:

	Year Ended June 30,	
	2021	2020
	(In thousands)	
Current:		
Federal	$ —	$ —
State	16	—
Total current tax expense	16	—
Deferred:		
Federal	200	—
State	43	—
Total deferred tax expense	243	—
Provision for income taxes	$ 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,			
	2021		2020	
	(In thousands)			
Tax at statutory rate	$ (12,185)	(21.00)%	$ (2,934)	(21.00)%
State income taxes, net of federal benefit	(2,461)	(4.24)%	(798)	(5.71)%
Stock based compensation	43	0.07 %	(35)	(0.25)%
Contingent consideration	(667)	(1.15)%	54	0.39 %
162(m) limitation	235	0.40 %	—	0.00 %
Transaction costs	160	0.28 %	—	0.00 %
Loss on debt extinguishment and interest expense	—	0.00 %	167	1.20 %
Change in valuation allowance	14,483	24.96 %	3,496	25.02 %
Other	651	1.13 %	50	0.35 %
Net income tax provision (benefit)	$ 259	0.45 %	$ —	0.00 %

Deferred income taxes arise from temporary differences in the recognition of certain items for income tax and financial reporting purposes. The approximate tax effects of significant temporary differences which comprise the deferred tax assets and liabilities are as follows for the respective periods:

	Year Ended June 30,	
	2021	2020
	(In thousands)	
Deferred tax assets:		
Net operating loss carry forward	$ 106,712	$ 37,191
Accrued Rebates	8,412	—
Share-based compensation	2,330	1,891
Accrued expenses	1,507	855
R&D credits	2,115	9
Interest	2,064	—
Inventory	1,704	789
Lease liability	1,031	261
Other	1,526	358
Total deferred tax assets	127,401	41,354
Less: valuation allowance	(116,494)	(39,552)
Deferred tax assets, net of valuation allowance	10,907	1,802
Deferred tax liabilities:		
Intangibles	(9,396)	(1,578)
ROU asset	(1,009)	(224)
Fixed assets	(745)	—
Total deferred tax liabilities	(11,150)	(1,802)
Net deferred tax liabilities	$ (243)	$ —

The Company has recorded a valuation allowance of $116.5 million and $39.6 million at June 30, 2021 and 2020, respectively, to reserve its net deferred tax assets. The change in valuation allowance is due to the acquisition of Neos, resulting in a $62.5 million valuation allowance being established at the acquisition date and the remainder of the change is due to the change in inventory of deferred items exclusive of indefinite lived deferred tax liabilities which can not 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 $466.7 million and $147.0 million as of June 30, 2021 and June 30, 2020, respectively that, subject to limitation, may be available in future tax years to offset taxable income. Of the available federal net operating losses, approximately $130.4 million can be carried forward indefinitely while the balance will begin to expire in 2024. As of June 30, 2021, the Company had research and development credits of $2.7 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 2038. Under the provisions of the Internal Revenue Code, substantial changes in the Company’s ownership may result in limitations on the amount of NOL carryforwards that can be utilized in future years. Net operating loss carryforwards are subject to examination in the year they are utilized regardless of whether the tax year in which they are generated has been closed by statute. The amount subject to disallowance is limited to the NOL utilized. Accordingly, the Company may be subject to examination for prior NOLs generated as such NOLs are utilized. As of June 30, 2021, 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, 2021 and 2020, the Company had gross unrecognized tax benefits related to uncertain tax positions of $11.5 million and $0, respectively. Changes in unrecognized benefits in any given year are recorded as a component of deferred tax expense. A tabular rollforward of the Company's gross unrecognized tax benefits is below.

	June 30,	
	2021	2020
	(In thousands)	
Beginning balance	$ —	$ —
Increase resulting from prior period tax positions	12,017	—
Increase resulting from current period tax positions	2	—
Decrease resulting from current period tax positions	(482)	—
Ending balance	$ 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.

12. Capital Structure

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, 2021 and June 30, 2020, the Company had 27,490,412 and 12,583,736 common shares issued and outstanding, respectively, and zero preferred shares issued and outstanding.

Included in the common stock outstanding are 1,958,876 shares of restricted stock issued to executives, directors and employees.

On June 8, 2020, the Company 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"). The Company simultaneously entered into a sales agreement with Jefferies, LLC, as sales agent, which allows the Company to sell and issue shares of the Company's common stock from time-to-time in "at-the-market" offerings under the 2020 Shelf ("Jefferies ATM"). Through June 30, 2020, the Company has issued 430,230 shares of common stock under the Jefferies ATM, with total gross proceeds of $6.8 million before deducting underwriting discounts, commissions and other offering expenses of $1.9 million, and has issued an additional 352,912 shares of common stock under the Jefferies ATM, with total gross proceeds of $3.6 million before deducting underwriting discounts, commissions and other offering expenses of $0.2 million from July 1, 2020 through June 2, 2021, when the Jefferies ATM was effectively terminated by the Company. On June 4, 2021, the Company entered into a sales agreement with Cantor Fitzgerald & Co., as sales agent, to provide for the offering, issuance and sale by the Company of up to $30.0 million of its common stock from time to time in "at-the-market" offerings under the 2020 Shelf (the "Cantor ATM"). During the year ended June 30, 2021, the Company has issued 2,310,400 shares of common stock under the Cantor ATM, with total gross proceeds of approximately $12.7 million before deducting underwriting discounts, commissions, and other offering expenses of $0.5 million.

The Company entered into three separate registered direct stock offerings on March 10, 2020, March 12, 2020 and March 19, 2020 (the "March Offerings") in which the Company issued a combination of common stock and warrants. In July 2020, the Company issued 92,302 warrants to purchase 92,302 shares of the Company's common stock

with a weighted-average exercise price of $15.99 to an investment bank. The warrants have a term of one year from the issuance date. These warrants had at issuance a fair value of approximately $0.4 million and were valued using a Black-Scholes model.

On December 8, 2020, the Company effected a reverse stock split in which each common stockholder received one share of common stock for every 10 shares held (herein referred to collectively as the “Reverse Stock Split”). All share and per share amounts in this report have been adjusted to reflect the effect of the Reverse Stock Split. On the date of the Reverse Stock Split, the Company had no preferred shares issued and outstanding, and as such it had no impact on the Company’s financial statements.

On December 10, 2020, the Company entered into an exchange agreement to exchange the $0.8 million of debt outstanding for 130,081 shares of the Company's common stock (see Note 18).

On December 10, 2020, the Company entered into an underwriting agreement with H.C. Wainwright & Co., LLC (“Wainwright”) (as amended and restated, the “Underwriting Agreement”). Pursuant to the Underwriting Agreement, the Company agreed to sell, in an upsized firm commitment offering, 4,166,667 shares (the “Shares”) of the Company’s common stock, $0.0001 par value per share (the “Common Stock”), to Wainwright at an offering price to the public of $6.00 per share, less underwriting discounts and commissions. In addition, pursuant to the Underwriting Agreement, the Company granted Wainwright 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. Wainwright exercised their over-allotment option in full, purchasing total common stock of 4,791,667 shares. The Company 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, the Company 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 fair value of approximately $1.3 million and are classified with the stockholders' equity. Effective June 2, 2021, the Company terminated the Underwriting Agreement with Wainwright; pursuant to such termination, there will be no future sales of the Company’s common stock under the agreement.

On March 19, 2021, upon closing of the Neos Merger, the Company issued 5,447,000 shares of its common stock to acquire all the outstanding shares of common stock of Neos. In addition, pursuant to the agreement in the Neos Merger, the Company issued 24,804 shares of common stock to settle the accelerated restricted stock units of former Neos directors and officers (see Note 4).

On March 20, 2021, the Company paid the CVR holders 103,190 shares of the Company’s common stock to satisfy one of two $1.0 million 2020 milestones, which relates to the Innovus achievement of $30.0 million in revenues during the 2020 calendar year.

Year Ended June 30, 2020

The number of shares of the Company’s common stock and warrant discussed below are adjusted to reflect the December 8, 2020 Reverse Stock Split discussed above in this note. As the preferred stocks were all converted to common stock prior to December 8, 2020, no adjustment has been made to the preferred stock.

Preferred stocks conversion

In September 2019, investors holding shares of Series C preferred stock exercised their right to convert 443,833 shares of Series C preferred stock into 44,383 shares of common stock. There are no remaining Series C preferred stock outstanding.

In October 2019, Armistice Capital converted 2,751,148 shares of Series E convertible preferred stock into 275,115 shares of common stock. There are no remaining Series E preferred stock outstanding.

In October 2019, the Company issued 10,000 shares of Series F Convertible preferred stock, with a face value of $1,000 per share, and convertible at a conversion price of $1.00 (the “Current Conversion Price”). The terms of the Series F Convertible Preferred include a conversion price reset provision in the event a future financing transaction is priced below the Current Conversion Price.

In November 2019, in connection with the Pediatric Portfolio acquisition, the Company issued 9,805,845 shares of Series G Convertible Preferred stock, which were converted into 980,585 shares of common stock in April 2020.

In February 2020, in connection with the Innovus Merger, the Company issued (i) 380,971 shares of the Company’s common stock and (ii) 1,997,902 shares of Series H Convertible Preferred stock, of which, all 1,997,902 shares of the Series H Convertible Preferred stock were converted into 199,774 shares of common stock in March 2020.

In addition, in March 2020, the following Convertible Preferred Stock issuances were converted into the Company’s common stock: (i) 400,000 shares of the Series D Convertible Preferred Stock were converted into 40,000 shares of the Company’s common stock, (ii) 10,000 shares of the Series F Convertible Preferred Stock, with a face value of $1,000 per share, and convertible at a conversion price of $1.00 (the “Current Conversion Price”), were converted into 1,000,000 shares of the Company’s common stock. There are no remaining shares of the Series D Convertible Preferred Stock and Series F Convertible Preferred Stock outstanding at June 30, 2020.

Cashless warrants

In addition and concurrent with the Series F Convertible preferred stock issuance, the Company issued 1,000,000 warrants, with an exercise price of $12.50 and a term of five years. These warrants feature a contingent cashless exercise provision. During the three months ended December 31, 2019, the cashless exercise contingency was satisfied, reducing the strike price of the October 2019 Warrants to $0. During the three months ended March 31, 2020, an investor exercised 500,000 of the warrants using the cashless exercise provision. In April 2020, another investor exercised the remaining 500,000 of the October 2019 warrants using the cashless exercise provision, resulting in no remaining October 2019 warrants.

On March 11, 2020, pursuant to the April 18, 2019 Note exchange agreement between the Company and Armistice, Armistice exercised the 291,577 warrants, resulting in no remaining April 2019 warrants.

The “March Offerings”

On March 19, 2020, the Company entered into a securities purchase agreement with certain institutional investors (the “the March 19, 2020 Purchasers”), pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 1,253,920 shares of the Company’s common stock (the “Common Stock”) at a purchase price per share of $15.95 and (ii) warrants to purchase up to 1,253,920 shares of Common Stock (the “March 19, 2020 Warrants”) at an exercise price of $14.70 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company. The March 19, 2020 Warrants are exercisable immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued 81,505 warrants with an exercise price of $19.938 per share to purchase up to 81,505 shares of common stock (the “March 19, 2020 Placement Agent Warrants”). The March 19, 2020 Placement Agent Warrants have a term of five years from the issuance date.

Since March 19, 2020, a total of 120,000 March 19, 2020 Warrants have been exercised, for total proceeds of $1.7 million. The remaining 1,133,920 March 19, 2020 Warrants expired on March 19, 2021.

On March 12, 2020, the Company entered into a securities purchase agreement with certain institutional investors, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 1,600,000 shares of the Company’s common stock at a purchase price per share of $12.50 and (ii) warrants to purchase up to 1,600,000 shares of Common Stock (the “March 12, 2020 Warrants”) at an exercise price of $12.50 per share, for aggregate gross proceeds to the Company of $20.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the “Registered Offering”). The March 12, 2020 Warrants are exercisable

immediately upon issuance and have a term of one year from the issuance date. In addition, the Company issued warrants with an exercise price of $15.625 per share to purchase up to 104,000 shares of common stock (the “March 12, 2020 Placement Agent Warrants”). The March 12, 2020 Placement Agent Warrants have a term of five years from the issuance date and expires on March 12, 2025.

Since March 12, 2020, a total of 1,300,000 March 12, 2020 Warrants have been exercised, for total proceeds of approximately $16.3 million. The remaining 300,000 March 12, 2020 Warrants expired on March 11, 2021.

On March 10, 2020, Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company agreed to sell and issue, in a registered direct offering, an aggregate of (i) 445,000 shares of the Company’s common stock (the “Common Stock”) at a purchase price per share of $11.50 and (ii) pre-funded warrants to purchase up to 337,607 shares of Common Stock (the “Pre-Funded Warrants”) at an effective price of $11.50 per share ($11.499 paid to the Company upon the closing of the offering and $0.001 to be paid upon exercise of such Pre- Funded Warrants), for aggregate gross proceeds to the Company of approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company (the “Registered Offering”). The Pre-Funded Warrants were immediately exercised upon close. In addition, the Company issued warrants with an exercise price of $14.375 per share to purchase up to 50,870 shares of common stock (the “March 10, 2020 Placement Agent Warrants”). The March 10, 2020 Placement Agent Warrants have a term of five years from the issuance date and expires on March 10, 2025.

Since March 10, 2020, a total of 598,200 shares of the Company’s October 2018 $15.0 Warrants (the “October 18 $15.0 Warrants”) were exercised through April 27, 2020, resulting in proceeds of approximately $9.0 million. The remaining 419,160 October 2018 $15.0 Warrants expires on October 8, 2023.

Innovus Notes conversion

On April 27, 2020, an investor who held four different notes (Innovus Notes) converted the four outstanding note agreements into 153,370 shares of common stock. In addition, On May 11, 2020, another investor who held two different notes (Innovus Notes) converted the two outstanding note agreements into 30,835 shares of common stock.

In April 2020, the issued a total of 16,500 shares of the Company’s common stock to three of the former Innovus board members engaged by the Company as consumer healthcare market advisors.

Other issuance

On March 31, 2020, the Company issued to the CVR holders 123,820 shares of the Company’s common stock to satisfy the first $2.0 million milestone, which related to the Innovus achievement of $24.0 million in revenues during the 2019 calendar year.

In March 2020 and April 2020, a total of 598,200 shares of the Company’s October 2018 $15.0 Warrants (the “October 18 $15.0 Warrants”) were exercised for total proceeds of approximately $9.0 million. The remaining 419,160 October 2018 $15.0 Warrants expires on October 8, 2023.

In May 2020, the Company issued 8,967 shares of common stock to Presmar in lieu of the $150,000 cash payment that was due as part of the November 2019 acquisition of Cerecor.

In June 2020, the Company issued approximately 3,271 shares of common stock to a former employee upon termination of employment with the Company.

13. Equity Incentive Plan

Aytu 2015 Plan. On June 1, 2015, the Company's stockholders approved the 2015 Stock Option and Incentive Plan (the "2015 Plan"), which, as amended in July 2017, provides for the award of stock options, stock appreciation rights, restricted stock and other equity awards for up to an aggregate of 3.0 million shares of common stock. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2015 Plan will be added back to the shares of common stock available for issuance under the Aytu 2015 Plan. On February 13, 2020, the Company's shareholders approved an increase to 5.0 million total shares of common stock in 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, whereas the restricted stock units have a vesting period 4 years. As of June 30, 2021, the Company had 2,937,710 shares that are available for grant under the Aytu 2015 Plan.

Neos 2015 Plan. Pursuant to the Neos Merger, 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. In addition to the 105,449 registered shares to cover the assumed awards, the remaining 1,255,310 shares available under the legacy Neos plan was added back to the new Neos 2015 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. The restricted stock units have a vesting period ranging from 2 to 4 years. As of June 30, 2021, the Company had 1,271,657 shares that are available for grant under the Neos 2015 Plan.

Stock Options

During the year ended June 30, 2021, there was no stock options granted under the Aytu 2015 Plan. The Company assumed 69,721 stock options previously granted under the Neos 2015 Plan.

The fair value of the options is calculated using the Black-Scholes option pricing model. In order to calculate the fair value of the options, certain assumptions are made regarding components of the model, including the estimated fair value of the underlying common stock, risk-free interest rate, volatility, expected dividend yield and expected option life. Changes to the assumptions could cause significant adjustments to valuation. The Company estimates the expected term based on the average of the vesting term and the contractual term of the options. The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of the grant for treasury securities of similar maturity. The fair value of all options granted during the year ended June 30, 2021 utilized the following range of assumptions:

	June 30, 2021
Expected volatility	100.0 %
Expected term (years)	5.00
Risk-free interest rate	0.90 %
Dividend yield	0.00 %

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding June 30, 2019	188	$ 3,259.57	6.95
Granted	76,950	12.42	
Exercised	(500)	9.70	
Expired	(24)	3,280.00	
Outstanding June 30, 2020	76,614	$ 19.39	9.67
Granted	69,721	6.35	
Forfeited/Cancelled	(33,380)	8.61	
Expired	(3,367)	14.77	
Outstanding at June 30, 2021	109,588	$ 14.52	8.07
Exercisable at June 30, 2021	54,539	$ 20.92	7.64

The following table details the options outstanding at June 30, 2021 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	58,316	$ 6.41	8.33	16,970	$ 6.51
$ 9.80 - 14.70	51,114	$ 13.75	8.08	37,411	$ 13.79
$ 2,800.00 - 4,200.00	158	$ 3,255.70	4.80	158	$ 3,255.70
	109,588	$ 14.52	8.21	54,539	$ 20.92

The weighted-average grant date fair value of options granted during the years ended years ended June 30, 2021 and June 30, 2020 was $3.81 and $9.68, respectively. As of June 30, 2021, there was $0.4 million of total unrecognized compensation costs adjusted for any 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 4.9 years.

Restricted Stock

On April 16, 2021, the Company granted 1,551,216 shares of restricted stock, with certain accelerated vesting conditions, to its directors pursuant to the Aytu 2015 Plan, of which 1/3 vest on April 16, 2022 and 1/12 on the first day of each quarter thereafter, subject to continuing employment with the Company through each vesting date until April 16, 2024. These restricted stocks grants have a grant date fair value of $6.49 per-share. Furthermore, on April 12, 2021, the Company granted 146,200 shares of restricted stock, with a grant date fair value of $6.84 per-share, to its employees pursuant to the Aytu 2015

Plan, of which 1/4 vested on the grant date and 1/16 each quarter thereafter on the three-month anniversary of the grant date thereafter, subject to continuing employment with the Company through each vesting date until April 12, 2024.

Restricted stock activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2019	234,623	$ 18.30
Granted	195,292	10.60
Vested	—	—
Forfeited	(11,461)	17.90
Unvested at June 30, 2020	418,454	$ 14.69
Granted	1,697,416	6.52
Vested	(160,602)	11.75
Unvested at June 30, 2021	1,955,268	$ 7.83

As of June 30, 2021, there was $13.4 million of total unrecognized compensation costs adjusted for any 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 3.6 years. The total fair value of the 160,602 restricted stocks vested during the year ended June 30, 2021 was $1.1 million.

The Company previously issued 158 shares of restricted stock outside of the Aytu 2015 Plan, which vest in July 2026. The unrecognized expense related to these shares was $1.0 million as of June 30, 2021 and is expected to be recognized over the weighted average period of 5.02 years.

Restricted Stock Units

In addition to the 35,728 RSUs that the Company assumed from the Neos 2015 Plan during the year ended June 30, 2021, on March 31, 2021, the Company granted 55,000 RSUs to a member of its management, of which 1/3 vest on April 1, 2022 and 1/12 on the first day of each quarter thereafter, subject to continuing employment with the Company through each vesting date until March 31, 2024. The grant date fair value of the RSUs was $7.60 per share. On April 8, 2021, the Company granted 13,000 RSUs, with certain accelerated vesting conditions, to its directors. The RSUs have a grant date fair value of $7.17 per-share and fully vest one year from the grant date, subject to continuing employment with the Company through April 8, 2022. The 13,000 RSUs issued to the directors, all of which were unvested, were forfeited upon the resignations of the directors.

Restricted stock units activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2020	—	$ —
Granted	103,728	6.96
Vested	(9,962)	4.99
Forfeited	(15,448)	7.00
Unvested at June 30, 2021	78,318	$ 7.20

As of June 30, 2021, there was $0.5 million of total unrecognized compensation costs adjusted for any 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 2.3 years. The total fair value of the 9,962 RSUs vested during the year ended June 30, 2021 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,	
	2021	2020
	(In thousands)	
Cost of sales	$ 16	$ —
Research and development	68	—
Selling and marketing	27	—
General and Administrative	3,463	1,079
Total stock-based compensation expense	$ 3,574	$ 1,079

The stock-based compensation expense included in the table above is attributable to stock options and restricted stock of $0.4 million and $3.2 million, respectively, for the year ended June 30, 2021. The stock-based compensation expense included in the table above is attributable to stock options and restricted stock of $0.1 million and $1.0 million, respectively, for the year ended June 30, 2020. Total recognized tax benefit from stock-based compensation was $1.2 million and $0.4 million during the year ended June 30, 2021 and June 30, 2020.

14. Warrants

In July 2020, the Company issued 92,302 shares of warrants with a weighted average exercise price of $15.99 per share in connection with the March Offerings. The warrants have a term of one year from the issuance date. These warrants have a fair value of value of $0.1 million and are classified within stockholders' equity.

On December 15, 2020, the Company issued 311,458 shares of warrants with an exercise price of $7.50 per share in connection with the December 15, 2020 offering. The warrants have a five-year term from the issuance date and expires on December 15, 2025. These warrants have a fair value of approximately $1.3 million and are classified within stockholders' equity.

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, 2019	1,621,938	$ 31.50	4.36
Warrants issued	4,462,740	12	—
Warrants exercised	(3,796,150)	—	—
Outstanding June 30, 2020	2,288,528	$ 30.26	2.00
Warrants issued	403,760	—	—
Warrants expired	(1,437,336)	—	—
Outstanding June 30, 2021	1,254,952	$ 35.85	2.83

On March 19, 2021, the remaining 1,133,920 March 19, 2020 Warrants with a weighted-average exercise price of $14.70 per share expired. There were no remaining March 19, 2020 Warrants outstanding as of June 30, 2021.

On March 11, 2021, the remaining 300,000 March 12, 2020 Warrants with a weighted-average exercise price of $12.5 per share expired. There were no remaining March 12, 2020 Warrants outstanding as of June 30, 2021.

During the year ended June 30, 2021, an additional 3,416 various other warrants expired.

As of June 30, 2021 and 2020, 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.

15. Employee Benefit Plan

The Company has a 401(k) plan that allows participants to contribute a portion of their salary, subject to eligibility requirements and annual IRS limits. The Company matches 50% of the first 6% contributed to the plan by employees. The Company's match was approximately $0.3 million and $0.2 million during the years ended June 30, 2021 and 2020, respectively.

16. Commitments and Contingencies

Commitments and contingencies are described below and summarized by the following table as of June 30, 2021:

	Total	2022	2023	2024	2025	2026	Thereafter
				(In thousands)			
Prescription database	$ 905	$ 905	$ —	$ —	$ —	$ —	$ —
Pediatric portfolio fixed payments and product Milestone	11,575	4,100	3,100	2,100	2,100	175	—
Inventory purchase commitment	1,472	1,472	—	—	—	—	—
CVR liability	12,000	2,000	5,000	5,000	—	—	—
Product contingent liability	2,700	50	—	50	—	550	2,050
Product milestone payments	3,000	3,000	—	—	—	—	—
Rumpus earn out payments	852	580	32	35	35	35	135
Other commitments	685	189	212	178	106		
Total	$ 33,189	$ 12,296	$ 8,344	$ 7,363	$ 2,241	$ 760	$ 2,185

Prescription Database

In May 2016, the Company entered into an agreement with a vendor that provides us with prescription database information. The Company agreed to pay approximately $1.6 million over three years for access to the database of prescriptions certain products. In January 2020, the Company amended the agreement and agreed to pay an additional $0.6 million to add access to the database of prescriptions written for the Pediatric Portfolio. The agreement was further amended to include all prescriptions written for the Rx Portfolio.

Pediatric Portfolio Fixed Payments and Product Milestone

The Company assumed two fixed, periodic payment obligations to an investor (the "Fixed Obligation"). Beginning November 1, 2019 through January 2021, the Company will pay monthly payments of $86,840, with a balloon payment of $15.0 million that was to be due in January 2021. A second fixed obligation requires the Company pay a minimum of $100,000 monthly through February 2026, except for $210,767 paid in January 2020.

On May 29, 2020, the Company entered into an Early Payment Agreement and Escrow Instruction (the "Early Payment Agreement") pursuant to which the Company agreed to pay $15.0 million to the investor in early satisfaction of

the Balloon Payment Obligation. The parties to the Early Payment Agreement acknowledged and agreed that the remaining fixed payments other than the Balloon Payment Obligation remain due and payable pursuant to the terms of the Agreement, and that nothing in the Early Payment Agreement alters, amends or waives any provisions or obligations in the Waiver or the Investor agreement other than as expressly set forth therein.

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 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. As a result of this, the Company recognized a loss of approximately $1.3 million during 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 make-whole payment is capped at $2.1 million each year. 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 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.

Inventory Purchase Commitment

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

CVR Liability

Upon closing the Innovus Merger, the Company entered into a CVR Agreement (see Note 4). Each CVR entitles its holder to receive its pro rata share, payable in cash or stock, at the option of the Company, of certain payment amounts if the targets are met. If any of the payment amounts is earned, they are to be paid by the end of the first quarter of the calendar year following the year in which they are earned. Multiple revenue milestones can be earned in one year.

On March 31, 2020, the Company issued to CVR holders 123,820 shares of the Company’s common stock to satisfy the $2.0 million obligation as a result of Innovus achieving the $24.0 million revenue milestone for calendar year ended December 31, 2019. As a result of this, the Company recognized a gain of approximately $0.3 million during the year ended June 30, 2020.

On March 20, 2021, the Company issued to the CVR holders approximately 103,190 shares of the Company’s common stock to satisfy one of two $1.0 million 2020 milestones, which relates to the Innovus achievement of $30.0 million in revenues during the 2020 calendar year. The $1.0 million 2020 milestone for achieving profitability was not met.

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. The discounted value as of June 30, 2021, is approximately $0.3 million.

In June 2017, Innovus entered into Exclusive License Agreement (“the Agreement”) with University of Iowa Research Foundation (“UIRD”) for the use of patent and technology know-how. Pursuant to the 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, 2021, is approximately $0.1 million.

Product Milestone Payments

In connection with its intangible assets, the Company has certain milestone payments, totaling $3.0 million, payable at a future date, are not directly tied to future sales, but upon other events certain to happen. These obligations are included in the valuation of the Company’s contingent consideration (see Note 10).

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 and Johns Hopkins, relating to AR101, which is a pivotal study-ready therapeutic 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 to Denovo and John Hopkins. 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.

Other commitments

In May 2021, the Company entered into commercial lease agreement for 6,352 square feet of office in Berwyn, Pennsylvania that commences on December 1, 2021 and ends on January 31, 2025. The initial monthly base rent was $14,300 with an approximate 2.5% increase in the base rent amount on an annual basis. On July 19, 2021, the Company and the lessor entered into an amendment, pursuant to which the parties agreed to amend the commencement date from December 1, 2021 to September 1, 2021. The Company will capitalize this lease as operating leases under ASC 842 in September 2021.

17. 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.

Aytu manages the Company and aggregated its operational and financial information in accordance with two reportable segments: Aytu BioPharma and Aytu Consumer Health. The Aytu BioPharma segment consists of the Company’s prescription products. The Aytu Consumer Health segment contains the Company’s consumer healthcare products, which was the result of the Innovus Merger. During the year ended June 30, 2021, the Aytu BioPharma

segment recognized a total impairment loss of $12.8 million related to divestiture of the Natesto licensed asset and the write-off of Tuzistra licensed asset (see Note 8).

Select financial information for these segments is as follows:

	Year Ended June 30,	
	2021	2020
	(In thousands)	
Consolidated revenue:		
Aytu BioPharma	$ 32,678	$ 17,249
Aytu Consumer Health	32,954	10,383
Consolidated revenue	$ 65,632	$ 27,632
Consolidated net loss:		
Aytu BioPharma	$ (50,529)	$ (10,464)
Aytu Consumer Health	(7,760)	(3,157)
Consolidated net loss	$ (58,289)	$ (13,621)

	June 30,	
	2021	2020
	(In thousands)	
Total assets:		
Aytu BioPharma	$ 236,449	$ 126,724
Aytu Consumer Health	29,219	26,569
Consolidated assets	$ 265,668	$ 153,293

18. Debt

The Aytu BioPharma Note. On February 27, 2020, the Company issued a $0.8 million promissory note (the "Note") and received consideration of $0.6 million. The Note had an eight-month term with principal and interest payable on November 1, 2020 and the recognition of approximately $0.2 million of debt discount related to the issuance of promissory notes. The discount is amortized over the life of the promissory notes through the fourth quarter of calendar 2020. During the year ended June 30, 2021, and June 30, 2020, the Company recorded approximately $47,000 and $0.1, respectively, of related amortization. On December 10, 2020, the Company agreed to exchange the Note for 130,081 shares of the Company's common stock in lieu of $0.8 million in cash that would otherwise have been due to satisfy this obligation on December 31, 2020. As a result of this exchange, the Company recognized a non-cash loss of approximately $0.3 million during the year ended June 30, 2021.

The Innovus Notes. On January 9, 2020, prior to the completion of the merger, Innovus Pharmaceuticals, Inc., entered into a note agreement upon which it received gross proceeds of $0.4 million with a principal amount of $0.5 million. The note required twelve equal monthly payments of approximately $45,000, and had $0.2 million outstanding as of June 30, 2020. As of June 30, 2021, the balance of the note has been paid.

The Neos Revolving Loan. On October 2, 2019, Neos entered into a senior secured credit agreement with Encina Business Credit, LLC ("Encina") as agent for the lenders (the "Loan Agreement"). Under the Loan Agreement, Encina will extend up to $25.0 million in secured revolving loans to Neos (the "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 bear variable interest through maturity at the one-month London Interbank Offered Rate ("LIBOR"), plus an applicable margin of 4.50%. In addition, Neos is required to pay 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, upon a prepayment of a loan and on the maturity date. The maturity date under the Loan Agreement is May 11, 2022.

In the event that, for any reason, all or any portion of the lender's commitment to make revolving loans is terminated prior to the scheduled maturity date, in addition to the payment of the principal amount and all unpaid accrued interest and other amounts due thereon, Neos is required to pay to the lender a prepayment fee equal to (i) 1.0% of the revolving loan commitment if such event occurs on or before October 2, 2021, and (ii) 0.5% of the revolving loan commitment if such event occurs after October 2, 2021 but before May 11, 2022. Neos may permanently terminate the revolving loan facility by prepaying all outstanding principal amounts and all unpaid accrued interest and other amounts due thereon, subject to at least five business days prior notice to the lender and the payment of a prepayment fee as described above.

The Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the Loan Agreement, including covenants and restrictions that, among other things, require Neos to satisfy certain capital expenditure and other financial covenants, and restrict Neos' ability to incur liens, incur additional indebtedness, engage in mergers and acquisitions or make asset sales without the prior written consent of the Lenders. A failure to comply with these covenants could permit the Lenders to declare Neos' obligations under the 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. Neos evaluated to determine if the embedded components in the agreement qualified as derivatives requiring separate recognition.

In connection with the closing of the Neos Merger, Neos and Encina entered into a Consent, Waiver and First Amendment to the Loan Agreement, dated as of March 19, 2021 (the "Encina Consent, Waiver and Amendment"). Pursuant to the Consent, Waiver and First Amendment, Encina (i) irrevocably waives the right to impose the default rate of interest solely to the extent resulting from the inclusion of a "going concern" qualification in the audited financial statements of Neos on a consolidated basis for the fiscal year ending December 31, 2020 (the "Specified Default), (ii) the right to impose the Default Rate of interest under Section 3.1 of the Loan Agreement, or to collect interest accruing at such Default Rate that Lenders had a lawful right to collect or apply with respect to any such Specified Default, and (iii) makes certain other modifications to the Encina Loan Agreement to reflect the consummation of the Neos Merger and the status of Neos as a wholly-owned subsidiary of Aytu, in each case subject to the terms and conditions of the Encina Consent, Waiver and Amendment.

The interest expense was $0.2 million for the period beginning March 20, 2021 and ended June 30, 2021. As of June 30, 2021, $7.9 million borrowing was outstanding under the Revolving Loan and Neos was in compliance with the covenants under the Loan Agreement as amended.

The Neos Senior Secured Credit Facility. On May 11, 2016, Neos entered into a $60.0 million senior secured credit facility (the "Facility") with Deerfield Private Design Fund III, L.P. (66 2/3% of Facility) and Deerfield Partners, L.P. (33 1/3% of Facility) (collectively, "Deerfield"). As of March 19, 2021, remaining principal on the Facility was $15.6 million, with $0.6 million due on April 11, 2021 and with a final payment of principal, interest and all other obligations under the Facility due May 11, 2022. In addition, upon the payment in full of the Obligations (whether voluntarily, in the connection with a Change of Control or an Event of Default and whether before, at the time of or after the Maturity Date), the Company shall pay to Deerfield a non-refundable exit fee in the amount of $1.0 million, which shall be due and payable in cash. Interest is due quarterly beginning in June 2021, at a rate of 12.95% per year. Borrowings under the Facility are collateralized by substantially all of Neos' assets, except assets under finance lease. If all or any of the principal are prepaid or required to be prepaid prior to December 31, 2021, then the Company shall pay, in addition to such prepayment and accrued interest thereon, a prepayment premium equal to 6.25% of the amount of principal prepaid. The terms of the Facility requires the Company to maintain cash on deposit of not less than $5.0 million.

Long-term debt consists of the following;

	June 30, 2021 (In thousands)
Neos Senior secured credit facility, due on May 11, 2022	$ 15,000
Exit fee	1,000
Unamortized premium	566
Financing leases, maturing through May 2024	282
Total debt	16,848
Less: current portion	(16,668)
Long-term debt	$ 180

In connection with the Neos Merger, Neos and Deerfield entered into a Consent, Waiver and Sixth Amendment to the Facility, dated as of March 19, 2021 (the "Deerfield Consent, Waiver and Amendment"). Pursuant to the Consent, Waiver and Sixth Amendment, Deerfield (i) consented to certain amendments to the Encina loan documents, (ii) irrevocably waive the Going Concern Conditions as described in the Deerfield Consent, Waiver and Amendment and their right to impose the default rate of interest as provided for in the Facility as of May 11, 2016, or to collect interest accruing at such default rate of interest, that the Lenders had a lawful right to collect or apply with respect to any such Event of Default for failure to satisfy such Going Concern Condition, (iii) subject the Company and its subsidiaries to certain restrictive covenants including limitations on the incurrence of debt, granting of liens and transfers of assets of the Company and its subsidiaries and (iv) makes certain other modifications to the Facility to reflect the consummation of the Neos Merger and the status of Neos as a wholly-owned subsidiary of the Company. Such modifications also include the prepayment of $15.0 million by the Company of the principal of the loan that was otherwise due on May 11, 2021 plus any accrued interest thereon through March 19, 2021, plus a make-whole payment equal to the interest that would otherwise have been due on that $15.0 million for the period beginning March 19, 2021 through May 11, 2021. The Sixth Amendment also eliminated the right of Deerfield to convert outstanding amounts of the loans into conversion shares and the right of Neos to make payments to Deerfield in the form of shares of common stock. The Company is a guarantor under the Facility.

Pursuant to the terms of the Facility, as amended, the $15.0 million principal prepayment was paid in cash on March 19, 2021, and the carrying amount of the remaining outstanding debt was $16.6 million. As the Neos Merger was accounted for as a business combination under Topic 805, Neos evaluated and determined that the fair value of the remaining outstanding debt was $17.4 million as of March 20, 2021. Accordingly, Neos recorded a premium of $0.8 million, which is the difference between carrying amount and the fair value of the debt and is being amortized into interest expense using the effective interest method over the remaining term of the debt. As of June 30, 2021, the Company was in compliance with the covenants under the Facility as amended. Total interest expense on the Facility, net of premium amortization, was $0.4 million for the period beginning March 20, 2021 and ended June 30, 2021.

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

	June 30, (In thousands)
2022	$ 16,102
2023	96
2024	84
2025	—
Thereafter	—
Future principal payments	16,282
Add unamortized premium	566
Less current portion	(16,668)
Long-term debt	$ 180

19. License Agreements

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. Under the NeuRx License, Neos made an upfront payment of $0.2 million to NeuRx upon the execution of the agreement. Neos made a payment of $0.2 million following receipt of notice of allowance of the first Licensed Patent by the United States Patent and Trademark Office ("USPTO"), as defined in the NeuRx License. Such Licensed Patent subsequently was issued by the USPTO. In April 2020, Neos met the completion of the first Pilot PK Study milestone, as defined in the NeuRx License, triggering the cash payment of $0.3 million. Neos may in the future 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.

On October 31, 2017, Neos received a paragraph IV certification from Teva Pharmaceuticals USA, Inc. ("Teva") advising Neos that Teva has filed an Abbreviated New Drug Application ("ANDA") with the FDA for a generic version of Cotempla XR-ODT, in connection with seeking to market its product prior to the expiration of patents covering Cotempla XR-ODT. On December 13, 2017, Neos filed a patent infringement lawsuit in federal district court in the District of Delaware against Teva alleging that Teva infringed Neos' Cotempla XR-ODT patents. On December 21, 2018, Neos entered into a Settlement Agreement (the "Teva Settlement Agreement") and a Licensing Agreement (the "Teva Licensing Agreement" and collectively with the Teva Settlement Agreement, the "Teva Agreement") with Teva that resolved all ongoing litigation involving Neos' Cotempla XR-ODT patents and Teva's ANDA. Under the Teva Licensing Agreement, Neos granted 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 its ANDA beginning on July 1, 2026, or earlier under certain circumstances. The Teva Licensing Agreement has been submitted to the applicable governmental agencies.

On July 25, 2016, Neos received a paragraph IV certification from Actavis Laboratories FL, Inc. ("Actavis") advising Neos that Actavis had filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. On September 1, 2016, Neos filed a patent infringement lawsuit in federal district court against Actavis alleging that Actavis infringed Neos' Adzenys XR-ODT patents. On October 17, 2017, Neos entered into a Settlement Agreement (the "Actavis Settlement Agreement") and a Licensing Agreement (the "Actavis Licensing Agreement" and collectively with the Actavis Settlement Agreement, the "Actavis Agreement") with Actavis that resolved all ongoing litigation involving Neos' Adzenys XR-ODT patents and Actavis's ANDA. Under the Actavis Licensing Agreement, Neos granted 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. The Actavis Licensing Agreement has been submitted to the applicable governmental agencies.

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 a lump sum, 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.

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.

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. Healight has demonstrated safety and efficacy in a proof-of-concept clinical study in SARS-CoV-2 patients, and the Company plans to advance this technology to further assess its safety and efficacy in additional randomized, controlled human studies, initially focused on SARS-CoV-2 patients.

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.

In April 2021, the Company acquired substantially all the assets of Rumpus. Through this transaction the Company secured exclusive global rights to AR101 from Denovo in the fields of rare genetic pediatric onset or congenital disorders outside of oncology. AR101 is a pivotal study-ready therapeutic candidate initially targeting the treatment of vEDS.

Under the terms of the transaction, the Company paid an upfront fee of $1.5 million in cash and payment of aggregated fees of $0.6 million to Denovo and John Hopkins. 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. In addition, the Company received assignments of third-party licenses from Denovo and Johns Hopkins and took over royalty obligations and performance-based milestones under these licenses.

20. Related Party Transactions

Tris Pharma, Inc.

On November 2, 2018, the Company entered into a Tris License Agreement. On November 1, 2019, the Company acquired the rights to Karbinal as a result of the acquisition of the Pediatric Portfolio from Cerecor, Inc. (See Notes 4 and 16). Mr. Ketan Mehta served as a Director on the Board of Directors of the Company, and is also the Chief Executive Officer of Tris. During the years ended June 30, 2021 and 2020, the Company paid Tris approximately $3.2 million and $1.3 million, respectively for a combination of royalty payments, inventory purchases and other payments as contractually required. The Company’s liabilities, including accrued royalties, contingent consideration and fixed payment obligations were $19.7 million and $22.9 million as of June 30, 2021 and 2020, respectively. In October 2020, the Company paid Tris approximately $1.6 million related to its Karbinal fixed payment obligation. On March 19, 2021, Mr. Ketan Mehta resigned as a Director on the Board of the Company, and Tris will no longer be considered a related party in the future.

21. Subsequent Events

On July 1, 2021, the Company and Avrio Genetics, LLC (“Avrio Genetics”) mutually agreed to terminate the Avrio agreement, effective as of June 29, 2021. In connection with the termination of the agreement, the Company

entered into a termination agreement with Avrio. Pursuant to the terms of this termination agreement, the original Avrio agreement and its amendments are terminated in their entirety, except for certain provisions that survive the termination as specified in such agreement.

Subsequent to the Avrio termination, on July 1, 2021, the Company signed an Asset Purchase Agreement (the "Asset Purchase Agreement") with UAB "Caerus Biotechnologies" ("UAB"). Pursuant to the terms and conditions of the agreement, UAB will acquire all existing intellectual property rights, technical information and know-how related to MiOXSYS as well as all existing inventory and all rights attached and related to the product and manufacturing thereof. As consideration, UAB agreed to pay the Company approximately $0.5 million and make royalty payments to the Company of five percent of net global revenue of the products for five years from the closing date of the transactions contemplated in the Asset Purchase Agreement.

[REDACTED] = Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

ASSET PURCHASE AGREEMENT

between

AYTU BIOPHARMA, INC.

and

UAB “Caerus Biotechnologies”

regarding purchase of

MiOXSYS Analyzer, MiOXSYS Sensors as well as all IP, know-how, copyrights, technical information and similar rights pertaining to MiOXSYS Analyzer and or MiOXSYS Sensors

1 July 2020

[REDACTED] = Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TABLE OF CONTENTS

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AGREEMENT ON ASSIGNMENT OF RIGHTS AND SALE OF GOODS

This Agreement on Assignment of Rights and Sale of Goods ("**Agreement**") is made and entered into as of the 1st day of July, 2021 ("**Signing Date**") by and between:

AYTU BIOPHARMA, INC., incorporated and existing under the laws of the State of Delaware, reporting file number 001-38247, registered business address 373 Inverness Parkway, Suite 206, Englewood, Colorado 80112, USA ("**Seller**"), and

UAB "Caerus Biotechnologies", incorporated and existing under the laws of Lithuania, code **305806105**, registered office address Mėnulio g. 11-101, Vilnius LT-04326, Lithuania ("**Buyer**"),

hereafter may individually be referred to as a "**Party**", or collectively as the "**Parties**".

PREAMBLE

(A) The Seller has exclusive rights (intellectual property rights, technical information, know-how and etc.) for production, manufacturing, marketing and selling of MiOXSYS Analyzer and MiOXSYS Sensors as shown in the Appendix 1 ("**Products**");

(B) Buyer is interested in acquiring and assuming the existing intellectual property rights (patents, trademarks, designs etc.), technical information and know-how related to the Products as well as existing inventory of the manufactured Products;

(C) Under the terms and conditions stipulated in this Agreement, the Seller is willing to sell and transfer to the Buyer and the Buyer is willing to purchase and take over from the Seller all rights attached and related to the Products and manufacturing thereof;

NOW, THEREFORE, in consideration of the mutual covenants herein contained, the Parties intending to be legally bound agree as follows:

1. DEFINITIONS AND INTERPRETATIONS

1.1. In addition to terms defined elsewhere in this Agreement, the following definitions shall apply throughout this Agreement, unless the context requires otherwise:

1.1.1. Affiliate	means, with respect to any individual, corporation, general partnership, limited partnership, limited liability company, trust, association, firm, organization, company, business, entity (Person), any other Person that as of the Signing Date or as of any subsequent date, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such specified Person.
1.1.2. Ancillary Agreements	has the meaning given to it under Clause 2.2.6 of this Agreement.
1.1.3. Assets	means the Patents, Trademarks, Technical Information, Other Assets and Existing Inventory and all pecuniary and

	non-pecuniary rights attached to them, including any IP Rights arising from or related to any such Assets.
1.1.4. Confidential Information	means all information of any kind or nature whatsoever, whether written or oral or whatsoever form, including, without limitation, financial information, trade secrets, customer lists, Appendixes to this Agreements and Ancillary Agreement, all information and documents related to the negotiations of the Agreement and Ancillary Agreements between the Parties and their Affiliates and other information regarding the Assets and IP Rights attached to them, which is not known to the general public.
1.1.5. Conditions Precedent	has the meaning given to it under Clause 2.2 of this Agreement.
1.1.6. Closing	means occurrence of the transactions stipulated under Clause 5.1 of this Agreement.
1.1.7. Closing Date	means the actual date when the Closing occurs, i.e. all conditions stipulated under Clause 5.1 are fulfilled.
1.1.8. Damages	means losses and damages (excluding punitive and special damages, except where payable to a third party), complaints, claims, demands, deficiencies, penalties, fines, costs, amounts paid in settlement, liabilities, obligations, taxes, liens, expenses or fees, including costs of investigation and attorneys' fees; provided, however, that for purposes of computing the amount of Damages incurred by any Person, there will be deducted an amount equal to the amount of any insurance proceeds, indemnification payments, contribution payments or reimbursements actually received by such Person or any of such Person's Affiliates in connection with such Damages or the circumstances giving rise thereto.
1.1.9. Documentation	means all documentation and information pertaining to the Assets listed in the Appendix 5, including, but not limited to, ownership (title) documents (certificates etc.).
1.1.10. Dispute	means any claim, demand, dispute, action, suit, arbitration, proceeding, investigation or other similar matter.
1.1.11. Due Diligence	means a legal, technical, financial and tax investigation of the Assets and IP Rights, Technical Information and Know-How which has commenced before the Signing Date by the Buyer and which shall conclude on the Due Diligence Date.
1.1.12. Due Diligence Date	means a day on which the Due Diligence will be considered as completed: either the 23rd day of July 2021 or the day of receipt by the Seller the Notice of Withdrawal, whichever is earlier.
1.1.13. Encumbrance	means any pledge, mortgage, lien, option, pre-emptive right, lease, commercial lease or any other right or

encumbrance or restriction to the benefit of the Seller, its Affiliate and/or any third person.

1.1.14. Existing Inventory means all inventory of existing manufactured Products owned or to be owned by the Seller on the Closing Date, in any case (i) [REDACTED] MiOXSYS Analysers, (ii) [REDACTED] MiOXSYS Sensors (iii) [REDACTED] MiOXSYS CVK, (iii) [REDACTED] MiOXSYS Socket Module Analyzer Replacement Component.

1.1.15. Good Condition with respect to the Assets, where and when applicable, means that they are approved (valid) or pending submitted in the Territory (unless disclosed by the Seller prior to Signing Date that they are denied or expired).

1.1.16. IP Rights means all intellectual property and proprietary rights of any kind, including any and all of the following in any country or region:

(i) copyrights - all copyrights, whether marked as such or not, and copyrightable works (including databases and other compilations of information, mask works and semiconductor chip rights), including all rights of authorship, use, publication, reproduction, distribution, performance, transformation, moral rights and rights of ownership of copyrightable works, and all registrations and rights to register and obtain renewals and extensions of registrations, together with all other interests accruing by reason of international copyright;

(ii) Patent Rights;

(iii) Trademark Rights; and

(iv) Trade Secrets.

IP Rights includes all rights (whether at law, in equity, by contract or otherwise) to enforce, enjoy or otherwise exploit any of the foregoing, including the rights to sue for and remedies against past, present and future infringements or misappropriations of any or all of the foregoing, and rights of priority and protection of interests therein under the laws of any jurisdiction worldwide.

1.1.17. Knowledge of the Seller shall mean the actual knowledge of the Seller and/or its management and any knowledge that would or could have been acquired by the Seller and/or its management upon reasonable inquiry and investigation.

1.1.18. Long Stop Date means the 30 September 2021.

1.1.19. Material Adverse Effect means (i) the occurrence after the Due Diligence Date of the events, circumstance, fact, change, development, condition, or effect that caused or are reasonably likely to cause an adverse effect on the Assets with individual or

aggregate (i.e. the total effect of all of the events and groups of events mentioned above) financial effect of at least [REDACTED] (fifteen thousand US dollars) compared to the respective standing before the occurrence of the Material Adverse Effect event; and/or (ii) any changes in the Good Condition of the Assets.

1.1.20. MA Manufacturer means the contract manufacturing organization (CMO) for the MiOXSYS Analyzers: [REDACTED].

1.1.21. MS Manufacturer means the contract manufacturing organization (CMO) for the MiOXSYS Sensors: [REDACTED].

1.1.22. Net Sales means the gross amounts invoiced and received by the Buyer or its Affiliates for any and all sales or transfers of any Product, less the following amounts to the extent actually incurred or paid by the Buyer or its Affiliates with respect to such sales or transfers:

(i) trade, cash and quantity discounts, charge backs, or rebates actually allowed or taken, including discounts or rebates to governmental agencies/entities; wholesalers and other distributors; pharmacies and other retailers; buying groups; health care insurance carriers; pharmacy benefit management companies; regulatory authorities; third parties associated with patient assistance programs; or managed care organizations;

(ii) credits or allowances actually given or made for rejection of, or return of previously sold Products;

(iii) any charges for insurance, freight, and other transportation costs directly related to the delivery of Product to the extent included in the gross invoiced price;

(iv) any tax, tariff, duty, or governmental charge levied on the sales, transfer, transportation or delivery of the Product (including any tax such as a value added or similar tax or government charge) borne by the seller thereof, other than franchise or income tax of any kind whatsoever; and

(v) any import or export duties or their equivalent borne by the seller;

All aforementioned deductions shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount consistent with the Buyer's or the Affiliate's (as the case may be) business practices consistently applied across its product lines and

accounting standards and verifiable based on conventional industry practices. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to Product and other products of the Buyer and its Affiliates and sublicensees such that a Product does not bear a disproportionate portion of such deductions. The transfer of the Product between or among the Buyer and its Affiliates will not be considered a sale, provided, that in the event an Affiliate is the end-user of Product, the transfer of Product to such Affiliate shall be included in the calculation of Net Sales at the average selling price charged in an arm's length sale to a third party who is not an Affiliate in the relevant period. Net Sales includes the cash consideration received on a sale and the fair market value of all non-cash consideration. Disposition of Product for, or use of the Product in, clinical trials or other scientific testing, as free samples, or under compassionate use, named patient sales, patient assistance, or test marketing programs or other similar programs or studies where the Product is supplied without charge shall not result in any Net Sales, however if the Buyer or any of its Affiliates charges for such Product, the amount billed will be included in the calculation of Net Sales.

1.1.23. Notice of Withdrawal has the meaning given to it under Clause 4.2 of the Agreement.

1.1.24. Other Assets means, in connection with the Products:

(i) any IP Rights and applications for the foregoing, in any country, supra-national organization or territory of the world;
(ii) any marketing material;
(iii) any domains owned by the Seller associated with the Products and/or oxidative stress, oxidative-reductive potential etc;
(iv) any other assets necessary for lawful production, manufacturing, marketing, distributing, and selling of Products in the Territory.

1.1.25. Patents means all patents (approved, pending, submitted) in connection with the Products as shown in the Appendix 2, including the patents registered in the name of a third party rather than the Seller.

1.1.26. Patent Rights means (A) all national, regional and international issued patents and patent applications (including provisional patent applications); (B) all patent applications filed either from the foregoing patents, patent applications or provisional applications or from an application claiming priority from or the benefit of either of these (including,

	additions, continuations, continuations-in-part, divisional, substitutions, converted provisionals, continued prosecution, reissue and re-examination applications); (C) any and all patents that have issued or in the future issue from the foregoing patent applications described in clauses (A) and (B), including utility, utility model, plant and design patents, and certificates of invention; and (D) patent revalidations, patent registrations, applications for patent registrations and any patent term extension or other action by a competent authority which provides rights beyond the original expiration date of a patent (including any supplementary protection certificates and the like), in each case with respect to the foregoing patents or patent applications described in clauses (A), (B) and (C).
1.1.27. Products	has the meaning given to it under Preamble (A) of the Agreement.
1.1.28. Purchase Price	has the meaning given to it under Clause 3.1 of this Agreement.
1.1.29. Registrable Assets	means the items, marked in Appendix 9 as registrable Assets, that will be transferred from the Seller to the Buyer prior to the Closing, to ensure occurrence of the Condition Precedent specified in Clause 2.2.2 below.
1.1.30. Seller's Account	means the Seller's bank account, account number Aytu BioPharma, Bank Name and address: [REDACTED] or other account indicated by the Seller.
1.1.31. Technical Information	any and all know-how, inventions, discoveries, unpatented and proprietary ideas, Trade Secrets, specifications, instructions, processes, formulae, materials, methods, protocols, expertise and other technology applicable to the MiOXSYS® commercial system or its manufacture (included but not limited to all documentation that collectively defines the manufacturing methods, test methods, specifications, materials, and other procedures, directions and controls associated with the manufacture and testing of MiOXSYS® commercial system), registration, use or marketing or to methods of testing components of the MiOXSYS® commercial system or processes for their manufacture, and including all biological, chemical, pharmacological, biochemical, toxicological, pharmaceutical, physical and analytical, safety, quality control, manufacturing, preclinical and clinical data, instructions, processes, formula, and expertise relating thereto. Technical Information also includes, but is not limited to:

(i) Design History file (including covenants related to Product development, manufacturing and post-marketing, information on complaints and other important issues), in the scope and content that are customary for such type of the Products and their use and would ensure that the quality and requirements for manufacturing of the Product are met in full;

(ii) Full set of relevant commercial and quality conditions required for the entry into the MS Agreement and MA Agreement on the terms, beneficial for the Buyer;

(iii) all protocols, process and results of in-house and other validation studies;

(iv) all available to the Seller protocols of published, ongoing, completed or not started clinical and other studies (all important information associated with these studies, all outstanding obligations by the Seller in relations to these studies;

(v) all regulatory submission information as list of submissions (submission dates, approval dates, certificates); list of rejected submission (dated) with the information by regulator on the reason for rejection);

(vi) all regulatory files and dossiers submitted (by country and territory), copies of key/important items of correspondence with regulators, including, but not limited to the lists of Patents and other Registrable Assets that refer to the latest date and amount of payment of applicable fees or levies, the period it covers and the next date and amount of payment;

(vii) quality management documentation, SOPs ISO and other quality related information (such as KAPAs etc), the list of registered complaints and records of action taken;

(viii) important contacts information, in the scope acceptable to the Buyer.

Technical Information is shown in the Appendix 4.

1.1.32. Territory means the entire world, i.e., all and any countries, states, and jurisdictions.

1.1.33. Trademarks means all non-registered (including well-known) and registered trademarks (approved, pending, submitted) in connection with the Products as shown in the Appendix 3.

1.1.34. Trademark Rights means all trademarks, registered trademarks, applications for registration of trademarks, service marks, registered service marks, applications for registration of service marks, trade names, registered trade names and applications for registration of trade names, service names, brand names, trade dress rights, logos, taglines, slogans, Internet domain names and Internet domain name registrations and web addresses, together with the goodwill associated with any of the foregoing; and including all intent to use any of the foregoing if not registered or subject to a pending application.

1.1.35. Trade Secrets means any trade secrets, or any confidential inventions (whether patentable or unpatentable, whether or not reduced to practice, whether or not in an invention disclosure and whether or not in writing), processes, formulae, developments, discoveries, technology, cell lines, biological materials, compounds, probes, sequences, technical information and data, software, methods, biological materials, bioassays, clones, molecules, protocols, reagents, experiments, lab results, tests, know-how, concepts, ideas, processes, research and development information and results, customer lists, supplier lists, pricing and cost information, business and marketing plans, strategies or other confidential information or materials which in the reasonable business judgment of the owner thereof have value or confer a competitive advantage to such owner due to being not generally known or not publicly disseminated.

2. SUBJECT MATTER OF THE AGREEMENT AND CONDITIONS PRECEDENT

2.1. Upon the terms and subject to the conditions set forth in this Agreement, at Closing the Seller shall sell, assign, and transfer and the Buyer shall buy, assume and acquire the Assets for the Purchase Price.

2.2. The obligation of each of the Parties to perform the Closing are subject to the following conditions precedent (the **Conditions Precedent**) being satisfied in accordance with this Clause 2.2:

2.2.1. The results of the Due Diligence reveal no material findings, and are reasonably acceptable to the Buyer; this Condition Precedent is deemed to have occurred if until the Due Diligence Date, the Seller did not receive the Notice of Withdrawal from the Buyer, as specified in Clause 4.2 below;

2.2.2. The Seller and the Buyer have concluded the transfer-acceptance deed on the transfer of title to the Registrable Assets, as required for the Seller's performance of the Condition Precedent specified in Clause 2.2.4 below;

2.2.3. the Seller has transferred (or has caused to transfer) to the Buyer all original Documentation, any documented know-how pertaining to the Products, all working process descriptions, technical drawings, blueprints, technical know-how, etc.;

2.2.4. The Seller has caused that all regulatory filings, registrations and entries are made with the respective authorities, institutions, and databases in the Territory as a result of which the Buyer's title to the Registrable Assets and all required regulatory permits to produce the Products, when applicable, are registered, at the Seller's cost, and in the manner reasonably acceptable to the Buyer; this Condition Precedent shall include:

2.2.4.1. the Seller's obligation to ensure payment of all fees, annuities, maintenance fees and other costs, fees and expenses related to maintenance and renewal of the validity and legal protection of Patents and Trademarks and any other Assets, to the extent it is applicable, and that they are duly covered, paid-up by the Seller for the period until the Closing Date or, in respect of the Patents and Trademarks, until 31 May 2022;

2.2.4.2. the Seller's obligation to ensure payment of all fees mentioned in Clause 2.2.4.1 also for all fees after the Closing Date until 31 May 2022, in order to ensure uninterrupted legal protection of Assets. Appendix 10 is a general estimate of the annuity fees to be paid, actual amount owned may be more or less, and shall not be re-charged to Buyer;

2.2.4.3. the Buyer's obligation to issue required powers of attorney or other similar supporting documentation for the Seller, in order to enable his performance of this Condition Precedent;

2.2.5. The Seller has caused that by the Closing Date the volumes of the Existing Inventory correspond to the numbers specified in Clause 1.1.14 above;

2.2.6. The Seller caused that the former engineers who worked on the Products with MA Manufacturer as well as former or current employees of MA Manufacturer liaise with the Buyer in relation to technology transfer;

2.2.7. The Seller has caused that no later than by the Long Stop Date the MS Manufacturer, the current producers of the Products, enter with the Buyer into the commercial agreements in the form attached as Appendix 6 ("**Ancillary Agreements**"), free of any Buyer's obligations or liability for the performance of the Seller's obligations towards these producers, and on the terms and conditions acceptable to the Buyer, in any case not worse than equivalent commercial agreements, currently concluded by the Seller.

2.3. No Material Adverse Effect has occurred prior to the Closing Date.

3. PURCHASE PRICE AND TERMS OF PAYMENT

3.1. The purchase price for the Assets shall be paid by the Buyer to the Seller by transferring respective funds to the Seller's Account via a bank transfer and shall consist of three parts (referred to in total as the "**Purchase Price**"):

3.1.1. fixed part ("**Fixed Part**") shall amount to [REDACTED]. The split of the Fixed Part per each item of Assets, excluding Existing Inventory, is provided in the Appendix 7, and shall be paid in accordance with the payment schedule as specified in Clause 3.2 below;

3.1.2. variable part – royalties ("**Variable Part**"), shall amount to [REDACTED] of net global revenue, equal to Net Sales of the Products per year for [REDACTED]from the Closing date, and shall be paid as specified in Clause 3.3 below;

3.1.3. fixed part for the Existing Inventory ("**Existing Inventory Part**") shall be calculated by multiplying the number of produced MiOXSYS Sensor items [REDACTED] per cost of [REDACTED] per item plus [REDACTED] margin, [REDACTED] MiOXSYS Analyzer per average cost of [REDACTED]per item, [REDACTED] MiOXSYS CVK per average cost of [REDACTED] per item, and [REDACTED]MiOXSYS Socket Module Analyzer Replacement Component per average cost of [REDACTED] shall be paid in accordance with the payment schedule as specified in Clause 3.4 below.

3.2. The Fixed Part shall be paid according to the following payment schedule:

3.2.1. [REDACTED] payable at the Signing Date;

3.2.2. [REDACTED] payable at the Closing Date;

3.2.3. 10 (ten) equal instalments amounting to [REDACTED] each, payable yearly, first instalment to be paid within 30 days following the first anniversary of the Closing Date;

3.2.4. [REDACTED] payable on the earlier of (a) the expiration of the 36 (thirty six) months' period after the Closing Date, or (b) written confirmation by the Buyer that the transfer of manufacturing of each of (i) MiOXSYS Analyzer and (i) MiOXSYS Sensors to another or additional manufacturer(s) (as the case may be) based in the European Union has been completed.

3.3. The Variable Part shall be calculated by the Buyer and paid annually within 90 days after the end of each financial year of the Buyer, ending on 31 December. Upon the Seller's request and within reasonable terms the Buyer shall provide the supporting documents of calculations of the Variable Part. The Variable Part shall be based on the annual Net Sales of Products received during the financial year of the Buyer and its Affiliates. For the year

when the Closing occurs and for the fifth year the annual revenue shall be prorated according to the number of full months that fall within the prescribed period established under Clause 3.1.2.

3.4. The Existing Inventory Part shall be calculated by the Closing Date and shall be payable quarterly in 4 (four) equal instalments each over a period of 12 months, first instalment payable within 90 days after the delivery of the Existing Inventory Part to the Buyer.

3.5. The Purchase Price is final and includes value added tax, if applicable, and all other taxes, fees and charges pertaining to the sale of the Assets.

4. DUE DILIGENCE

4.1. The Seller acknowledges that the Buyer shall be entitled to perform the Due Diligence until the Due Diligence Date and shall provide all information and documents reasonably requested by the Buyer in connection with the Due Diligence. For the avoidance of doubt, the Seller's obligation to provide information and documents shall include, but not be limited to, provision of the Documents and detailed description of Assets, including Patents and Technical Information.

4.2. If the Buyer identifies until the Due Diligence Date that any Assets are not of Good Condition and, due to that, at the Buyer's sole discretion it deems that the Buyer no longer has any interest in purchasing the Assets and rights attached to them, or if the Seller fails to provide the Buyer with the necessary information and documents required for the Due Diligence, the Buyer shall serve the Seller with a 10 (ten) days' notice of withdrawal on or before the Due Diligence Date ("**Notice of Withdrawal**") and upon maturity of which the Agreement shall be terminated, in accordance with Clause 11.1 of this Agreement.

5. CLOSING

5.1. The Parties shall take or cause to be taken all other actions which are necessary or appropriate in order to fully effect the sale of the Assets to the Buyer and for completion of this Agreement in all other respects not later than until the Long Stop Date. At the Closing the Parties shall carry out the actions listed below:

5.1.1. the Parties shall confirm that all Conditions Precedent specified in Clause 2.2 above have occurred and that the Buyer has paid the part of the Fixed Part, specified under Clause 3.2.1;

5.1.2. the Seller shall transfer to the Buyer the title to all Assets, excluding Registrable Assets, that have been already transferred to the Buyer prior to the Closing;

5.1.3. the Seller shall present to the Buyer (i) the invoice for the Fixed Part specifying the Price for each part of the Assets as provided in Appendix 7 and (ii) the invoice for the Existing Inventory Part;

5.1.4. the Buyer shall pay to the Seller the part of the Fixed Part, specified under Clause 3.2.2;

5.1.5. the Seller and the Buyer shall sign the Closing Certificate confirming that the Closing actions stipulated in this Clause 5.1 have occurred.

5.2. The Closing shall not be deemed to have occurred until all Closing actions above have been completed or waived by the respective Party.

6. NON ASSUMPTION OF EMPLOYEES

6.1. The Seller warrants that under this Agreement and the transactions contemplated herein, as of the Signing Date and the Closing Date there are no employment contracts with the Seller which must be or will be transferred to the Buyer as a result or which must be or will be transferred by virtue of the applicable law.

6.2. If after the Closing Date it appears that the Seller's representation provided in this section 6 is not true, and under the applicable law employment contracts must be transferred from the Seller to the Buyer, the Seller unconditionally undertakes to indemnify the Buyer in full and compensate all the Buyer's reasonable costs incurred and associated with any such transfers.

7. POST-CLOSING ACTIONS

7.1. As soon as practically possible but no later than within a 36 (thirty six) months period after the Closing Date (or, for the obligations specified in Clause 7.1.2.8 - 7.1.2.11 below – within a 5 (five) years period after the Closing Date):

7.1.1. the Buyer shall take all necessary actions in order to transfer all the rights and responsibilities in terms of manufacturing of each of (i) the MiOXSYS Analyzer and (ii) the MiOXSYS Sensor to another or additional (as the case may be) contract manufacturing organization chosen at the Buyer's discretion, i.e., to perform the technology transfer.

7.1.2. The Seller shall take all necessary actions and provide all necessary technical information and know-how support to make a prompt and efficient transfer of manufacturing of MiOXSYS Analyzer as established herein, including, but not limited to:

7.1.2.1. provide all reasonable support requested by the Buyer in searching and finding potential contract manufacturing organisations (**CMO**) for the Products in the European Union, which are able to manufacture the Products and have all appropriate necessary credentials, resources, authorizations and licences;

7.1.2.2. assist, provide information and consultancy in preparing the requests for proposal (RfP) for potential CMOs, establishing requirements and criteria for potential CMOs;

7.1.2.3. assist and consult the Buyer in all matters related to assessing potential CMOs and their proposals, including without limitation, all stages of due diligence; technical evaluation of CMOs proposals, provide all necessary related information and consultancy thereof;

7.1.2.4. provide all necessary support in choosing the CMOs for the Products, including, but not limited to, assistance in establishing the requirements and designs for test products for the purpose of choosing the CMOs as well as assessing and evaluating the results of the trial runs, i.e. assessing and evaluating the quality of the test products produced;

7.1.2.5. provide all reasonable assistance in negotiation with the potential CMOs regarding manufacturing of the Products;

7.1.2.6. provide full information and technical support on the first manufacturing cycle of the Products by the Buyer, to ensure quality equivalent to the quality of the current Products, and the quantity not less then 400 and release of the Products under the MS Agreement;

7.1.2.7. support and assist in any other matters not mentioned above, which are related to transferring the manufacturing of the Products;

7.1.2.8. ensure that the Seller's employees or agents will be available on a reasonable basis, for questions and trouble-shooting support to effect the successful transfer of manufacturing of the Products;

7.1.2.9. inform the Buyer within a reasonable period of time of any circumstances it becomes aware of which may have a material influence on the manufacture or safety of the Products;

7.1.2.10. provide technical guidance to the Buyer on how to achieve a smooth transition in the course of technology transfer and how to improve the manufacture technology and quality standards of the products;

7.1.2.11. assist the Buyer in establishing and maintaining Products quality testing and management procedures and processes.

7.2. Within a 5 (five) years period as of the Closing Date, at no further cost to the Buyer, the Seller shall:

7.2.1. provide all necessary support and assistance to the Buyer, instruct and train the Buyer's personnel as may be required for the proper performance of the Ancillary Agreements;

7.2.2. provide the Buyer with all information of which it has knowledge regarding legal and regulatory requirements applicable to the manufacturing, marketing and selling of the Products in the Territory,

7.2.3. instruct and assist the Buyer with regard to all legal and regulatory requirements including, but not limited to applicable laws, regulations, ordinances, regulatory guidelines and guidance which are necessary for and relate to the manufacture, marketing and selling of Products in the Territory;

7.2.4. support the Buyer, if required: with all matters related to re-certification, re-submission of applications for registration of any Patents and/or Trademarks in the Territory; with handling all IP Rights related to the Products, including preparing, filing out and filing any applications or forms regarding any changes as well as assisting with any other related regulatory filings in the Territory.

7.2.5. instruct and train the Buyer's personnel as may be required to ensure a fast and smooth transfer of the technology and know-how in connection with the Products to the Buyer as well as provide all other necessary requirements and information about current practices at the Seller in order to maintain the Products regulatory fit in the Territory.

7.3. The Seller shall provide to the Buyer the warranty for the Existing Inventory, valid for the period of 1 (one) year as of the Closing Date. During this period, the Buyer will have the option to require the Seller to replace any part of the Existing Inventory, or claim for the refund of the respective amount.

8. SELLER'S WARRANTIES

8.1. The Seller hereby warrants to the Buyer that as at the Signing Date and the Closing Date (unless a warranty is explicitly given as of another date) the following warranties are true:

8.1.1. **Title to Assets, no Encumbrances**. The Seller holds valid title to the Assets, where applicable, and transfers the sold Assets and respective IP Rights to them, where applicable, free and clear of any Encumbrances and any rights of third parties (other than Encumbrances).

8.1.2. **Unrestricted right to dispose**. The Seller is fully authorized to dispose of the Assets and has the absolute and unrestricted right and authority to execute and deliver this agreement on assignment of rights and sale of goods and to perform its obligations herein.

8.1.3. **Authorizations and approvals**. All permits, authorizations, approvals and consents necessary for conclusion, performance of this Agreement and transfer of title to Assets for the benefit of the Buyer were duly received and obtained.

8.1.4. **Charges and fees**. All fees, annuities, maintenance fees and other costs, fees and expenses related to maintenance and renewal of the Patents and Trademarks and

any other Assets, to the extent it is applicable, are paid-up by the Seller up to the Closing Date and in respect of the Patents and Trademarks shall be paid up until 31 May 2022.

8.1.5. **Documentation**. Documentation includes: all original documents pertaining to the Assets, including without limitation, all working process descriptions, technical drawings, blueprints, formulae, protocols etc. marketing material of the Products in possession of the Seller; all customer data that the Seller has available (including placements) for regulatory and quality assurance and device vigilance in connection with the Products together with copies of contracts with the customers; and any other documents or information which is necessary for the Seller to conduct the business of designing, manufacturing, distributing and selling of the Products in the Territory as currently is conducted by the Seller. The Seller did not omit any documents that may be important or required by the Buyer from submitting them to the Buyer. In case after the Signing Date the Seller has any documents or information that would have needed to be transferred to the Buyer it will do so immediately after finding of such facts.

8.1.6. **Sufficiency of the Assets**. Assets: (i) constitute all of the material properties, interests, assets and rights of the Seller and any of its Affiliates used or held for use exclusively in business of designing, manufacturing, distributing and selling of the Products in the Territory; (ii) are sufficient for the Seller to continue immediately following the Closing to conduct the business of designing, manufacturing, distributing and selling of the Products in the Territory as currently is conducted by the Seller; and (iii) includes all authorizations that are sufficient for the Buyer to continue immediately following the Closing to manufacture and market the Products in all material respects in the Territory as and to the extent the Products are currently being manufactured and marketed by Seller.

Buyer understands and acknowledges Seller is required to renew their ISO Certification on 31st October 2021 Buyer further understands and acknowledges that Seller will not take steps to renew their ISO Certification, which may have an impact on the sufficiency of the assets. It being understood, however, that ISO Certification will be valid until all Existing Inventory is manufactured and transferred from the Seller to the Buyer. Seller shall not be responsible for any costs, damages, or liability subject to this Section 8.1.6, as a result of not taking steps to renew their ISO Certification.

8.1.7. **Registered IP Rights**. Appendixes 2 and 3 sets forth a true, complete and accurate list of all the Patents (and Patent Rights), Trademarks (and Trademark Rights), owned by the Seller that concerns the Products, setting forth in each case the jurisdictions in which Patents have been issued and Patent applications have been filed and Trademarks have been registered and Trademark applications have been filed, along with the current owner, the respective application, registration or filing number.

8.1.8. **Technical Information**. Appendix 4 sets forth a true, complete and accurate list of all Technical Information with respect to the Products that are owned by the Seller and that are material to conduct the business of designing, manufacturing, distributing and selling of the Products in the Territory as currently is conducted by the Seller.

8.1.9. **Inbound licenses and rights**. There are no agreements in effect under which any third party has licensed or sublicensed (exclusively or non-exclusively), granted or conveyed to the Seller any right, title or interest in or to any IP Rights that are necessary for the development, manufacture, sale, marketing, distribution or use of any of the Products, or are otherwise material to the manufacture, marketing or sale of the Products as being conducted as of the Signing Date (In-Licensed Rights).

8.1.10. **Out-licensed rights**. The Seller has not licensed, sublicensed, granted or conveyed to any third party any right, title or interest in or to any IP Rights with respect to the Assets (Out-Licensed Rights).

8.1.11. **No outstanding orders**. To the Knowledge of the Seller, the IP Rights with respect to the Assets, to the extent applicable under legal requirements of applicable jurisdiction of the Territory are valid, subsisting and enforceable and are not subject to any outstanding writ, judgement, decree, injunction, settlement, or similar order of or approval by any competent authority (in each case, whether preliminary or final).

8.1.12. **No infringement of third-party IP Rights**. To the Knowledge of the Seller, the Products and the business of manufacturing, marketing and selling of the Products do not infringe, misappropriate or violate any valid and enforceable IP Rights of any other third parties. The Seller has not received any written charge, complaint, claim, demand, notice or other written communication from any third party alleging that it is interfering with, infringing upon, misappropriating, violating or otherwise coming into conflict with any IP Rights of such third party in connection with any of the Products or the conduct of the respective business of manufacturing, marketing and selling of the Products.

8.1.13. **Legal Proceedings**. To the Knowledge of the Seller, there is no lawsuit or other legal proceeding (including arbitration) pending or, to the Knowledge of Seller, being threatened against the Seller, or in the case of any such proceedings first arising after the date of this Agreement that would reasonably be expected to result in a Material Adverse Effect, and in each case that (a) involves the Assets and IP Rights attached to them; or (b) challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, the sale of the Assets and assignment of respective IP Rights or any of the transactions contemplated by this Agreement.

8.1.14. **No royalties**. The Seller does not have any obligations to pay any third parties any royalties, fees, commissions or other amounts for the use by the Seller of any Assets.

8.1.15. **Existing Inventory**. The Existing Inventory is merchantable and fit for the purpose for which it was procured or manufactured, and with respect to such inventory that is trade finished product inventory, and was manufactured in conformity with the specifications for the Products good manufacturing practices and legal requirements.

8.2. The Buyer does not assume any rights and obligations of the Seller under any contract belonging to the Assets. List of the contracts related to the Assets is provided as Appendix 11. To the extent a contract should be transferred by operation of law, the Seller shall indemnify the Buyer.

8.3. The Buyer does not assume any liability of the Seller. In the event of a transfer of a liability by operation of law, Seller shall indemnify and hold harmless Buyer from and against all claims of third parties relating to the liability and reimburse Buyer for all reasonable costs and expenses incurred in connection therewith to the extent such liability was incurred prior to the Closing Date.

9. PARTIES' WARRANTIES

9.1. Each Party warrants to each other that each warranty, set forth in this Clause, is true, correct, accurate and not misleading in any material respect on the Signing Date and the Closing Date:

9.1.1. the Party is a company duly incorporated and legally existing under the applicable laws and has been in continuous existence since its incorporation;

9.1.2. the Party is not subject to any reorganization (and does not take part in any reorganization of any third entity), restructuring, spin-off, transformation, insolvency, bankruptcy or liquidation;

9.1.3. the Party has the full capacity, right, power and authority (including required decisions and consents from its bodies, creditors and authorities) and has taken all actions necessary to execute and to exercise its rights and perform its obligations under this Agreement and each document to be executed at or before the Closing;

9.1.4. unless explicitly otherwise set forth in this Agreement, the Party has obtained all permits that may be required to ensure validity, enforceability, due authorization, execution and performance of the Agreement and the transaction contemplated under the Agreement, which have not been annulled or revoked;

9.1.5. the Agreement and the performance by the Party of its obligations under the Agreement and any other document or instrument executed in connection with the

Agreement will, when executed, constitute valid and binding obligations of the Party, enforceable in accordance with the respective terms;

9.1.6. there is no claim, action, suit, proceeding, arbitration, investigation or hearing, pending or threatened, by or before any authority or dispute resolution body against the Party that prevent the Party from performing its obligations under this Agreement.

10. LIABILITY

10.1. **General provisions**:

10.1.1. Subject to the terms and conditions of this Agreement, a Party shall be liable for and shall compensate in full amount the direct loss suffered by the aggrieved Party.

10.1.2. For the purposes of this Agreement, a liability which is contingent shall not constitute a loss unless and until such contingent liability becomes an actual liability and is due and payable by the aggrieved Party.

10.1.3. In the event of a claim by the aggrieved Party for the loss, the breaching Party shall have the right, exercisable upon 10 business days written notice to the aggrieved Party, to attempt to cure the breach in question during a period of 60 business days (in case the breach constitutes the failure to execute Closing – during a period of 10 business days) following the date of notice of the claim.

10.2. **Liability for failure to execute Closing**. If:

10.2.1. the Conditions Precedent are fulfilled, but the Closing does not occur until the Long Stop Date due to fault, or negligence of the Party or its' Affiliate (for the avoidance of doubt, if the Notice of Withdrawal is served by the Buyer, it shall be deemed that the Condition Precedent set out in Clause 2.2.1 is not fulfilled due to the Seller's fault, only if the Notice of Withdrawal was served due to the Seller's failure to provide required information, and due to the Buyer's fault – only if the Notice of Withdrawal was served without reasonable ground for that); or

10.2.2. the Condition Precedent set out in Clause 2.2.3- 2.2.8 above is not fulfilled until the Long Stop Date, it shall be deemed that the Condition Precedent is not fulfilled due to the Seller's fault;

a Party in breach shall pay a penalty equal to 5% of the Purchase Price (which by the agreement of the Parties is deemed just, fair, reasonable and non-questionable (undisputable) compensation of losses of the aggrieved Party) and compensate other direct losses of the aggrieved Party incurred due to the failure of the first Party to complete the transaction exceeding the aforementioned penalty.

10.3. **Seller's liability for the breach of warranties**. The aggregate liability of the Seller under this Agreement shall be limited by the amount of the Purchase Price. The limitation period

for making claims for the breach of the Seller's warranties under this Agreement shall be 36 months from the Closing Date.

10.4. If the Buyer receives notice or otherwise obtains knowledge of any dispute or any threatened dispute that may reasonably be expected to give rise to a claim against the Buyer, then the Buyer will deliver to the Seller a written notice describing such dispute in reasonable detail as soon as reasonably practicable; provided, however, that the failure to so notify the Seller shall not relieve the Seller from any liability that it may have to the Buyer, except to the extent that such failure materially prejudices the Seller's ability to defend the related dispute. The Seller will have the right, exercisable by written notice to the Buyer, at its election and at its sole expense, to assume the defence of any such Dispute with its own counsel, reasonably acceptable to the Buyer. If the Seller elects to assume the defence of any such Dispute, then:

10.4.1. the Seller will not be required to pay or otherwise indemnify the Buyer against any attorneys' fees or other expenses incurred on behalf of the Buyer in connection with such Dispute following the Seller's election to assume the defence of such Dispute other than the reasonable costs of investigation and of assistance as contemplated by this Section 10.4.1; provided, however, that if, in the opinion of outside counsel to the Buyer, it is advisable for the Buyer to be represented by separate counsel due to actual or potential conflicts of interest, the Buyer shall have the right to employ counsel to represent it and in that event the fees and expenses of such separate counsel shall be paid by the Seller;

10.4.2. the Buyer and the Seller will each make available to the other all books, records and other documents and materials that are under the control of such Party, its Affiliates, advisors and representatives that may be reasonably considered necessary or desirable for the defence of such Dispute;

10.4.3. the Buyer and the Seller will execute such documents and take such other actions as may be reasonably requested by the other for the purpose of facilitating the defence of, or any settlement, compromise or adjustment relating to, such Dispute;

10.4.4. the Buyer will otherwise fully cooperate as reasonably requested by the Seller in the defence of such Dispute; provided, however, that such actions and cooperation by the Buyer will not unduly disrupt the operations of the Buyer's business or cause the Buyer to waive any statutory or common law privileges, breach any confidentiality obligations owed to third parties or otherwise cause any confidential information of the Buyer to become public;

10.4.5. the Buyer will not admit any liability with respect to such Dispute without the Seller's prior written consent (such consent not to be unreasonably withheld, conditioned or delayed); and

10.4.6. the Seller will have the exclusive right to settle, adjust or compromise such Dispute on behalf of the Buyer on terms that: (A) the Seller may consider appropriate with

the consent of the Buyer (which consent may not be unreasonably withheld or delayed); or (B) meet all of the following conditions: (i) can be resolved by money damages alone; (ii) obligate the Seller to pay the full amount of any Damages in connection with such Dispute; and (iii) completely and unconditionally release the Buyer in connection with such Dispute.

10.5. If (i) the Seller elects not to assume the defence of such Dispute; (ii) after electing to assume the defence of a Dispute, the Seller does not timely assume and conduct the defence of such Dispute; or (iii) the Buyer reasonably determines that the Seller is not adequately representing or, because of a conflict of interest, may not adequately represent the interests of the Buyer, then the Buyer will be entitled to conduct its own defence of such Dispute at the Seller's cost and expense: provided, however, that the Buyer may not settle, adjust or compromise such Dispute without the Seller's consent (such consent not to be unreasonably withheld or delayed).

10.6. **Seller's liability for post-closing obligations**. If the Seller fails to perform any obligation specified in Section 7, the Buyer shall be entitled to suspend its payment obligations until proper discharge of the Seller's obligations. If the Seller's breach of any obligation specified in Section 7 lasts for more than 30 days, the Buyer shall be entitled to claim a penalty in the amount of [REDACTED] per each case of the Seller's breach (in case of continuous breach – one case of the Seller's breach shall be deemed as a Seller's failure to perform a specific required action during 30 days, and the new period(s) of 30 days or the Seller's failure to perform another type of action during 30 days shall constitute a new breach). The Buyer will be entitled to set-off the penalty applied under this clause against any upcoming payment obligation by the Buyer.

11. TERMINATION

11.1. **Termination before Closing**. Either Party may unilaterally without applying to the respective dispute resolving institution terminate this Agreement by a prior 10 business days' written notice to the other Party, if until the Long Stop Date the Closing has not occurred. In this case, the consequences specified in Clause 10.1-10.2 and Clause 11.2 shall apply.

11.2. **Consequences of termination before Closing**. In case of termination of the Agreement prior to Closing, the Parties will return **everything** they have received from each other, i.e. the Buyer shall return to the Seller title to all Registrable Assets, whereas the Seller shall refund the Buyer of any amounts paid by the Buyer until that day. The Parties shall take up all actions and sign any deeds, additional agreements and any other documents necessary to implement the restitution established herein. All costs associated with such restitution shall be borne by the defaulting Party (for the sake of clarity, it will always be considered that the Party initiating the termination in the manner established herein is not the defaulting Party).

11.3. **Termination after Closing**. The Agreement may be terminated unilaterally without applying to the respective dispute resolving institution by a prior 10 business days' written notice to the other Party:

11.3.1. by the Buyer:

(a) within a time period of 5 (five) years as of the Closing Date in case of failure of commercialization of the Products, i.e. if the business targets set out in the business plan attached under the Appendix 8 are not reached, by serving a written notice to the Seller;

(b) if technology transfer to the Buyer with respect to MiOXSYS Analysers fails or becomes commercially unreasonable for the Buyer; or

(c) if technology transfer to the Buyer or additional CMO with respect to MiOXSYS Sensors fails or becomes commercially unreasonable for the Buyer under the respective Ancillary Agreement.

11.3.2. by the Seller, if the payment obligations of the Buyer under this Agreement are overdue for more than 60 days.

11.4. In the cases specified in Clause 11.3, the consequences specified in Clause 10.1 and Clause 11.5 shall apply.

11.5. **Consequences of termination after Closing**. With respect to Clauses 11.3.1 (a) and (b), any payments under this Agreement made by the Buyer to the Seller up to the date of termination shall stay with the Seller (i.e. they will not have to be refunded) and, upon request of the Seller, the Assets can be transferred by the Buyer to the Seller "as is" at the moment of the termination.

12. OTHER MATTERS

12.1. **Confidentiality**. Each Party undertakes to keep confidential the terms and conditions of the Agreement and all Ancillary Agreements and not to use or disclose any Confidential Information unless (i) required to do so by law or pursuant to any order of court or other competent authority or tribunal (ii) required to do so by any applicable stock exchange regulations or the regulations of any other recognised market place (iii) such disclosure has been consented to by the other Party in writing (such consent not to be unreasonably withheld) or (iv) to its professional advisers (who are bound to such Party by a duty of confidentiality). If a Party becomes required, in circumstances described above, to disclose any information, the disclosing Party shall use its reasonable efforts to consult with the other Party prior to any such disclosure.

12.2. **Notices**. Any notice or other communication under this Agreement must be in English and in writing (which, for the purposes of this Clause, includes e-mail, but not fax) and must be addressed as set out below or to such **other** address (contact details) of the Party as may

be notified in writing (if the Party fails to inform about the change of its address, dispatch of the notice to the last known address shall be considered sufficient):

If to the Buyer:	
Attn:	Valdemaras Rodzko
Address:	Mėnulio g. 11-101, LT-04326 Vilnius, Lithuania
E-mail:	[REDACTED]
If to the Seller:	
Attn:	Joshua Disbrow
Address:	373 Inverness Parkway, Suite 206, Englewood, Colorado 80112, USA
E-mail:	[REDACTED]
w/ copy to:	
Attn:	Legal Department
Address:	373 Inverness Parkway, Suite 206, Englewood, Colorado 80112, USA
E-mail:	[REDACTED]

All notices and other communications under the Agreement shall be deemed to have been received by a Party: (a) if delivered by hand (in person) or registered post or courier – on the date of actual delivery; (b) when sent by e-mail, on the day the receiving Party confirms its receipt (the confirmation to be provided by e-mail).

12.3. **Entire Agreement**. The Agreement contains the entire understanding between the Parties hereto and **supersedes** any arrangements, understandings, promises or agreements made or existing between the Parties prior to the Agreement regarding the Agreement's subject matter.

12.4. **Assignment**. The Agreement may not be assigned by any Party without the prior written consent of the **other** Party, except that the Buyer may assign the Agreement without the Seller's consent to any of its Affiliates provided the Buyer remains jointly liable with such Affiliate for the undertakings assumed herein.

12.5. **Severability**. If any provision of the Agreement or the application of it shall be declared or deemed void, **invalid** or unenforceable in whole or in part for any reason, the Parties shall amend the Agreement to give effect to the spirit of the Agreement, so far as is possible. If the Parties fail to amend the Agreement, the provision(s) which is void, invalid or unenforceable, shall be deemed deleted and the remaining provisions of the Agreement will remain in full force and effect.

12.6. **Governing law and settlement of disputes**. This Agreement shall be governed, construed and interpreted in **accordance** with the substantive laws of the Switzerland. All disputes arising out of connection or in connection with the present Agreement, including disputes on its conclusion, binding effect, amendment and termination, shall be resolved, to the

exclusion of the ordinary courts by an Arbitral Tribunal in accordance with the International Arbitration Rules of the Zurich Chamber of Commerce.

12.7. **Good faith to implement**. The Parties shall cooperate in good faith and put best efforts and sign all necessary documents and take all necessary actions in order to achieve that all transactions provided for under the Agreement are implemented timely, properly and fully.

12.8. **Appendixes**. The appendixes and any attachments and exhibits thereto form an integral part of the Agreement and shall be construed and shall have the same full force and effect as if expressly set forth in the body of the Agreement:

Appendix 1 – Technical information sheet on MiOXSYS Sensors and MiOXSYS Analyzers;
Appendix 2 – List of Patents;
Appendix 3 – List of Trademarks;
Appendix 4 – List of Technical Information;
Appendix 5 – List of Documentation;
Appendix 6 – Form of Ancillary Agreements;
Appendix 7 – List of Assets with Prices;
Appendix 8 – Business plan (commercial targets);
Appendix 9 – List of Registrable Assets;
Appendix 10 – List of Patent Renewals;
Appendix 11 – List of Contracts related to the Assets.

The Appendices may be supplemented or amended based on the findings of the Due Diligence by Agreement of the Parties.

IN WITNESS WHEREOF, the duly authorised representatives of the Parties have executed this Agreement in 2 (two) identical counterparts in English language, each deemed to be of equal legal power and effect. Each Party shall retain 1 (one) original counterpart of the agreement.

On behalf of the Buyer:	**On behalf of the Seller**:
Full name _____	Full name _____
Title _____	Title _____
Signature _____	Signature _____

Appendix 1 - Technical information sheet on MiOXSYS Sensors and MiOXSYS Analyzers

MiOXSYS Technical Document	Document Number
[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

Appendix 2 – List of Patents

Reference #	Title	Ctry	Serial #	Filed Date	Patent #	Issue Date	Status
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5753-16-PEA	Multiple Layer Gel	EA	201491808	4/19/2013			ABANDONED

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Reference #	Title	Ctry	Serial #	Filed Date	Patent #	Issue Date	Status
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Reference #	Title	Ctry	Serial #	Filed Date	Patent #	Issue Date	Status
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Appendix 3 – List of Trademarks

Mark Name	Status	Jurisdiction	Serial Number	Class(es)	Application Date	Registration Date	Owner	Registration Number	Renewal Fee Due Date
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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Appendix 4 – List of Technical Information

Document Title	Document Number
[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
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[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]

Appendix 5 – List of Documentation

Title	Company	Category
Health Canada Medical Device	Health Canada	Regulatory
Australian Register of Therapeutic Goods (sensors and controls)	ARTG	Regulatory
Australian Register of Therapeutic Goods (analyzer)	ARTG	Regulatory
Declaration of Conformity	Aytu BioPharma	Regulatory
60601 Engineering Report	Atlas Compliance	Engineering
UL Report	UL	Engineering

Appendix 6 – Form of Ancillary Agreements

Title	Company	Category
Quality Agreement	LasX Micro Med Solutions	Manufacturing

Appendix 7 – List of Assets with Prices

The Parties agree that the Fix Price for the Assets shall be broke down as follows:

No.	Asset	Price
1.	Patents	[REDACTED]
2.	Trademarks	[REDACTED]
3.	Technical Information and Other Assets	[REDACTED]

Appendix 8 – Business plan (commercial targets)

Year	Number of MiOXSYS Sensors sold	Average Net Sales per 1 MiOXSYS Sensor
2021	[REDACTED]	[REDACTED]
2022	[REDACTED]	[REDACTED]
2023	[REDACTED]	[REDACTED]
2024	[REDACTED]	[REDACTED]
2025	[REDACTED]	[REDACTED]

Appendix 9 – List of Registrable Assets

The Registrable Assets comprise from Patents (Appendix 2) and Trademarks (Appendix 3).

Appendix 10 – List of Patent Renewals

Patents Reference #	Country Name	Entity Size	Serial #	Assignee Name	Deadlines	Cost Estimates
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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Appendix 11 – List of Contracts Related to the Assets

No.	Contract details	Territory	Contact details
1.	1 January 2016, TECOmedical AG	[REDACTED]	Attn: CEO +41619858100
2.	29 September 2016, ATL R&D. Reproductive Biology & Genetics	[REDACTED]	Attn: Scientific Director +33130480178
3.	5 January 2018, AK&KBA	[REDACTED]	
4.	17 October 2016, NAKA International Corporation	[REDACTED]	Attn: President and CFO +81425299313
5.	1 October 2018, LogixX Pharma Solutions Ltd.	[REDACTED]	Attn: Michael Close (CEO) +44(0)1189011747
6.	October 2018, Beijing Dahua Sanxin Technology Development Co., Ltd.	[REDACTED]	
7.	15 January 2019, Seeder Medical LLC	[REDACTED]	Attn: Managing Director +47444349191
8.	15 January 2020, F-G-4S	[REDACTED]	SPD Scientific (M) Sdn Bhd
9.	1 March 2020, UAB Grynumber Healrh	[REDACTED]	

Exhibit 10.80

[REDACTED] = Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

TERMINATION AGREEMENT

On January 20, 2021, **Aytu BioScience, Inc.**, now **Aytu BioPharma, Inc**., a Delaware corporation with offices at 373 Inverness Pkwy, Suite 206, Englewood, CO 80112 ("AYTU"), and **Avrio Genetics, LLC**, a Commonwealth of Pennsylvania limited liability corporation with offices at 3467 Trexler Blvd, Allentown, PA 18104 ("Licensee") entered into an Exclusive License Agreement ("Agreement") relating to the Patent Rights, Trademark Rights and Technical Information, as defined therein.

On February 4, 2021, Aytu and Licensee agreed to amend the Agreement by entering into a First Amendment to Exclusive License Agreement. On March 4, 2021, Aytu and Licensee agreed to further amend the Agreement by entering into a Second Amendment to Exclusive License Agreement.

AYTU and Licensee now wish to terminate the Agreement.

By mutual agreement, evidenced by this signed Termination Agreement, AYTU and Licensee terminate the Agreement pursuant to the terms of Section 7.2(f). The date of termination shall be: June 29, 2021.

Pursuant to the terms of the Agreement, Licensee shall pay the royalties, cost for inventory, original shipping fees, and patent fees as described in Appendix A.

Aytu shall arrange for a courier to pick up the inventory as described in Appendix B, on July 2, 2021.

Licensee acknowledges that Aytu shall assume responsibility for inventory produced by LasX, approximately [REDACTED] sensors, and Aytu acknowledges that Licensee may sell any other currently held, or returned inventory, in accordance with Section 7.3.

Both AYTU and Licensee acknowledge and agree that the terms of Sections 7.3, 7.5, 7.6 and 7.7 of the Agreement shall survive termination.

Acknowledged and agreed, effective as of the date written above:

LICENSEE:
Avrio Genetics, LLC

By: _____
Name: Brandon Hensinger
Title: CEO

AYTU:
Aytu BioPharma, Inc.

By: _____
Name: Joshua Disbrow
Title: Chief Executive Officer

[REDACTED] = Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX A
FEES DUE

AYTU BioPharma, Inc.
373 Inverness Parkway
Suite 206
Englewood, CO 80112
Phone: (720) 437-6580
Fax:

INVOICE

Invoice No.	06292021
Date	06/29/2021
Order No.	
Shipper ID	
Order Type	Invoice
Customer ID	AVRIOGENET

BILL TO:	SHIP TO:
Avrio Genetics [REDACTED]	Avrio Genetics [REDACTED]

F.O.B. POINT	SHIP VIA	ORDERED BY	CUSTOMER P.O. NO.
ORDER DATE	**TERMS**	**SALES PERSON**	**SITE**
6/29/021	[REDACTED]		HOMEOFFICE Home Office - Englewood

PART NUMBER	QTY ORDERED	UNITS	QTY SHIPPED	QTY BO	PRICE	DISC %	EXT. PRICE
00001							

- [REDACTED] for royalties
- [REDACTED] for sold inventory
- [REDACTED] for patent fees
- [REDACTED] shipping fees
- [REDACTED] Sensors

Total due: [REDACTED]

Payment schedule: Twelve (12) equal installment payments in the amount of [REDACTED] due by the 1st of each month, starting August 1, 2021. [REDACTED] late fee for any payment not received by the 3rd day of each month.

Please remit payment to:
Wells Fargo Bank N.A.
ACH Payments:
Routing: [REDACTED]
Account: [REDACTED]
Wire Payments:
Routing: [REDACTED]
Account: [REDACTED]
SWIFT/BIC Code for USD payments: [REDACTED]

Sales Total	[REDACTED]
Shipping & Handling	
Misc. Charges	[REDACTED]
Tax Total	[REDACTED]
	[REDACTED]
Less Paid Amount	[REDACTED]
TOTAL	[REDACTED]

[REDACTED] = Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit have been omitted as the registrant has determined that certain confidential information contained in this document, marked by brackets, has been omitted because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

APPENDIX B
INVENTORY TO BE REPOSSESSED

[REDACTED]

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	Nevada
4.	Novalare, Inc	Nevada
5.	Supplement Hunt, Inc.	Nevada
6.	Delta Prime Savings Club, Inc	Nevada
7.	Neos Therapeutics, Inc.	Delaware
8.	Neos Therapeutics Commercial, LLC	Delaware
9.	Neos Therapeutics Brands, LLC	Delaware
10.	Neos Therapeutics, LP	Texas
11.	PharmaFab Texas, LLC	Texas

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Aytu BioPharma, Inc. and Subsidiaries' Registration Statements on Form S-8 (File No. 333-255325,333-205462 and 333-236598), Form S-3 (File No. 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 28, 2021, relating to the fiscal year 2021 consolidated financial statements that appear in this Annual Report on Form 10-K.

/s/ Plante & Moran, PLLC

Denver, Colorado
September 28, 2021

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, 2021 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 28, 2021

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, Richard Eisenstadt, certify that:

1. I have reviewed this report on Form 10-K for the year ended June 30, 2021 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 28, 2021

By: /s/ Richard Eisenstadt
Richard Eisenstadt
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, 2021 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 28, 2021

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

I Richard Eisenstadt, 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, 2021 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 28, 2021

By: /s/ Richard Eisenstadt
Richard Eisenstadt
Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)