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, 2024

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 No.)
7900 East Union Avenue, Suite 920, Denver, Colorado	**80237**
(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(s)	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 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 (§232.405 of this chapter) 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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 13(a) of the Exchange Act. ☐

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of December 29, 2023, the aggregate market value of common stock held by non-affiliates of the registrant was $10,712,951 based on the last reported sales price of $2.84 as quoted on the Nasdaq Capital Market on such date.

As of September 16, 2024, there were 6,148,993 shares of common stock outstanding.

AYTU BIOPHARMA, INC.
FORM 10-K

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CAUTIONARY INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended June 30, 2024, ("Form 10-K" or "Annual Report"), includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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," "potential," 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 Part I, Item 1A, *Risk Factors* below and elsewhere in 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. and its wholly owned subsidiaries.*

This Form 10-K refers to registered trademarks that we currently own or license, such as Aytu, Aytu BioPharma, Aytu RxConnect, Neos Therapeutics, Adzenys, Adzenys ER, Adzenys XR-ODT, Cotempla, Cotempla XR-ODT, Karbinal, Poly-Vi-Flor and Tri-Vi-Flor, 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 following summary is further elaborated on by the full text of the risk factors provided in Part I, Item 1A, *Risk Factors* of this Annual Report. All capitalized terms in this section not defined herein shall have the meanings given to them elsewhere in this Annual Report. Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, the following:

Risks Related to Our Business and Financial Position

- We have incurred losses to date and can give no assurance of profitability.
- We have not established sources of ongoing revenue sufficient to cover operating costs.
- We may need to raise additional funding, which may not be available on acceptable terms, or at all.
- 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.
- The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.
- We are currently engaged in discussions with various parties regarding potential strategic transactions and there can be no assurance that these discussions will result in the pursuit or consummation of any potential transaction.
- We have indefinitely suspended development of our AR101 (enzastaurin) clinical development program and shifted our strategic focus towards accelerating the growth of our commercial business. If we fail to execute successfully on this reprioritized strategic focus, our business, results of operations and financial condition could be materially and adversely affected.
- We have been and, in the future, may become a defendant in one or more stockholder derivative, class-action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

Risks Related to Commercialization

- We are heavily dependent on the commercial success of our commercial products. To date, we have not generated sufficient revenues from the sales of these products to achieve companywide profitability and we may never achieve or maintain profitability.
- We rely on third parties to manufacture certain products, and third-party manufacturing risks and inefficiencies may result in costs and delays that prevent us from successfully commercializing products and adversely affect our ability to produce our products.
- If our contract manufacturer fails to manufacture our ADHD products in sufficient quantities and at acceptable quality and pricing levels, or fails 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 be unable to meet market demand, and may be unable to generate potential revenues.
- Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.
- Our financial results will depend on the acceptance among clinicians, third-party payors and the medical community of our products.

- 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 our products at a profit, our ability to sell those products and our results of operations will be harmed.

- Adzenys and Cotempla contain controlled substances, and their manufacture, use, sale, importation, exportation, prescribing and distribution are subject to regulation by the DEA.

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.

- The expiration or loss of patent protection may adversely affect our future revenues and operating results.

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

Risks Related to Our Organization, Structure and Operations

- Our efforts to expand and transform our businesses may require significant investments; if our strategies are unsuccessful, our business, results of operations and/or financial condition may be materially adversely affected.

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

- In fiscal 2024, 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.

- Our accounts receivable subjects us to credit risk.

- Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to the Company.

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

- Certain of our stockholders own a significant percentage of our stock and their interests may conflict with yours.

PART I

ITEM 1. BUSINESS

Company Overview

Aytu BioPharma, Inc. ("Aytu," the "Company," "we," "us," or "our") is a pharmaceutical company focused on commercializing novel therapeutics. The Company was originally incorporated as Rosewind Corporation on August 9, 2002, in the state of Colorado and was re-incorporated as Aytu BioScience, Inc. in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. ("Neos") in March 2021 (the "Neos Acquisition"), the Company changed its name to Aytu BioPharma, Inc. Our common stock trades on the Nasdaq Capital Market under the ticker symbol "AYTU." Our principal office is located at 7900 East Union Avenue, Suite 920, Denver, Colorado 80237, and our telephone number is (720) 437-6580.

We operate through two business segments: (i) the Rx segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers (the "Rx Segment") and (ii) the consumer health segment, which consists of various consumer healthcare products sold directly to consumers through certain e-commerce platforms (the "Consumer Health Segment").

The Rx Segment primarily consists of two product portfolios. The first consists of Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets ("Adzenys") and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets ("Cotempla") for the treatment of attention deficit hyperactivity disorder ("ADHD") (the "ADHD Portfolio"). The second consists primarily of Karbinal® ER (carbinoxamine maleate extended-release oral suspension) ("Karbinal"), an extended-release first-generation antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions, and 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 (the "Pediatric Portfolio").

The Consumer Health Segment consists of multiple consumer health products competing in large healthcare categories, including allergy, hair regrowth, diabetes support, digestive health, sexual and urological health, and general wellness, commercialized through direct mail and e-commerce marketing channels. To date, the Consumer Health Segment has generated negative cash flows. We began to wind down the Consumer Health Segment in fiscal 2024. During the first quarter of fiscal 2025, we completed the wind down of operations and entered into a definitive agreement to divest the Consumer Health Segment to a private, e-commerce focused company (the "Consumer Health Divestiture"). The divested business encompasses the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for us to receive up to $0.5 million of revenue-based royalty payments on future sales of former Consumer Health Segment products. We expect the savings realized from the strategic shift away from the Consumer Health business, coupled with incremental margin improvements expected from the previously announced closure of our Grand Prairie, Texas manufacturing site, to significantly enhance our operating results and drive stockholder value.

We have incurred significant losses in each year since inception. Our net loss was $15.8 million for the year ended June 30, 2024, and as of June 30, 2024, we had an accumulated deficit of $320.0 million. We expect to continue to incur significant expenses in connection with our ongoing activities, although we do expect to become profitable through the continued growth of our commercial business.

In light of our own business activities and external developments in the biotechnology and biopharmaceutical industries, Aytu management and our board of directors (the "Board" or the "Board of Directors") regularly reviews our performance, prospects and risks such as the potential impact to our business resulting from the Company's competitive landscape (i.e., entry of generic competitors, payer pressures, new branded entrants, etc.). These reviews have included consideration of potential partnerships, collaborations, and other strategic transactions such as acquisitions or divestitures of programs or technology to enhance stockholder value. Aytu's management and Board continues to evaluate potential strategic transactions and business combinations.

Recent Business Development

As part of our ongoing strategic evaluation and go-forward operating plan, we continue to prioritize growing our Rx Segment given the encouraging prescription trends for our ADHD Portfolio and the current market trends supporting our products' growth. We believe focusing resources on our most profitable, growing products provides the most effective pathway to achieve companywide profitability and continued growth. As part of our plan, we began winding down the Consumer Health Segment in fiscal 2024 and completed the wind down of operations and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025.

For fiscal 2024, our Rx Segment recorded net revenue of $65.2 million. During the year, the ADHD market continued to encounter several supply chain interruptions, causing a shortage of medications for patients receiving stimulant prescriptions for the treatment of ADHD. We were able to continue to increase the production of our ADHD medications, Adzenys and Cotempla, to provide patients with alternative solutions to products that have experienced supply interruptions. As a result, we recorded the highest prescription levels for both Adzenys and Cotempla during fiscal 2024, resulting in $57.8 million of net revenue for our ADHD Portfolio, the highest achieved in our history. We saw a reduction in net revenue from our Pediatric Portfolio products, largely due to payor changes impacting coverage and recusing prescriptions.

To reduce the costs associated with the manufacture of Adzenys and Cotempla we transferred the manufacturing of these products to a United States-based third-party manufacturer in the fourth quarter of fiscal 2024. Prior to this, we manufactured these products in our facility in Grand Prairie, Texas.

As an additional result of focusing on building the portfolio of revenue-generating products and generating profitability, in fiscal 2023 we indefinitely suspended active development of our clinical development programs including AR101 (enzastaurin) and terminated our license agreements relating to Healight and NT0502 (N-desethyloxybutynin). AR101 is a development-stage asset we had been developing as an investigational treatment for Vascular Ehlers-Danlos Syndrome ("VEDS"), a rare connective tissue disorder for which there are no approved treatments. AR101 has received Orphan Drug Designation from both the United States Food and Drug Administration ("FDA") and from the European Commission, thus making AR101 eligible for market exclusivity upon product approval. AR101 also received Fast Track Designation from the FDA given the urgent, unmet need in VEDS. We do not expect the development of AR101 to advance until we are able to either fund development through operating cash flows, or through an out-license or sale to a strategic partner as we focus our resources on our commercial operations.

Debt and Equity Financings

Eclipse Agreement

In June 2024, we and certain of our subsidiaries entered into a Consent, Joinder and Amendment No. 5 (the "Eclipse Amendment No. 5") to the loan and security agreement dated October 2, 2019, as amended by Amendment No. 1, dated March 19, 2021, Amendment No. 2, dated January 26, 2022, Amendment No. 3, dated June 1, 2022, Amendment No. 4 dated March 24, 2023, and the Eclipse Amendment No. 5 (together the "Eclipse Agreement") with Eclipse Business Capital LLC ("Eclipse"), as agent, and the lenders party thereto (agent and such lenders, collectively, the "Eclipse Lender"). Under the Eclipse Amendment No. 5, we have two loan agreements, a term loan (the "Eclipse Term Loan") and a revolving credit facility (the "Eclipse Revolving Loan").

The Eclipse Term Loan consists of a principal amount of $13.0 million, at an interest rate of the secured overnight financing rate as administered by the SOFR Administrator ("SOFR") plus 7.0%, with a four-year term and a straight-line loan amortization period of seven years, which would provide for a loan balance at the end of the four-year term of $5.6 million to be repaid on June 12, 2028, the maturity date. We used the proceeds of the Eclipse Term Loan and a portion of the proceeds from warrant exercises described below to repay in full a $15.0 million term loan.

The Eclipse Revolving Loan allows us to borrow up to $14.5 million at an interest rate of SOFR plus 4.5%. In addition, we are required to pay an unused line fee of 0.5% of the average unused portion of the maximum Eclipse Revolving Loan amount during the immediately preceding month. The ability to make borrowings and obtain advances of the Eclipse Revolving Loan remains subject to a borrowing base and reserve, and availability blockage requirements and the maturity date, as amended, is June 12, 2028.

Equity Financings

In June 2023, we raised gross proceeds of $4.0 million from the issuance of (i) 1,743,695 shares of our common stock, and (ii) in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 430,217 shares of common stock (the "June 2023 Pre-Funded Warrants") and (iii), accompanying Tranche A warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche A Warrants"), (iv) and accompanying Tranche B warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche B Warrants"). We received $3.4 million in proceeds net of underwriting fees and other expenses.

In June 2024, the Tranche B Warrants were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of common stock and 1,806,434 "pre-funded" warrants to purchase shares of common stock with an exercise price of $0.0001 per share (the "Tranche B Pre-Funded Warrants"). We used a portion of these proceeds as part of the $15.0 million term loan repayment described above.

Commercial Business Overview

We operate through two business segments (i) the Rx Segment, consisting of various prescription pharmaceutical products sold through third parties, and (ii) the Consumer Health Segment, which consists of various consumer health products sold directly to consumers. We completed the wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025. We generate revenue by selling our products through third party intermediaries in our marketing channels as well as directly to our customers. We transitioned the manufacturing of our ADHD products to a third-party manufacturer during the fourth quarter of fiscal 2024 and continue to use third party manufacturers for all other products.

Rx Segment

Our Rx Segment consists of our ADHD Portfolio and our Pediatric Portfolio. Our prescription products are sold primarily in the United States and are distributed through multiple channels, including sales to pharmaceutical wholesalers, distributors and pharmacies, using third-party logistics enterprises.

Our ADHD products are extended-release ("XR") medications formulated in patient-friendly, orally disintegrating tablets ("ODT") that utilize the internally developed microparticle modified-release drug delivery technology platform. Products containing amphetamine or methylphenidate are the most commonly prescribed medications in the United States for the treatment of ADHD. Adzenys (for patients six years of age and above) and Cotempla (for patients six to seventeen years of age) are the first and only FDA-approved amphetamine and methylphenidate extended-release, orally disintegrating tablets, respectively, for the treatment of ADHD.

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

We commercialize our Rx Portfolio through our internal commercial organization that includes approximately forty sales territories for our ADHD Portfolio and approximately five sales territories for our Pediatric Portfolio.

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

In July 2023, we entered into an exclusive collaboration, distribution and supply agreement with Medomie Pharma Ltd ("Medomie"), a privately owned pharmaceutical company, for Medomie to sell Adzenys and Cotempla in Israel and the Palestinian Authority. We will supply Adzenys and Cotempla to Medomie, who will be responsible for seeking local regulatory approvals and marketing authorizations for each product. This agreement represents Aytu's first international commercial agreement for Adzenys and Cotempla.

Consumer Health Segment

Our Consumer Health Segment was dedicated to commercializing safe and effective "over-the-counter" ("OTC") medicines, personal care products, and dietary supplements to improve health and vitality. Our core products competed in categories such as hair loss, digestive health, urological health, diabetes management, and allergy.

The Consumer Health Segment sold directly to consumers primarily in the United States through e-commerce platforms, including branded websites and Amazon.com, which utilized marketing strategies focused on search engine optimization, search marketing and affiliate marketing. Additionally, the segment sold products through direct mail solicitations and advertisements, allowing consumers to purchase directly through business reply mail, through call centers, or online with shipment directly to their homes.

In fiscal 2023, we announced we would wind down the Consumer Health Segment. We completed the wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025.

Development Portfolio – AR101

In April 2021, we entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, and Rumpus Vascular, LLC (together "Rumpus") pursuant to which we acquired commercial global licenses, relating primarily to the pediatric-onset rare disease development asset enzastaurin, or AR101. AR101 is initially being developed for the treatment of VEDS with the potential to treat other connective tissue disorder diseases such as Marfan's syndrome.

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. Harry "Hal" C. Dietz III, M.D. developed the first preclinical model that mimics the human condition and recapitulates VEDS, and this model serves as the basis for the plausible clinical benefit and rationale for conducting a clinical trial with AR101 in VEDS. This novel knock-in mouse 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 VEDS-related vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that vascular structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high-throughput RNA sequencing of the aorta displayed a molecular signature for excessive PKC/ERK cell signaling that is the purported driver of disease. PKC inhibitors proved efficacious in multiple pre-clinical and murine models and indeed prevented death due to vascular rupture.

We have secured exclusive global rights to AR101 in the field of connective tissue disorders with the initial license covering VEDS. AR101 is protected by a suite of pending patents being pursued in major markets globally which have been licensed from The Johns Hopkins University ("Johns Hopkins") and have an earliest priority date of March 2017. In December 2021, the FDA granted Orphan Drug Designation ("ODD") to AR101 for the treatment of EDS, inclusive of VEDS, allowing for seven years of marketing exclusivity in the United States. The FDA has cleared the IND application for AR101, although, we do not expect to advance development of AR101 until we are able to either fund development through operating cash flows or through an out-license or sale to a strategic partner.

Strategy

Our goal is to become a leading pharmaceutical company that improves the lives of patients. We will do this by employing a focused approach of in-licensing, acquiring, developing, and commercializing novel prescription therapeutics. Our primary focus is on commercializing innovative prescription products that address conditions frequently developed or diagnosed in childhood, including ADHD.

Our strategic priorities are to continue to increase revenues from our Rx Segment and enhance our financial performance through operational and manufacturing efficiencies and portfolio prioritization. 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 brands, which consist primarily of Adzenys, Cotempla, Karbinal, 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 increase prescribing our medicines;

- leverage our novel Aytu RxConnect patient support platform, which is designed to reduce access barriers to medicines facing patients and HCPs by providing coverage for all commercially insured patients, regardless of their individual insurance plan, thus establishing an affordable and predictable monthly co-pay for patients, and eliminating many of the hassles facing HCPs and their staffs by improving availability of Aytu products at participating pharmacies; and

- improve gross margins for our ADHD product franchise through the manufacturing transfer of Adzenys and Cotempla to a contract manufacturing organization, a transition that was completed in the fourth quarter of fiscal 2024.

We believe our history of acquiring companies and in-licensing and acquiring products and pipeline assets, along with our success in building out commercial organizations and executing product growth strategies, is a distinct competitive advantage. Our transactional adeptness and execution orientation enable us to continue to seek growth opportunities through both organic growth and opportunistic in-licensing or strategic acquisitions. Further, our commercial infrastructure and advanced analytics capability is scalable and lends itself to additional on-market assets and future product candidates that fit within our commercial capabilities and infrastructure. 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.

Products and Markets

Prescription Products: ADHD Portfolio

ADHD Market and Treatment Options

ADHD is a neurobehavioral disorder characterized by a persistent pattern of inattention and/or hyperactivity/impulsivity that interferes with functioning and/or development. ADHD can have a profound impact on an individual's life, causing disruption at school, work, home and in relationships. It is one of the most common developmental disorders in children and often persists into adulthood. The Centers for Disease Control and Prevention ("CDC") reported that six million children in the United States ages 3 to 17 had previously received an ADHD diagnosis between 2016-2019, up 36% since 2003. Current ADHD treatment guidelines recommend a multi-faceted approach that uses medications in conjunction with behavioral interventions.

In 2023, approximately 96.0 million prescriptions for medications with ADHD labeling were written in the United States, generating $27.4 billion in sales. Approximately 89% of these prescriptions were for stimulant medications, such as amphetamine and methylphenidate, which are and have remained the standard of care for several decades. 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 59% of ADHD prescriptions. The most prescribed extended-release medications for ADHD, Adderall XR® and Concerta® (and each of their generic equivalents), are long-acting versions of previously short-acting amphetamine and methylphenidate 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 based upon our internally developed proprietary microparticle delivery technology and are the only approved extended-release orally disintegrating tablet formulations of amphetamine and methylphenidate for the treatment of ADHD.

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:

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

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

- A non-stimulant treatment for ADHD was approved by the FDA and commercially launched by Supernus in the United States in 2021 is being sold under the brand name Qelbree®. Other branded and generic non-stimulant treatments remain available in the United States but are no longer promoted.

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 Cingulate Therapeutics, NLS Pharma, Tris Pharma and Neurovance, a subsidiary of Otsuka Pharmaceutical Co., Ltd.

ADHD Product Portfolio Overview

Our modified-release drug delivery technology platform has enabled us to create extended-release 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 and Cotempla are the first and only XR-ODT products for the treatment of ADHD. These XR-ODT products offer unique attributes to ADHD patients and caregivers, including:

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

- taste-masking of bitter ADHD medications, with pleasant-tasting flavor; and

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

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

Adzenys is approved by the FDA for the treatment of ADHD in patients six years and older and is the first FDA-approved amphetamine XR-ODT for the treatment of ADHD. The New Drug Application ("NDA") for Adzenys relies on the efficacy and safety data that formed the basis of FDA approval for the reference listed drug, Adderall XR, 30 mg, together with bioequivalence, bioavailability, and aggregate safety data from the Adzenys clinical program. Adzenys 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 tableting excipients using our patented Rapidly Disintegrating Ionic Masking ("RDIM") technology. The result is amphetamine with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth without the need for water. Adzenys is available in 30-day supply, child-resistant blister packs.

The suite of composition-of-matter patents for Adzenys are scheduled to expire in 2026 and 2032. These patents are listed in the FDA's publication of approved drug products with therapeutic equivalence evaluations (the "Orange Book"). In addition, we entered into a settlement agreement with Actavis Laboratories FL, Inc. ("Actavis") (acquired by Teva Pharmaceutical Industries), which resolved all ongoing litigation involving Adzenys patents and Actavis' ANDA with the FDA for a generic version of Adzenys. Under the agreement with Actavis, Actavis has the right to manufacture and market its approved generic version of Adzenys under the ANDA beginning on September 1, 2025, or earlier under certain circumstances.

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

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

The FDA approved Cotempla for the treatment of ADHD in patients six to seventeen years old. The Cotempla NDA relies on the efficacy and safety data that formed the basis of FDA approval for the reference listed drug, Metadate CD®, together with bioavailability/bioequivalence data and efficacy/safety data from the Cotempla clinical program. The results of the Cotempla Phase 3 clinical efficacy and safety trial showed a statistically significant improvement in ADHD symptom control compared to placebo across the school 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 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 tableting excipients using our RDIM technology. The result is methylphenidate with an *in vivo* extended-release profile delivered through a tablet that quickly disintegrates in the mouth. Cotempla is available in 30-day supply, child-resistant blister packs. Cotempla is the first FDA-approved methylphenidate XR-ODT for the treatment of ADHD.

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

In conjunction with the approval of the Cotempla NDA, the FDA required us to perform additional clinical studies in preschool (age four to five years) children with ADHD as a post-marketing requirement. A pharmacokinetic study in this population was completed in 2019. In light of a new draft guidance for industry that was published in May 2019, "Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment Guidance for Industry," we remain in discussions with the FDA to gain concurrence on the design of the protocols required to meet the remaining post-marketing requirements.

Prescription Products: Pediatric Portfolio

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

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

More than 100 million people in the United States experience various types of allergies each year. Allergic conditions are one of the most common health issues affecting children in the United States. Numerous allergy treatments exist to address allergies and allergic symptoms depending upon the symptom(s). Oral antihistamines are considered a mainstay of allergy treatment, and the prescription antihistamine market is a large category with approximately 54 million antihistamine prescriptions written in 2023. The prescription antihistamine category is dominated by generic products and consists of first-generation and second-generation molecules. Generally, first-generation antihistamines block both histaminic and muscarinic receptors and pass the blood-brain barrier. Second-generation antihistamines mainly block histaminic receptors, but they do not pass the blood-brain barrier. First-generation antihistamines, which are generally characterized as more sedating, accounted for 6% of 2023 total prescriptions, while non-sedating, second-generation antihistamines accounted for 94% of total prescriptions. The most widely prescribed oral, second-generation antihistamines are cetirizine (brand name Zyrtec®) and loratadine (brand name Claritin®). Diphenhydramine (brand name Benadryl®) is the most widely prescribed first-generation molecule.

Karbinal is the only FDA-approved, 12-hour carbinoxamine oral suspension and is an effective antihistamine with a broad range of indications. Karbinal 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 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 is indicated for children as young as two years of age. Karbinal has a pleasant strawberry-banana taste and is available in 480 mL bottles.

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

Two core patents protect Karbinal in the United States, and both patents 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.

Along with second-generation prescription oral antihistamines, Karbinal also faces competition from OTC products such as non-sedating antihistamines, sedating antihistamines as well as nasal steroids, nasal antihistamines, and anticholinergics.

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

Poly-Vi-Flor and Tri-Vi-Flor are two complementary prescription fluoride-based supplement product lines containing combinations of vitamins and sodium fluoride in various oral formulations. These prescription supplements are prescribed for infants and children to treat or prevent fluoride deficiency due to poor diet or low levels of fluoride in drinking water and other sources while also providing multi-vitamin support and folic acid supplementation. Because these products contain at least .25 mg of sodium fluoride, Poly-Vi-Flor and Tri-Vi-Flor are classified as products that should be administered under the supervision of a licensed prescriber.

Fluoride supplementation has been proven to protect teeth from decay. Community water fluoridation prevents tooth decay by providing frequent and consistent contact with low levels of fluoride. By keeping the teeth strong and solid, fluoride stops cavities from forming and can rebuild the tooth's surface. Community water fluoridation began in the United States in 1945 and 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, Americans living in municipalities that do not fluoridate the water supply or in rural areas that rely on well water supplies frequently do not receive recommended levels of fluoride through fluoridation. Therefore, many children living in these areas 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 easier-to-take multi-vitamin drops while older children are prescribed tablet formulations.

In 2023, 7.1 million multi-vitamin prescriptions were written in the United States. Of those prescriptions, multi-vitamins containing sodium fluoride accounted for 0.9 million total prescriptions. Common multi-vitamin combinations contain vitamins A, B, C, D and E, but no other prescription pediatric multi-vitamin products contain Metafolin, which makes the Poly-Vi-Flor and Tri-Vi-Flor product lines distinct, single-source brands. Other brands include Tri-Vite (marketed by Method Pharmaceuticals), Floriva (marketed by BonGeo Pharmaceuticals) and Quflora (marketed by Carwin Pharmaceutical Associates).

Poly-Vi-Flor is available in both chewable tablet and oral liquid suspension multivitamin formulations in six different product presentations: Poly-Vi-Flor Chewable Tablets .25 mg, .50 mg, and 1 mg tablets, Poly-Vi-Flor Chewable Tablets with Iron, Poly-Vi-Flor Oral Suspension and Poly-Vi-Flor Oral Suspension with Iron. Poly-Vi-Flor contains Vitamin A, Vitamins 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 and licensed from Merck & Cie ("Merck"). Beginning in the second half of fiscal 2023, we introduced Poly-Vi-Flor and Tri-Vi-Flor containing Arcofolin, Arcofolin offers an improved profile over Metafolin as a body ready L-methylfolate. Arcofolin's low water content and low molecular weight of the counterion yield higher levels of assayed folate than other forms of L-methylfolate currently available on the market. It also has an improved purity profile, enhanced water solubility and an excellent overall stability profile. The addition of Arcofolin also broadens the brands' IP protection and extends the patent life and provides further differentiation with this novel ingredient.

Tri-Vi-Flor is available as an oral liquid suspension (.25 mg fluoride) containing Vitamin A, Vitamin C, Vitamin D3, Sodium Fluoride, Sodium Benzoate and L-methylfolate. By virtue of its L-methylfolate content, Tri-Vi-Flor offers a similar clinical profile: a fluoride-based multivitamin containing a proprietary, body-ready L-methylfolate.

Arcofolin®, which we also licensed exclusively in our field of use, is Merck's manufactured calcium salt of L-5-methyltetrahydrofolic or L-methylfolate. Arcofolin 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 caused 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 patients may have at least one MTHFR genetic mutation while 40% may have two mutations. These mutations lead to impaired function of the enzyme and result in folate deficiency. Both Arcofolin and Metafolin are unaffected by the MTHFR mutation, thereby directly delivering bioavailable L-methylfolate, and offering a distinct clinical advantage over other folic acid supplements.

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

The prescription multi-vitamin market is dominated by generic products, with brands accounting for 12.3% of the multivitamin plus fluoride market for the calendar year ending December 31, 2023. Poly-Vi-Flor and Tri-Vi-Flor primarily compete in the generic prescription multi-vitamin fluoride market and with the branded products FLORIVA and QFLORA.

Manufacturing

ADHD Product Portfolio

During fiscal 2024 we completed the process of transferring the manufacturing of our ADHD products to a United States-based contract manufacturing organization ("CMO"). The transfer of the manufacturing of pharmaceutical products required several steps including knowledge and method transfer, manufacturing of materials for feasibility studies and confirmation batch materials, bioequivalence studies, inspections from regulatory agencies, and regulatory filings. We completed the required steps, including the successful completion of bioequivalence studies, which were required in order to enable the transfer of both Adzenys and Cotempla. Our CMO started manufacturing both Adzenys and Cotempla during the third quarter of the 2024 fiscal year and will manufacture all of our ADHD products going forward. We are responsible for supplying the active pharmaceutical ingredients for the ADHD products to our CMO. Our CMO is responsible for manufacturing the products, conducting quality control, quality assurance, validation activities, stability testing, packaging and providing related services for the manufacture of the products. We are required to purchase all of our ADHD products from them, with certain exceptions. Our agreement with this CMO has an initial term beginning in November 2023, and ending in November 2028, and automatically renews after the initial term for successive terms of three years, with certain termination rights for both parties as outlined in the agreement

Pediatric Product Portfolio

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

- Karbinal is purchased through a supply agreement with Tris. This agreement terminates in August 2033, subject to earlier termination or extension in accordance with the terms of the agreement.

- Poly-Vi-Flor and Tri-Vi-Flor drops are purchased through supply agreements with CMOs based in the United States. Merck & Cie is responsible for providing Metafolin and Arcofolin to our designated CMO.

We believe the third-party manufacturers have adequate capacity to manufacture sufficient quantities of our products to meet anticipated commercial demands. As we rely on CMOs, we continue to employ personnel with extensive technical, manufacturing, supply chain management, 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.

Research and Development

We have indefinitely suspended product candidate research and development activities in order to focus our resources on our commercialization efforts. Due to the suspension of product candidate research and development, the development of AR101, our lead product candidate, is on indefinite hold. We are pursuing strategic partnerships in order to advance this program but can make no assurance that a partnership will be consummated.

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 in September 2014 following Lilly's discontinuation of the enzastaurin development program.

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

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

In fiscal 2022 we received Orphan Drug Designation for AR101 in Ehlers-Danlos Syndrome including VEDS and in Europe, allowing for seven years' marketing exclusivity in the United States and ten years in Europe. We also received Fast Track designation for AR101 in VEDS by the FDA, allowing for an accelerated review timeline upon submission of the New Drug Application ("NDA") and more frequent interaction with the FDA during the development process.

AR101 is protected by a suite of five pending patents being pursued in major markets globally which have been licensed from Johns Hopkins and have an earliest priority date of March 2017. The cornerstone of the intellectual property family surrounds enzastaurin initially targeting the treatment of VEDS focused on the United States 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 2018. The second 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 2017, in select geographies. The third pending patent, titled "Targeted Epigenetic Therapy for Inherited Aortic Aneurysm Conditions," broadens the coverage of the potential therapeutic application of AR101/Enzastaurin and has a priority date of September 2017. The fourth pending patent, titled "Pathway Targets for the Treatment of Vascular Ehlers-Danlos Syndrome", and the fifth pending patent, titled "Endothelin-1 Signaling Contributes to Vascular Rupture Risk", deepens the scientific evidence of the pathophysiology of Vascular Ehlers-Danlos Syndrome and are highly confirmatory of the therapeutic approach for AR101/Enzastaurin. These pending patents have priority dates of September 2020 and February 2022 respectively. Additional molecule specific 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.

Intellectual Property

We seek trademark protection in the United States when appropriate. We currently own or license registered trademarks for Aytu, Aytu BioPharma, Aytu RxConnect, Neos Therapeutics, Adzenys, Adzenys ER, Adzenys XR-ODT, Cotempla, Cotempla XR-ODT, Karbinal, Poly-Vi-Flor and Tri-Vi-Flor in the United States, as well as trademarks related to our DTRS technology.

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

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The FDCA and the FDA's implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record-keeping, reporting, distribution, import, export, sale, advertising and promotion of our products and product candidates. We may seek approval for, and market, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, 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 United States. NDAs in the case of new drugs may require extensive studies and submission of a large amount of data by the applicant, including the following:

Preclinical Testing

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

Clinical Trials

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

- Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.

- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product's effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects ("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 primary basis on which the FDA evaluates a drug's safety and effectiveness when considering the product application.

Post-Approval Regulation

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

DEA Regulation

Our ADHD products are considered a "controlled substance" as defined in the Controlled Substances Act of 1970, or CSA, because Adzenys contains amphetamine and Cotempla contains methylphenidate. Because amphetamine and methylphenidate are Schedule II controlled substances, the DEA has Adzenys and Cotempla listed and regulated as Schedule II controlled substances. None of our pediatric products (Karbinal, Poly-Vi-Flor and Tri-Vi-Flor) are considered "controlled substances."

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in and/or imported into the United States-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 manufacturers' quotas of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our manufacturers' quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations.

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 September 16, 2024, we employed 102 employees, of which 99 were full-time employees. Of our 102 employees, 14 are involved in operations, 58 are involved in commercialization and 30 are involved in general and administrative activities. All of our colleagues are located in the United States. Of these colleagues, 50% are female and 50% are male. Our colleagues are not represented by a labor union.

Our values – team-oriented, hard-working, relentlessly determined, integrity, visionary, entrepreneurial, and servant-minded – are built on the foundation that the colleagues we hire and the way we treat one another promote innovation, and high 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.

Available Information

Our principal executive offices are located at 7900 East Union Avenue, Suite 920, Denver, Colorado 80237, and our phone number is (720) 437-6580.

We maintain a website on the internet at *https://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 United States Securities and Exchange Commission ("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 or incorporated into any other filings we make with the SEC. In addition, the public may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C., 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330.

Code of Ethics

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

ITEM 1A. RISK FACTORS

Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in this Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our securities to decline and could cause you to lose all or part of your investment.

Risks Related to Our Business and Financial Position

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

We have incurred losses in each year since our inception. Our net loss for the years ended June 30, 2024, and 2023, was $15.8 million and $17.1 million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date. Even though we expect to have revenue growth in the next several fiscal years, it is uncertain that the revenue growth will be significant enough to offset our expenses and generate a profit in the future. Potential investors should evaluate us in light of the expenses, delays, uncertainties, and complications typically encountered by healthcare businesses, many of which will be beyond our control. These risks include the following:

- uncertain market acceptance of our products;
- difficulties in maintaining coverage and reimbursement for our products;
- lack of sufficient capital;
- United States and foreign regulatory approval of our products;
- unanticipated problems, delays, and expense relating to product development and implementation;
- lack of sufficient intellectual property;
- the ability to attract and retain qualified employees;
- the introduction of generic competition;
- competition; and
- technological changes.

As a result of 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 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, we must succeed, either alone or with others, in a range of challenging activities, including expanding markets for our existing products, manufacturing, marketing and selling our existing products, satisfying any post-marketing requirements, and obtaining reimbursement for our products from private insurance or government payors. We, and our collaborators, as applicable, may not be successful in these activities and, even if we or our collaborators do, we may never generate revenues that are sufficient to achieve profitability.

We have not established sources of ongoing revenue sufficient to cover operating costs.

Since our inception, we have had significant operating losses. As of June 30, 2024, we had accumulated deficit of $320.0 million. Even though during fiscal 2024 we mitigated the conditions that gave rise to substantial doubt about our ability to continue as a going concern, we may continue to incur net losses, and our ability to generate positive cash flows from operating activities is uncertain for the foreseeable future. We have not established an ongoing source of revenue sufficient to cover operating costs. Our ability to continue as a going concern is dependent on our continued operational improvements, refinancing, or obtaining adequate capital to fund operating losses until we become profitable. If we are unable to generate sufficient cash flows or obtain adequate capital, we may be unable to develop and commercialize our product offerings and we could be forced to cease operations.

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 growth efforts or other operations. Further, future sales and issuances of our common stock or rights to purchase common stock will result in dilution of the percentage ownership of our existing stockholders and could cause our stock price to fall.

We are expending resources to commercialize our prescription products and to service our debt obligations. We may require additional funding through public or private equity or debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements, or a combination of these approaches. As of June 30, 2024, our cash and cash equivalents totaled $20.0 million. During the year ended June 30, 2024, we received $13.0 million of proceeds from the Eclipse Term Loan and $3.6 million of proceeds from the exercise of warrants, a portion of which was used for the repayment of a $15.0 million term loan, which was replaced by the Eclipse Term Loan.

Our operating plans may change as a result of many factors currently unknown to us, and we could need additional capital in the future to continue our operations and may need to seek additional funds sooner than planned. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations.

If we sell common stock, convertible securities or other equity securities in more than one transaction, any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to those of our existing common stockholders. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. Any future grants of securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could also have an adverse effect on the market price of our common stock.

In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. The incurrence of additional indebtedness would result in increased fixed payment obligations, and we may be required to agree to additional restrictive covenants, such as further limitations on our ability to incur additional debt, additional 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 products or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be unable to expand the market for our products or expand our operations generally or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due.

We have a $13.0 million term loan and up to $14.5 million of secured revolving loans with the Eclipse Lender. As of June 30, 2024, $2.4 million was outstanding under the secured revolving loan. All obligations under our loans are secured by substantially all of our existing property and assets subject to certain exceptions. These debt financings and any future debt financings may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity.

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 products 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, and finance our operations and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail, or eliminate one or more of our programs.

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

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

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

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

We are actively engaged in discussions regarding a potential strategic transaction. There can be no assurance that this process will result in the pursuit or consummation of any potential transaction.

We are engaged in discussions regarding a potential strategic transaction which could include a sale or licensing of assets, acquisition, merger, business combination, and/or other strategic transaction or series of related transactions. This process, including any uncertainty created by this process, involves a number of risks which could impact our business and our stockholders, including the following:

- significant fluctuations in our stock price could occur in response to developments relating to the process or market speculation regarding any such developments;
- we may encounter difficulties in hiring, retaining and motivating key personnel during this process or as a result of uncertainties generated by this process or any developments or actions relating to it;
- we may incur substantial increases in general and administrative expense associated with increased legal fees and the need to retain and compensate third-party advisors; and
- we may experience difficulties in preserving the commercially sensitive information that may need to be disclosed to third parties during this process or in connection with an assessment of our strategic options.

The review process also requires significant time and attention from management, which could distract them from other tasks in operating our business or otherwise disrupt our business. Such disruptions could cause concern to our suppliers, strategic partners or other constituencies and may have a material impact on our business and operating results and volatility in our share price.

There can be no assurance that this process will result in the pursuit or consummation of any potential transaction or strategy, or that any such potential transaction or strategy, if implemented, will provide sufficient funding to conduct our operations. Any outcome of this process would be dependent upon a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, regulatory approvals, and the availability of financing on reasonable terms. The occurrence of any one or more of the above risks could have a material adverse impact on our business, financial condition, results of operations and cash flows.

We have indefinitely suspended development of our AR101 (enzastaurin) clinical development program and shifted our strategic focus towards accelerating the growth of our commercial business. If we fail to execute successfully on this reprioritized strategic focus, our business, results of operations and financial condition could be materially and adversely affected.

We have indefinitely suspended our AR101 (enzastaurin) clinical development program and shifted our focus towards accelerating the growth of our commercial business and achieving operating cash flows. Though we expect that the suspension of this program will save us costs related to a projected future study that if started would cost over $20 million and take three years to complete, the process of reorienting our business strategy may be costly, time consuming and complex, and we have incurred, and may in the future incur, costs related to this strategic shift. Our strategic reprioritization may result in unexpected expenses or liabilities and/or write-offs. There is no assurance that we will be successful at executing on our revised strategy or that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results.

If we are unable to execute successfully on our reprioritized strategic focus, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected.

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

As of June 30, 2024, we had federal net operating loss carryforwards of $519.6 million. The available net operating losses, if not utilized to offset taxable income in future periods, will continue to expire 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 "IRC") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income.

Ownership changes have limited our ability to offset, post-change, United States federal taxable income. Section 382 of the IRC 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. Previous acquisitions, financing transactions, and equity ownership changes in the past five years have caused a significant limitation on our ability to use all $519.6 million of pre-acquisition net operating loss carryovers. The ownership changes result in increased future tax liability and are a driver of the change from a zero percent effective tax rate.

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 quarter ended September 30, 2022, 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 accounting for complex warrant issuances and the classification of these issued warrants. In addition, we concluded that we had a material weakness in internal control over financial reporting for the year ended June 30, 2023, related to our analysis for the accounting for valuation of our inventory.

As previously reported in our public reports, our Audit Committee conducted an internal investigation to identify and determine a plan to remediate the material weaknesses described above and to enhance our overall control environment. We undertook steps to remediate these deficiencies and strengthen our internal control over financial reporting by enhancing existing controls and establishing additional review and procedure controls over the process of reviewing significant and complex contracts and agreements, and the valuation of inventory. Given the remediation efforts and that a sufficient period of time has passed with successful testing performed, management has concluded that the material weaknesses set forth above were remediated as of March 31, 2024.

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

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

We have been and, in the future, may become a defendant in one or more stockholder derivative, class-action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows.

We and certain of our officers and directors have been and may in the future become defendants in one or more stockholder derivative actions or other class-action lawsuits. For example:

- Two putative class action lawsuits were filed on February 9, 2022, and March 7, 2022, derivatively and on behalf of all Aytu stockholders, challenging the grant in 2021 of certain stock option awards to directors and officers, and seeking rescission of the awards, unspecified damages to stockholders as a result of the awards, and attorneys' fees.

- A stockholder derivative suit was filed on September 12, 2022, derivatively and on behalf of all Aytu stockholders, against certain of our current and former directors and stockholders, alleging breaches of fiduciary duties in connection with certain acquisitions, and seeking unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees.

See Part I, Item 3, *Legal Proceedings* for more information on these lawsuits.

These lawsuits can divert our management's attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). In connection with these lawsuits, we may be required to pay material damages, consent to injunctions on future conduct and/or suffer other penalties, remedies or sanctions, or issue additional shares upon the exercise of certain warrants, which may cause additional dilution. In addition, any such future lawsuits could adversely impact our reputation and/or ability to launch and commercialize our products, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters and any future matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our common stock.

Risks Related to Commercialization

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

Our ability to become profitable depends upon our ability to generate increased revenues from sales of our prescription portfolios. While we have been selling pharmaceutical products for several years, we have limited commercial experience selling our current lineup of pharmaceutical products, having only generated revenues from the sale of our pediatric products since acquiring that portfolio in November 2019 and from our ADHD products since acquiring that portfolio in March 2021. None of our marketed prescription have thus far generated product revenue at levels sufficient for us to attain profitability. We have not generated any revenue from product sales of any other product candidates and, to date, have incurred significant operating losses. Due to the completion of our wind down and divestiture of our Consumer Health Segment in the first quarter of fiscal 2025, we will not generate significant revenue from the Consumer Health Segment in the future.

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

If we are unable to differentiate our products from branded drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve additional generic products that compete with any of our products, our ability to successfully commercialize such products 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 is or will be differentiated from branded drugs and their generic counterparts, if any, including through clinical efficacy or through improved patient compliance, ease of administration, and our patient support programs, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products and accompanying support services against other drugs, the opportunity for our products to achieve premium pricing and be commercialized successfully would be adversely affected.

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

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as our Rx Portfolio products, can be lost to the generic version. Accordingly, competition from generic equivalents to our products could 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 products. For example, on July 25, 2016, we received a paragraph IV certification from Actavis advising them that Actavis filed an ANDA with the FDA for a generic version of Adzenys XR-ODT. On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement with Actavis (which is now owned by Teva), pursuant to which we granted Actavis the right to manufacture and market its now approved generic version of Adzenys XR-ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. On October 31, 2017, we received a paragraph IV certification from Teva advising them that Teva filed an ANDA with the FDA for a generic version of Cotempla XR-ODT. On December 21, 2018, we 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 now approved generic version of Cotempla XR-ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances.

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

Various commercial, regulatory, and manufacturing factors may impact our ability to maintain or grow revenues from sales of our pharmaceutical product offerings. Moreover, we have limited experience selling some of our current products given their acquisition from other companies or their recent approval. We sometimes estimate for planning purposes the timing of the accomplishment of various scientific, clinical, regulatory, and other product development objectives and, from time to time, we may publicly announce the expected timing of some of these milestones. The achievement of many of these milestones may be outside of our control and if we fail to achieve announced milestones in the timeframes we announce and expect, the commercialization of our products may be delayed and our business, prospects and results of operations may be harmed. Specifically, we may encounter difficulty by virtue of the following, each of which could be negatively impacted if expected timeframe goals are not achieved:

- our available capital resources;
- our inability to have clear proprietary rights to the products;
- our inability to manufacture or cost-effectively manufacture the products;
- our inability to adequately market and increase sales of any of these products;
- of adverse side effects that make using the products less desirable;
- our inability to attract and retain a skilled support team, marketing staff and sales force necessary to increase the market for our approved products and to maintain market acceptance for our 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 United States, or the inability of those selected partners to gain the required regulatory, reimbursement, and other approvals needed to enable commercial success of our products.

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 currently manufactured and commercialized products.

Some of our products are produced infrequently and by single-source suppliers, including but not limited to Halo Pharmaceutical, Inc. Due to the limited production quantities, production of these products may not be prioritized by the third-party manufacturer and may not be scheduled and produced at all. We are reliant on a limited number of suppliers for resin, drug compounds, coating and other component substances of our final products. If any of these single-source suppliers were to breach or terminate its supply agreement, with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our products. If we fail to procure supply of our products, we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected.

Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our 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 a decrease in sales of our approved products, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an FDA Prior Approval Supplement process which could result in further delay. 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 products.

These factors could cause a delay of commercialization of our products, 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.

We rely on third parties to manufacture certain products, and third-party manufacturing risks and inefficiencies may result in costs and delays that prevent us from successfully commercializing products and adversely affect our ability to produce our products.

We completed the process of outsourcing the manufacturing of our ADHD products to a third-party manufacturer based in the United States, to produce commercial quantities of our ADHD products during fiscal 2024. If the third-party is not successful or does not meet our expectations (for example, timeliness of production, quantity of production, maintenance of needed documentation or regulatory compliance), we may have to find a different manufacturer and incur expenses and delays in the process. Manufacturers of our ADHD products must comply with good manufacturing practice ("GMP") requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our FDA regulated products may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, DEA, 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.

We do not expect to have our own manufacturing capabilities, thus for all other products and any future products, we expect to use third-party manufacturers. 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.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured these components ourselves, including:

- reliance on third parties for regulatory compliance and quality assurance;
- possible breaches of manufacturing agreements by the third parties because of factors beyond our control;
- possible regulatory violations or manufacturing problems experienced by our suppliers; and
- possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us.

Further, if we are unable to secure the needed financing to fund our internal operations, we may not have adequate resources required to effectively and rapidly transition to a third-party CMO for our ADHD products. We may not be able to meet the demand for our products if one or more of any third-party manufacturers is unable to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers for any of our products in a timely manner and on terms acceptable to us.

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's attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers.

Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our products. 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.

If our contract manufacturer fails to manufacture our ADHD products in sufficient quantities and at acceptable quality and pricing levels, or fails 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 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 our third-party is 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 would be jeopardized. We purchase raw materials and components from various suppliers in order to manufacture our ADHD products. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing our ADHD products, and may not be able to meet customer demand for our products.

In addition, our contract manufacturer 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 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 successfully commercialize such products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in commercialization of our products, entail higher costs or adversely impact our commercialization of our products. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

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

We may enter into collaborations with third parties to commercialize and manufacture our products. 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 products.

Collaboration agreements typically provide for the ownership of intellectual property. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration and we may be limited in our ability to use, make or sell these inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property.

Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize our products. Collaborations involving our products 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 products in favor of developing or commercializing their own or another party's products; 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 products 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. 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 and may not generate meaningful revenues.

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

The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete with companies that design, manufacture and market already-existing and new products. We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and/or our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in product marketing and new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. Our competitors may be more successful in acquiring new products than we are. If we fail to acquire new products, implementation of our business plan would be delayed, which could have a negative adverse effect on our business and prospects. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable. Our ability to compete successfully will depend largely on our ability to:

- expand the market for our approved products, especially our pharmaceutical and devices regulated by the FDA;
- successfully commercialize our products alone or with commercial partners;
- discover and develop products 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 products.

Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our products 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 products we are developing.

We compete with companies that design, manufacture and market treatments that compete with our products. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than that of our products or any product candidate that we are currently developing or that we may develop.

We anticipate that we will face increased competition in the future as new companies enter the market with new technologies our competitors improve their current products, and companies introduce generic equivalents. 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. 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 Patient Protection and Affordable Care Act (the "PPACA") and the Health Care and Education Reconciliation Act (the "Health Care Reconciliation Act") significantly impacted the provision of, and payment for, health care in the United States. 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 United States, could influence the purchase of medicines and medical devices and reduce demand and prices for our products, 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 approved in the future, and could cause an increase in our compliance, manufacturing or other operating expenses. In addition, in certain foreign markets, the pricing of prescription drugs and devices is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell any approved product at a price acceptable to us or any of our future collaborators.

In addition, in some foreign countries, the proposed pricing for a drug or medical device must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. A member state may require that physicians prescribe the generic version of a drug instead of our approved branded product. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products or product candidates. Historically, pharmaceutical products launched in the EU do not follow price structures of the United States and generally tend to have significantly lower prices.

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

Physicians may not choose to prescribe our products if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side-effect profiles and other factors, our product is preferable to existing medicines or treatments. Our future success depends on the acceptance by our target customers, third-party payors, and the medical community that our products are reliable, safe, and cost-effective. We cannot predict the degree of market acceptance of any of our approved products. Many factors may affect the market acceptance and commercial success of our products, including:

- our ability to convince our potential customers of the advantages, safety and economic value our products and product candidates over existing technologies and products;
- the approved labeling for the product and any required warnings;
- the prevalence and severity of adverse events or publicity;
- potential product liability claims;
- the relative convenience and ease of our products over existing technologies and products;
- the introduction of new technologies and competing products that may make our products less attractive for our target customers;
- our success in training medical personnel on the proper use of our products;
- the willingness of third-party payors to reimburse our target customers that adopt our products;
- increases in rebate payments with payors;
- the acceptance in the medical community of our products;
- the extent and success of our manufacturing, marketing, and sales efforts; and
- general economic conditions.

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

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

While our pharmaceutical products are approved and generating revenues in the United States, they may not receive, or continue to receive, clinician or patient acceptance, or they may not maintain adequate reimbursement from third party payors. In the future, we might possibly sell other products to target customers substantially all of whom receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid, other domestic and foreign government programs, private insurance plans and managed care programs. Reimbursement decisions by particular third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost-effective diagnosis methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for procedures and devices deemed to be experimental.

Obtaining coverage and reimbursement approval for a product from each government or third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our potential product to each government or third-party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit or even cover their costs.

Third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and reimbursement available for any product or product candidate, which in turn, could negatively impact pricing. If our customers are not adequately reimbursed for our products, they may reduce or discontinue purchases of our products, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

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

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

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations.

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

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

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

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

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

Our future profitability may depend, in part, on our ability to commercialize our products in foreign markets for which we intend to primarily rely on collaboration with third parties such as the agreement we entered into with Medomie in July 2023 to sell Adzenys and Cotempla in Israel and the Palestinian Authority. If we commercialize our products 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 could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

We are subject to United States and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

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

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

We are subject to various health care fraud and abuse and reimbursement laws pertaining to the marketing of our approved products.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products, including inducements to potential patients to request our products and services. Additionally, any product promotion educational activities, support of continuing medical education programs, and other interactions with health-care professionals must be conducted in a manner consistent with the FDA regulations, Physician Payments Sunshine Act, 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 products, which may have a material adverse effect on our business, operating results and financial condition.

Adzenys and Cotempla contain controlled substances, and their manufacture, use, sale, importation, exportation, prescribing and distribution are subject to regulation by the DEA.

Adzenys and Cotempla, (collectively, our "Controlled Substance Products"), which are approved by the FDA, are regulated by the DEA as Schedule II controlled substances. Before any commercialization of any product candidate that contains a controlled substance, the DEA determines the controlled substance schedule of a drug, taking into account the recommendation of the FDA. Our Controlled Substance Products are, and our other future products 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 products. 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 United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances are considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances.

Amphetamine and methylphenidate, which are the active ingredients in our Adzenys and Cotempla products, respectively, 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. Our United States-based contract manufacturer of our Controlled Substance Products is also registered with and inspected by the DEA.

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

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule.

Because of their restrictive nature, these laws and regulations could limit commercialization of our products containing controlled substances. Failure to comply with these laws and regulations could also result in withdrawal of our DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties, and state actions, among other consequences.

The design, development, manufacture, supply and distribution of our products are technically complex and require regulatory compliance.

Our third-party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of our ADHD products is a regulated drug product and subject to the DEA and state-level regulations, we have had to, and will continue to, need to secure state licenses from each required state in which we intend to sell such product allowing us to distribute a regulated drug product in such state.

If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or revocation of a pre-existing approval, or civil or criminal penalties. As a result, our business, financial condition and results of operations may be materially harmed.

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

Title II of the Drug Quality and Security Act of 2013 provided increased FDA oversight over tracking and monitoring of the sale and distribution of prescription drugs. We are required to provide product identification information, or serialization, at the manufacturing batch, or lot level. In addition, we are required to track and verify wholesaler and pharmacy authentication and verification. We are required to conduct unit level tracking throughout the entire supply chain. We are now serializing our products and are compliant with the Drug Quality and Security Act, but there is no guarantee that we will be able to continue 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.

Failure to comply with health and data protection laws and regulations could lead to United States 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 United States 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 which are subject to privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health ("HITECH"). To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers, the federal government, and media outlets with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Compliance with United States 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, 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.

Risks Related to Our Intellectual Property

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

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

From time to time, we may renegotiate the terms of our existing licensing agreements or other material contracts. There can be no guarantee that the terms of the renegotiated license agreement will be viewed favorably by the market although the renegotiated terms might be advantageous to our business or that the other party would agree to material changes to benefit the Company. For example, in May 2022, we negotiated to terminate the License, Development, Manufacturing and Supply agreement with Tris. The negotiations resulted in reducing the future minimum payments we owed to Tris by approximately $8.0 million. If we were unable to renegotiate the terms of the agreement, it would have had a material negative impact on our cash flows and financial position.

The expiration or loss of patent protection may adversely affect our future revenues and operating results.

The suite of composition-of-matter patents for Adzenys are scheduled to expire in 2026 and 2032. The composition-of-matter patents in the United States for Cotempla expire in 2032, and the method-of-use patent expires in 2038. There is no guarantee that we will be able to extend the life of these patents or to obtain additional patents, licenses, or other instruments that can provide us with a comparable level of exclusivity to the intellectual property underlying the expiring patents.

We rely on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of our products. In particular, patent protection is, in the aggregate, important in our marketing of products in the United States. Patents covering our products normally provide market exclusivity, which is important for the profitability of many of our products.

As patents for certain of our products expire, we may face competition from lower priced generic or bioequivalent products. In general, the expiration or loss of patent protection for a product may allow market entry by substitute products that could significantly reduce sales for the original product in a short amount of time. If our competitive position is compromised because of generic or bioequivalent products or otherwise, it could have a material adverse effect on our business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic or bioequivalent products. Any such proposals that are enacted into law could increase the negative effect of generic competition.

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

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

Obtaining and maintaining a patent portfolio entails significant expense and resources. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. In addition, the patent scope can be limited in prosecution or by the courts after issuance.

In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

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

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

In addition to patent protection, because we operate in the highly technical field of 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 United States 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 United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and medical devices. This could make it difficult for us to stop the infringement of some of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In addition, some countries allow patents to be challenged by third parties in administrative proceedings, which may result in a reduction in scope or cancelation of some or all of the claims. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

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

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

There is significant litigation in the pharmaceutical industry 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 infringe the intellectual property rights of others. If our development and commercialization activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs, compositions or devices that relate to our prescription and consumer health business. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies or universities involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation, wrongful disclosure of confidential information, or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's intellectual property rights;

- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or

- we or our collaborators having to enter into license arrangements that may not be available on commercially reasonable or acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, prospects and financial condition. As a result, we could be prevented from commercializing our products.

Risks Related to Our Organization, Structure and Operation

Our efforts to expand and transform our businesses may require significant investments; if our strategies are unsuccessful, our business, results of operations and/or financial condition may be materially adversely affected.

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

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

- diversion of management time and attention away from existing operations;
- requiring capital investment that could otherwise be used for the operation and growth of our existing businesses;
- disruptions to important business relationships;
- increased operating costs;
- limitations imposed by various governmental entities; and
- difficulties due to lack of or limited prior experience in any new markets we may enter.

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

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

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

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

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

In fiscal 2024, 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, 2024, and 2023. During the years ended June 30, 2024, and 2023, three customers accounted for 70% of gross revenue, respectively. While all of these customers have been and continue to be consistently financially strong, the loss of one or more of our significant customers could have a material adverse effect on our business, operating results or financial condition. Any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline. If we are unable to diversify our customer base, we will continue to be susceptible to risks associated with customer concentration.

Our accounts receivable subjects us to credit risk.

We are also subject to credit risk from our accounts receivable related to our product sales. As of June 30, 2024, three customers accounted for 80% of gross accounts receivable. Our profitability and cash flow are dependent on receipt of timely payments from customers. Any delay in payment by our customers may have an adverse effect on our profitability, working capital and cash flow. There is no assurance that we will be able to collect all or any of its trade receivables in a timely matter. If any of our customers face unexpected situations such as financial difficulties, we may not be able to receive full or any payment of the uncollected sums or enforce any judgment debts against such clients, and our business, results of operations and financial condition could be materially and adversely affected.

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

Our success depends to a significant degree upon the technical and management skills of our directors, officers, and key personnel. Any of our directors could resign from our board at any time and for any reason. Although our named executive officers (individually "NEO" and collectively "NEOs"), Joshua R. Disbrow, Mark K. Oki, Jarrett T. Disbrow and Greg Pyszczymuka have employment agreements, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time, and the agreements obligate us to pay Joshua R. Disbrow a lump sum severance of two and a half years his base salary, for Mr. Jarrett T. Disbrow a lump sum severance of two years his base salary, and for Mr. Oki, and Mr. Pyszczymuka one year of their base salary paid in installments over 12 months in accordance with the company's payroll schedule. If we terminate them without cause, as defined in their respective agreements, or if a NEO leaves for "Good Reason" as defined in their respective employment agreements, such severance payments could negatively affect our liquidity. The loss of the services of any of these individuals would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, marketing, technical, and sales executives and personnel. We do not maintain key person life insurance for any of our officers or key personnel. The loss of any of our directors or key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business.

We compete for such personnel, including directors, against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so could have a material adverse effect on our business, prospects, financial condition, and results of operations.

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

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 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.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical, medical device, dietary supplement and personal care products. 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 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 ADHD 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 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.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to the Company.

Our certificate of incorporation provides that we will indemnify our directors to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our bylaws provide that:

- we may, in our discretion, indemnify other officers, employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and executive officers in connection with defending a proceeding, except that such directors or executive officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our bylaws to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by our Board of Directors, (iii) such indemnification is provided by us, in our sole discretion, pursuant to the powers vested in the corporation under applicable law or (iv) such indemnification is required to be made pursuant to our amended and restated bylaws;
- the rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

As a result, if we are required to indemnify one or more of our directors or executive officers, it may reduce our available funds to satisfy successful third-party claims against us, may reduce the amount of money available to us and may have a material adverse effect on our business and financial condition.

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, Neos, which we now own, received citations advising Neos that the County of Harris Texas and the County of Walker Texas 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. 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 cases noted above 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 products, 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. 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.

Certain of our stockholders own a significant percentage of our stock and may and their interests may conflict with yours.

As of June 30, 2024, two stockholders hold approximately 18.2% and 9.5%, respectively, of our outstanding common stock and hold warrants and pre-funded warrants which can be exercised to purchase additional shares of our common stock resulting in an ownership of 19.99% of our currently outstanding common stock, and in excess of 19.99% subject to stockholder approval. Accordingly, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring security holder approval.

In addition, in connection with our recent public offering of securities in June 2023, the 18.2% stockholder has been granted the right to designate an individual to join our Board of Directors, who has since joined the board of directors, and to nominate an additional candidate who is acceptable to us to be elected to the Board, subject to Nasdaq regulations. To date this shareholder only occupies one board seat. The interests of this stockholder could conflict with the interests of our other stockholders.

***Our business could be negatively affected as a result of the actions of activist stockholder*s.**

Proxy contests have been waged against many companies in the pharmaceutical industry over the last several years. It is possible that one or more of our stockholders may publicly voice opposition to certain aspects of our corporate governance and strategy or undertake a proxy contest to reconstitute our board. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or other type of activism which would be disruptive to our business. Even if we are successful, our reputation and/or business could be adversely affected by a proxy contest or other form of stockholder activism because:

- responding to proxy contests and other actions by activist stockholders can be costly and time-consuming, disrupting operations and diverting the attention of management and employees;

- perceived uncertainties as to our company and future strategic direction may result in the loss of potential financing, acquisitions, collaboration, in-licensing or other business opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and

- if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders.

Any or all of these activities could cause our stock price to decline or experience periods of volatility and could be particularly problematic as our company seeks to transition to a commercial enterprise in a challenging environment.

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.

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

We have effected five 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, on June 21, 2024, Nasdaq filed a proposed rule change with the SEC that would change how it views reverse stock splits. Nasdaq's proposal suggests it would initiate the delisting process for any company whose common stock bid price had closed below $1.00 per share for 30 consecutive business days (the "Minimum Bid Requirement") if, within the prior year, the company conducted a reverse stock split, regardless of the ratio. Given our history of effectuating reverse stock splits in order to comply with the Minimum Bid Requirement, there can be no assurance that our securities will continue to be listed on Nasdaq if we do not comply with the Minimum Bid Requirement.

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.

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 Annual Report, these factors include:

- the success of products we acquire for development or commercialization relative to the success of our competitors;
- product safety;
- conditions or trends in the healthcare, biotechnology and pharmaceutical industries, including healthcare payment systems;
- our ability to effectively manage operations, financial decisions, internal controls over financial reporting or disclosure controls, performance relative to projections, and attract and retain employees;
- our dependence on third parties, including CROs and scientific and medical advisors;
- adverse regulatory decisions or changes in laws or regulations;

- disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our products;

- general political and economic conditions and effects of natural or man-made catastrophic events; and

- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stocks of small-cap healthcare, biotechnology, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "*Risk Factors*" section and elsewhere in this Annual Report could have a dramatic and material adverse impact on the market price of our common stock. You might not be able to resell your shares at or above the price you paid for them.

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

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

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

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

- the authorization of 50.0 million shares of "blank check" preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval;

- limiting the removal of directors by the stockholders;

- allowing for the creation of a staggered Board of Directors;

- eliminating the ability of stockholders to call a special meeting of stockholders; and

- establishing advance notice requirements for nominations for election to the Board of Directors or for proposing matters that can be acted upon at stockholder meetings.

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

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

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

We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock.

We are and may continue to be subject to short selling strategies.

Short sellers of our stock may be manipulative and may attempt to drive down the market price of shares of our Common Stock. Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller's best interests for the price of the stock to decline, many short sellers (sometime known as "disclosed shorts") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum and generate profits for themselves after selling a stock short. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by blogging have allowed many disclosed shorts to publicly attack a company's credibility, strategy and veracity by means of so-called "research reports" that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market, on occasion in large scale and broad base. Issuers who have limited trading volumes and are susceptible to higher volatility levels than large-cap stocks, can be particularly vulnerable to such short seller attacks. These short seller publications are not regulated by any governmental, self-regulatory organization or other official authority in the United States, are not subject to certification requirements imposed by the SEC and, accordingly, the opinions they express may be based on distortions or omissions of actual facts or, in some cases, fabrications of facts. In light of the limited risks involved in publishing such information, and the enormous profit that can be made from running a successful short attack, unless the short sellers become subject to significant penalties, it is more likely than not that disclosed short sellers will continue to issue such reports.

Significant short selling of a company's stock creates an incentive for market participants to reduce the value of that company's common stock. Short selling may lead to the placement of sell orders by short sellers without commensurate buy orders because the shares borrowed by short sellers do not have to be returned by any fixed period of time. If a significant market for short selling our common stock develops, the market price of our common stock could be significantly depressed.

General Risk Factors

Our business and operations would suffer in the event of system failures, cybersecurity attacks, data leakages or other 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 cybersecurity 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 cybersecurity 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. 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 products could be delayed.

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

Major bank failure or sustained financial market illiquidity, could adversely affect our business, financial condition and results of operations.

We face certain risks in the event of a sustained deterioration of domestic or international financial market liquidity. In particular:

- We may be unable to access funds in our deposit accounts on a timely basis. Any resulting need to access other sources of liquidity or short-term borrowing would increase our costs.

- In the event of a major bank failure, we could face major risks to the recovery of our bank deposits. A substantial portion of our cash and cash equivalents are either held at banks that are not subject to insurance protection against loss or exceed the deposit insurance limit. While we are not currently aware of any liquidity issues directly impacting the financial institutions where we hold cash deposits or securities, if financial liquidity deteriorates, there can be no assurance we will not experience an adverse effect, which may be material, on our ability to access capital and on our business, financial condition and results of operations.

Deterioration in general economic conditions in the United States and globally, including the effect of prolonged periods of inflation on our customers and suppliers, could harm our business and results of operations.

Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include but are not limited to inflation, rising interest rates, availability of capital markets, energy availability and costs (including fuel surcharges), the negative impacts caused by pandemics and public health crises (such as the COVID-19 pandemic), negative impacts resulting from the military conflicts between Russia and Ukraine and between Israel and Palestine, and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our business in the form of a reduced customer base and/or potential for new bookings due to possible reductions in pharmaceutical and biotech industry-wide spend on research and development and/or economic pressure on our suppliers to pass on increased costs.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risks

We rely on internal and third-party information technology systems and networks to process, transmit and store electronic information in our operations, including our proprietary business information and that of our customers, suppliers and employees. We use various internal and third-party information technology systems and networks to manage our operations and maintain effective internal control over financial reporting. We also collect and store sensitive data, including intellectual property, proprietary business information and personal information of our customers, suppliers and employees, in our data centers and on our networks. The secure operation of these information technology systems and networks, and the processing and maintenance of this information, are critical to our business operations and strategy.

Despite our security measures, our internal and third-party information technology systems and networks may be subject to damage, disruption, or unauthorized access due to a variety of factors, including cyber-attacks by computer hackers, computer viruses, ransomware, phishing, denial-of-service attacks, physical or electronic break-ins, employee error or malfeasance, power outages, natural disasters, or other catastrophic events. Any such damage, disruption, or unauthorized access could compromise our internal and third-party networks and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disruption to our operations, damage to our reputation, loss of customers, potential harm to our competitive position and additional costs to remediate the issue.

Cybersecurity Practices

We have implemented various measures to manage our risk of information technology systems and networks damage, disruption, or unauthorized access, including regular employee training, monitoring of our systems and networks, maintenance of backup and protective systems and use of modern endpoint detection and response tools, which are integrated into Aytu's risk management systems and processes. We have implemented multi-factor authentication ("MFA") across many of our systems and email accounts to prevent unauthorized access and impersonation. We also utilize a cloud-based environment for a large portion of our operations, which enhances our scalability, flexibility and resilience and utilize third parties to perform early external vulnerability assessment and risk identification. We have established extensive backup and recovery procedures to ensure the continuity of our operations in a cyber incident. We also maintain cyber liability insurance coverage as part of our comprehensive risk management program. However, these measures may not be sufficient to prevent, detect, or mitigate the impact of such damage, disruption, or unauthorized access. Moreover, the regulatory environment related to information security, data protection and privacy is increasingly demanding and complex, and compliance with applicable laws and regulations may result in significant costs or require changes in our business practices that could adversely affect our operations.

Cybersecurity Governance

Our Board of Directors is actively involved in overseeing our cybersecurity risk management. Our Board of Directors delegates certain oversight functions to our Audit Committee, which reviews our cybersecurity policies, procedures, controls and audit results. Our Audit Committee receives quarterly updates on our cybersecurity posture, threats and incidents from Aytu's management. Our Board of Directors and our Audit Committee regularly assess the adequacy of our cybersecurity risk management framework and the effectiveness of our mitigation strategies.

Our cybersecurity operations are led by our Chief Financial Officer. He is responsible for overseeing the development and implementation of our cybersecurity strategy, policies, standards and practices. He also oversees our cybersecurity team, which includes a staff member who has over 20 years of experience in the field. Our cybersecurity team monitors, detects, responds and reports on cybersecurity threats and incidents, and coordinates with our internal and external stakeholders to ensure the security of our information assets.

Aytu adheres to the National Institute of Standards and Technology ("NIST") Cybersecurity Framework 2.0, which provides a set of standards, guidelines and best practices to manage cybersecurity-related risks. We have developed and documented our systems disaster recovery plan, which outlines the roles, responsibilities and procedures for restoring our critical systems and data in the event of a cyber incident. We have also crafted internal policies to help maintain a secure environment, such as our information security policy, our data classification policy, our incident response policy and our password policy. We regularly conduct phishing simulations, vulnerability scans and audits to test the effectiveness of our controls and backups, and to identify and remediate any gaps or weaknesses in our cybersecurity posture.

Cybersecurity Incidents

Despite our efforts to prevent and mitigate cybersecurity incidents, we cannot guarantee that we, or third-party providers that we rely on, will not experience any breaches, disruptions, or unauthorized access to our information technology systems and networks. During fiscal 2024, we did not experience any cybersecurity incidents that materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition, however, there can be no assurance that the measures we have taken to address IT and cybersecurity risks will prove effective in the future. For additional discussion of the IT and cybersecurity risks facing our business, please refer to Part 1, Item 1A, *Risk Factors* of this Annual Report.

We prioritize investment in cybersecurity risk management and governance. We continually assess the adequacy of our resources and capabilities to address emerging threats, regulatory requirements and changes in technology. As cybersecurity threats evolve, we may need to further enhance our processes and technologies, which could require additional financial resources.

ITEM 2. PROPERTIES

We lease or sublease various properties, including office buildings, manufacturing, research and development facilities and sales offices within the United States. 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, 2024:

Location	Leased/Owned	Purpose
Denver, CO	Leased	Corporate headquarters
Berwyn, PA	Leased	Office
Grand Prairie, TX [1]	Leased	Administrative offices, laboratory and manufacturing facilities
Oceanside, CA [2]	Leased	Warehouse

[1] In the fourth quarter of fiscal 2024, in connection with the transfer of our manufacturing of Adzenys and Cotempla to a United States-based third-party manufacturer, we ceased using this property. This lease expires on December 31, 2024.

[2] In the fourth quarter of fiscal 2024, in connection with the wind down of our Consumer Health Segment, we ceased using this property. This lease expires December 31, 2026.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we become involved in or are threatened with legal disputes arising out of our business and operations in the normal course of business. Most of these disputes are not likely to have a material effect on our business, financial condition, or operations. As of the filing of this report, no legal proceedings are pending against us that we believe individually or collectively are likely to have a materially adverse effect upon our financial condition, results of operations, or cash flows.

Witmer Class-Action Securities Litigation. A stockholder derivative suit filed on September 12, 2022, in the Delaware Chancery Court by Paul Witmer, derivatively and on behalf of all Aytu stockholders, and later amended, against Armistice Capital, LLC, Armistice Capital Master Fund, Ltd., Steven Boyd (Armistice's Chief Investment Officer and Managing Partner, and a former director of Aytu) (collectively "Armistice"), and certain other current and former directors of Aytu, Joshua R. Disbrow, Gary Cantrell, John Donofrio, Jr, Carl Dockery and Ketan B. Mehta. The amended complaint alleges that (i) Armistice facilitated the sale of assets of Cerecor, Inc., in 2019 and Innovus Pharmaceuticals, Inc., in 2020 to Aytu in exchange for convertible securities, which it subsequently converted and sold at a profit on the open market; (ii) the Armistice defendants breached their fiduciary duties, were unjustly enriched and wasted corporate assets in connection with these acquisitions; (iii) the Armistice defendants breached their fiduciary duties by engaging in insider trading; and (iv) the other directors breached their fiduciary duties, and aided and abetted the Armistice defendants' breaches of fiduciary duties, in connection with these acquisitions. The amended complaint seeks unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees. While the Company believes that this lawsuit is without merit and has vigorously defended against it, the Company has agreed to settle the matter, as against it and the director defendants other than Mr. Boyd, for various corporate governance modifications and the payment of plaintiff's attorneys' fees. That settlement is subject to court approval, the hearing on which has not yet been scheduled.

Sabby Litigation. A complaint was filed on February 22, 2023, in the Supreme Court of the State of New York by Sabby Volatility Warrant Master Fund Ltd ("Sabby") and Walleye Opportunities Master Fund Ltd ("Walleye"), holders of certain warrants to purchase common stock, against the Company. The complaint alleges that the Company improperly adjusted the exercise price of the warrants and miscalculated the number of shares the warrant holders may receive, and that the Company failed to provide prompt notice to the warrant holders of such adjustment. The complaint seeks a declaratory judgment of the warrant share calculation, that 575,000 warrant shares be due to Sabby on exercise of its warrants rather than 312,908 shares, and that 100,000 warrant shares be due to Walleye on exercise of its warrants rather than 54,146 shares. In October 2023, the Company entered into a settlement agreement and general release with Sabby and Walleye.

Stein Litigation. Cielo Stein ("Stein"), a former sales specialist, filed a complaint on February 1, 2023, in Jefferson County Circuit Court in Kentucky against the Company and its wholly owned subsidiary Neos. The complaint alleges that Aytu retaliated against Stein in violation of the Kentucky Civil Rights Act after she opposed what she contends was unwelcome behavior by her supervisor. The complaint also alleges that the Company's response to Stein's subsequent complaint to human resources was inadequate. The complaint seeks an award of unspecified compensatory damages, emotional-distress damages, and attorneys' fees and costs. The Company removed the lawsuit to the United States District Court for the Western District of Kentucky and filed a motion to dismiss the complaint, which was denied. A Section 16 pretrial conference was held on June 3, 2024. In August 2024, the Company entered into a settlement agreement and general release with Stein. The case has been dismissed with prejudice.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

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

On September 16, 2024, the closing price as reported on the Nasdaq of our common stock was $2.57, and there were 187 holders of record of our common stock.

Equity Compensation Plan Information

On May 18, 2023, our stockholders approved the adoption of the Aytu BioPharma, Inc. 2023 Equity Incentive Plan (the "2023 Equity Incentive Plan"). Prior to our adoption of the 2023 Equity Incentive Plan, we awarded equity incentive grants to our directors and employees under the Aytu BioScience, Inc. 2015 Stock Option and Incentive Plan ("Aytu 2015 Plan") and the Neos Therapeutics, Inc. 2015 Stock Options and Incentive Plan ("the Neos 2015 Plan") (collectively the "2015 Plans"). For the 2023 Equity Incentive Plan, the stockholders approved (a) 200,000 new shares, (b) 87,155 shares available for grant under the 2015 Plans be "rolled over" to the 2023 Equity Incentive Plan and (c) any shares that are returned to the Company under the 2015 Plans be added to the 2023 Equity Incentive Plan.

The following table displays equity compensation plan information as of June 30, 2024, 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	172,419	$	6.18	182,322
Equity compensation plans not approved by security holders [2]	1,255	$	—	—
Total	173,674	$	6.18	182,322

[1] This reflects the weighted-average exercise prices of options outstanding. Restricted stocks and restricted stock units do not have exercise prices (see *Note 15 - Equity Incentive Plans*).

[2] This reflects the equity plan we assumed pursuant to the Neos Acquisition and restricted stock previously issued outside of the Aytu 2015 Plan (see *Note 15 - Equity Incentive Plans*).

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 debt agreements. 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 Part 1, Item 1A, Risk Factors 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 year ended June 30, 2024, and our financial condition as of June 30, 2024. The MD&A is provided as a supplement to, and should be read in conjunction with, our consolidated financial statements and notes thereto.

Overview

We are a pharmaceutical company focused on commercializing novel therapeutics. In fiscal 2024 and fiscal 2023, we operated two business segments: (i) the Rx Segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers and (ii) the Consumer Health Segment, which consists of various consumer health products sold directly to consumers. We use third parties to manufacture all of our products.

We have incurred significant losses in each year since inception. Our net losses were $15.8 million and $17.1 million for the years ended June 30, 2024, and 2023, respectively. As of June 30, 2024, and 2023, we had an accumulated deficit of $320.0 million and $304.1 million, respectively. We expect to continue to incur significant expenses in connection with our ongoing activities, including the integration of our acquisitions and the commercialization of our product pipeline.

In light of our own business activities and external developments in the biotechnology and biopharmaceutical industries, Aytu management and our Board regularly reviews our performance, prospects and risks such as the potential impact to our business resulting from the Company's competitive landscape (i.e., entry of generic competitors, payer pressures, new branded entrants, etc.). These reviews have included consideration of potential partnerships, collaborations, and other strategic transactions such as acquisitions or divestitures of programs or technology to enhance stockholder value. Aytu's management and Board continues to evaluate potential strategic transactions and business combinations.

Significant Developments

Business Environment

We have continued to experience inflationary pressure and have experienced supply chain disruptions related to the sourcing of raw materials, energy, logistics and labor during fiscal 2024. While we do not have sales or operations in Russia or Ukraine and we do not have material sales or operations in the Middle East, it is possible that the conflict or actions taken in response, could adversely affect some of our markets and suppliers, economic and financial markets, costs and availability of energy and materials, or cause further supply chain disruptions. We expect that inflationary pressures and supply chain disruptions could continue to be significant across the business throughout fiscal 2025. The Company has not experienced stock outages for its ADHD products since the launch of those products, and the pediatric product supply has remained adequate to satisfy demand for the preceding three years.

Rx Segment

During the fourth quarter of fiscal 2024, we successfully completed the transition of all manufacturing of our ADHD products to a United States-based third-party manufacturer to improve the profitability of these products.

As part of our realization of post-acquisition synergies and product prioritization, we have implemented a portfolio rationalization plan whereby we discontinued or divested five non-core products in our Rx Segment: Cefaclor Oral Suspension, Flexichamber, Tussionex, Tuzistra XR, and ZolpiMist. These products, collectively, contributed $0.1 million and $1.6 million in net revenue during the years ended June 30, 2024, and 2023, respectively.

In July 2023, we entered into an exclusive collaboration, distribution and supply agreement with Medomie Pharma Ltd ("Medomie"), a privately owned pharmaceutical company, for Medomie to sell Adzenys and Cotempla in Israel and the Palestinian Authority. We will supply Adzenys and Cotempla to Medomie, who will be responsible for seeking local regulatory approvals and marketing authorizations for each product. This agreement represents Aytu's first international commercial agreement for Adzenys and Cotempla.

Consumer Health Segment

As previously announced, in fiscal 2024 we began the wind down of the Consumer Health Segment in order to maximize profitability. During the first quarter of fiscal 2025, we completed the wind down of operations and entered into and entered into a definitive agreement to effect the Consumer Health Divestiture. The divested business encompasses the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for us to receive revenue-based royalty payments on future sales of former Consumer Health Segment products. We expect the savings realized from the strategic shift away from the Consumer Health business, coupled with incremental margin improvements expected from the previously announced closure of our Grand Prairie, Texas manufacturing site, to significantly enhance our operating results and drive stockholder value.

Debt and Equity Financings

Eclipse Agreement

In June 2024, we and certain of our subsidiaries entered into the Eclipse Amendment No. 5, with the Eclipse Lender. Under the Eclipse Agreement No. 5, we have two loan agreements, the Eclipse Term Loan and the Eclipse Revolving Loan.

The Eclipse Term Loan consists of a principal amount of $13.0 million, at an interest rate of SOFR plus 7.0%, with a four-year term and a straight-line loan amortization period of seven years, which would provide for a loan balance at the end of the four-year term of $5.6 million to be repaid on June 12, 2028, the maturity date. We used the proceeds of the Eclipse Term Loan and a portion of the proceeds from warrant exercises described below to repay in full a $15.0 million term note.

The Eclipse Revolving Loan allows us to borrow up to $14.5 million at an interest rate of SOFR plus 4.5%. In addition, we are required to pay an unused line fee of 0.5% of the average unused portion of the maximum Eclipse Revolving Loan amount during the immediately preceding month. The ability to make borrowings and obtain advances of the Eclipse Revolving Loan remains subject to a borrowing base and reserve, and availability blockage requirements and the maturity date, as amended, is June 12, 2028.

Equity Financings

In June 2023, we raised gross proceeds of $4.0 million from the issuance of (i) 1,743,695 shares of our common stock, and (ii) in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 430,217 shares of common stock (the "June 2023 Pre-Funded Warrants") and (iii), accompanying Tranche A warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche A Warrants"), (iv) and accompanying Tranche B warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche B Warrants"). We received $3.4 million in proceeds net of underwriting fees and other expenses.

In June 2024, the Tranche B Warrants were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of common stock and 1,806,434 "pre-funded" warrants to purchase shares of common stock with an exercise price of $0.0001 per share (the "Tranche B Pre-Funded Warrants"). We used a portion of these proceeds as part of the $15.0 million term loan repayment described above.

Results of Operations

Comparison of the Years Ended June 30, 2024, and 2023

	Year Ended June 30,		
	2024	**2023**	**Change**
		(in thousands)	
Net revenue	$ 81,002	$ 107,399	$ (26,397)
Cost of sales	26,416	40,767	(14,351)
Gross profit	54,586	66,632	(12,046)
Operating expenses:			
Advertising and direct marketing	4,875	17,217	(12,342)
Other selling and marketing	22,083	24,231	(2,148)
General and administrative	22,514	28,630	(6,116)
Research and development	2,791	4,095	(1,304)
Amortization of intangible assets	5,212	4,788	424
Restructuring costs	2,365	—	2,365
Impairment expense	—	5,705	(5,705)
Gain from contingent consideration	—	(969)	969
Total operating expenses	59,840	83,697	(23,857)
Loss from operations	**(5,254)**	**(17,065)**	**11,811**
Other income, net	568	184	384
Interest expense	(4,792)	(4,963)	171
Derivative warrant liabilities (loss) gain	(4,004)	4,793	(8,797)
Loss on extinguishment of debt	(594)	—	(594)
Loss before income tax	**(14,076)**	**(17,051)**	**2,975**
Income tax expense	(1,768)	—	(1,768)
Net loss	$ **(15,844)**	$ **(17,051)**	$ **1,207**

Revenue by Segment

	Year Ended June 30,		
	2024	**2023**	**Change**
		(in thousands)	
Rx Segment net revenue	$ 65,183	$ 73,799	$ (8,616)
Consumer Health Segment net revenue	15,819	33,600	(17,781)
Total net revenue	$ 81,002	$ 107,399	$ (26,397)

During the year ended June 30, 2024, net revenue decreased by $26.4 million, or 25% compared to the year ended June 30, 2023. The decrease in our Consumer Health Segment was a result of our decision to wind down this business, which we completed in the first quarter of fiscal 2025. We incurred a $18.1 million decrease in net revenue from our Pediatric Portfolio, which was primarily driven by payer changes that negatively affected prescription coverage, and a $1.4 million decrease that resulted from the discontinuation of certain products. These declines were partially offset by an increase in net revenue from the ADHD Portfolio of $10.9 million, driven by a consistent and reliable supply of our ADHD Portfolio products and strong commercial execution. During fiscal 2025 we anticipate minimal net revenue from the Consumer Health Segment due to its wind down and divestiture during the first quarter of fiscal 2025, and an increase in net revenue from our Rx Segment due to continued commercial execution.

Gross Margin

	Year Ended June 30,	
	2024	**2023**
Rx Segment gross margin	75%	71%
Consumer Health Segment gross margin	35%	43%
Consolidated gross margin	67%	62%

During the year ended June 30, 2024, gross profit decreased by 19% compared to the year ended June 30, 2023. Gross margin increased to 67% for the year ended June 30, 2024, compared to 62% for the year ended June 30, 2023. The improvement was primarily due to a decline in the lower-margin Consumer Health Segment net revenue from the wind down of our Consumer Health Segment and improvements in the higher gross margin ADHD Portfolio, which were primarily due to efficiencies in production related to higher demand for Adzenys and Cotempla. We expect gross margin to continue to increase in fiscal 2025 due to the completed wind down and divestiture of the Consumer Health Segment and due to reduced costs associated with the successful transition of our ADHD product manufacturing to a United States-based CMO.

Advertising and Direct Marketing

During the year ended June 30, 2024, advertising and direct marketing expenses decreased by $12.3 million, or 72%, compared to the year ended June 30, 2023. Advertising and direct marketing expense include direct-to-consumer marketing, advertising, sales, and customer support and processing fees related to our Consumer Health Segment. The reduction in advertising and direct marketing costs were primarily due to our wind down of the Consumer Health Segment during fiscal 2024. We expect advertising and direct marketing expense to decrease in fiscal 2025 primarily from the completed wind down and divestiture of the Consumer Health Segment.

Other Selling and Marketing

During the year ended June 30, 2024, other selling and marketing expense decreased by $2.1 million, or 9%, compared to the year ended June 30, 2023. The decreases were primarily driven by commission expense based on prescriptions generated by our sales force and commercial marketing program fees that decrease as product sales decreased. We expect other selling and marketing expense to increase during fiscal 2025 related to increased commission expense and commercial marketing program fees from anticipated increases in prescription product sales.

General and Administrative

During the year ended June 30, 2024, general and administrative expense decreased by $6.1 million or 21%, compared to the year ended June 30, 2023. The decrease was primarily a result of ongoing cost-cutting initiatives and operational improvements. We expect general and administrative expense to decrease during fiscal 2025 primarily from the completed wind down and divestiture of the Consumer Health Segment and due to reduced costs associated with the successful transition of our ADHD product manufacturing out of our Grand Prairie, Texas-based manufacturing facility to a United States-based CMO.

Research and Development

	Year Ended June 30,		
	2024	**2023**	**Change**
		(in thousands)	
Research and development:			
AR101	$ 973	$ 1,880	$ (907)
ADHD	1,743	1,803	(60)
Healight	10	250	(240)
Others	65	162	(97)
Total research and development	$ 2,791	$ 4,095	$ (1,304)

During the year ended June 30, 2024, research and development expense decreased by $1.3 million, or 32%, compared to the year ended June 30, 2023. Historically, our research and development costs were primarily associated with AR101 and to a lesser extent, the development of Healight and support for our commercialized products. In October 2022, we announced the suspension of the development of AR101 and Healight to focus on our commercial operations. As a result, research and development spending has significantly declined. Research and development spending on AR101 during fiscal 2024 relates to $0.5 million charge to wind down the clinical trial and the remaining relates to minimum expenses required for regulatory filings and maintenance of our AR101 intellectual property, and spending on ADHD relates to regulatory filings and maintenance of our intellectual property. We expect our research and development expenses to slightly decrease in the future as we continue to look for cost savings and focus on commercial operations.

Amortization of Intangible Assets

During the year ended June 30, 2024, amortization expense of intangible assets, excluding amounts included in cost of sales, were relatively consistent compared to the year ended June 30, 2023. We expect amortization of intangible assets expense to decrease during fiscal 2025 as a result of certain intangible assets that became fully amortized towards the end of fiscal 2024.

Restructuring Costs

During the year ended June 30, 2023, we recognized $2.4 million of restructuring costs, excluding $0.7 million of inventory write-down included in cost of sales, related to the wind down of our Consumer Health Segment and the closure of our Grand Prairie, Texas manufacturing site. We expect restructuring costs to decrease during fiscal 2025 as the majority of our restructuring activities were completed during fiscal 2024. See *Note 17 – Restructuring Costs* in the accompanying notes to the consolidated financial statements for further information.

Impairment Expense

During the year ended June 30, 2024, there was no impairment expense recorded except for impairment expense related to exit and disposal activities recorded to the restructuring costs financial statement line item discussed above and we do not anticipate impairment charges during fiscal 2025 at this time.

During the year ended June 30, 2023, we recognized total impairment expense of $5.7 million, consisting of (i) $5.6 million intangible assets, and (ii) $0.1 million other assets. The impairments were due to increased focus on our commercial efforts in the Rx Segment and discontinued product distributions in the Consumer Health Segment. See *Note 7 – Intangible Assets* in the accompanying notes to the consolidated financial statements for further information.

Gain from Contingent Consideration

We fair value our acquisition-related contingent considerations based on our projected results, any changes are reflected through income or expense. During the year ended June 30, 2024, there was no gain from contingent consideration, compared to $1.0 million for the year ended June 30, 2023. The decrease was primarily due to all contingent considerations (including CVRs) expiring or winding down during fiscal 2023. As a result, we do not expect any contingent consideration gain or loss in fiscal 2025.

Other Income, Net

During the year ended June 30, 2024, other income, net was relatively consistent compared to the year ended June 30, 2023. We expect other income, net to continue to be relatively consistent during fiscal 2025.

Interest Expense

During the year ended June 30, 2024, interest expense was relatively consistent with a decreased of $0.2 million, or 3%, compared to the year ended June 30, 2023. We expect interest expense to decrease during fiscal 2025 due to the extinguishment of our $15.0 million term loan while entering into the $13.0 million Eclipse Term Loan on more favorable terms.

Derivative Warrant Liabilities (Loss) Gain

The fair value of derivative warrant liabilities is calculated using either the Black-Scholes option pricing model or the Monte Carlo simulation model are revalued at each reporting period and changes are reflected through income or expense. For the year ended June 30, 2024, we recognized an unrealized loss of $4.0 million from the fair value adjustment primarily driven by an increase in our stock price during fiscal 2024. For the year ended June 30, 2023, we recognized an unrealized gain of $4.8 million from the fair value adjustment primarily driven by a decrease in our stock price during fiscal 2023.

Income Tax Expense

For the year ended 2024, there was $1.8 million of income tax expense, which was an effective tax rate of negative 12.6%. This income tax expense was primarily driven by the limitations on losses as a result of Section 382 of the IRC changes in ownership coupled with existing valuation allowances. We expect that income tax expense will increase during fiscal 2025 due primarily to increased profitability.

For the year ended 2023, income tax expense was zero with an effective tax rate of zero percent and reflecting the full valuation allowance.

Liquidity and Capital Resources

Cash Flows

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

	Year Ended June 30,		
	2024	2023	Change
	(in thousands)		
Net cash used in operating activities	$ (1,388)	$ (5,129)	$ 3,741
Net cash used in provided by investing activities	$ (329)	$ (117)	$ (212)
Net cash (used in) provided by financing activities	$ (1,262)	$ 8,871	$ (10,133)

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 impairment, stock-based compensation expense, gain or loss on derivative warrant liabilities, depreciation, amortization and accretion, and other charges.

During the year ended June 30, 2024, net cash used in operating activities totaled $1.4 million. The use of cash was primarily the result of the decrease in accounts payable and accrued liabilities, partially offset by positive cash earnings (net loss offset by non-cash items primarily from depreciation, amortization and accretion, stock-based compensation expense, derivative warrant liabilities adjustment, inventory write-down, and other certain non-cash adjustments). Additionally, these were partially offset by funds from the Employee Retention Credit program recorded in other operating liabilities (see *Note 9 – Other Liabilities*) and a decrease in accounts receivable, net, inventories and a net decrease in various other operating assets and liabilities.

During the fiscal year ended June 30, 2023, net cash used in operating activities totaled $5.1 million. The decrease in net cash used was primarily the result of the decrease in operating loss, and increases in accounts payable and accrued liabilities, partially offset by an increase in accounts receivable, inventory, and prepaid expenses.

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 and disposal of assets related to exit and disposal costs.

Net cash used in investing activities was $0.3 million during the year ended June 30, 2024, and net cash used in investing activities was $0.1 million during the year ended June 30, 2023, which was primarily used for the purchase of various property and equipment.

Net Cash from Financing Activities

Net cash used in financing activities of $1.3 million during the year ended June 30, 2024, was primarily from $15.7 million of payments made related to the extinguishment of our term loan, $2.6 million for fixed payment arrangements and $0.3 million of payments for debt issuance costs. This financing cash used was partially offset by $13.0 million of proceeds from the Eclipse Term Loan, $3.5 million of net proceeds from the issuance of common stock and warrants and $0.9 million of proceeds from our Eclipse Revolving Loan.

Net cash provided by financing activities of $8.9 million during the year ended June 30, 2023, was primarily from $3.4 million of net proceeds from our securities purchase agreement in June 2023, $9.1 million of net proceeds from our August 2022 equity raise, and $2.9 million net proceeds from our sales under the ATM Sales Agreement; partially offset by $2.3 million of net payments made under our revolving credit facility, and fixed payment arrangements totaling $4.3 million.

Capital Resources

Sources of Liquidity

We have obligations related to our loan agreements and milestone payments for licensed products and manufacturing purchase commitments. We finance our operations through a combination of sales of our common stock and warrants, borrowings under our revolving credit facility and cash generated from operations.

Shelf Registrations

On September 28, 2021, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 7, 2021. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the "2021 Shelf"). As of June 30, 2024, $82.4 million remains available under the 2021 Shelf. This availability is subject to SEC 1.B.6 limitations of Form S-3. The 2021 Shelf expires on October 7, 2024. Given the upcoming expiration of the 2021 Shelf, concurrent with the filing of this Form 10-K we expect to file a new shelf registration statement to cover the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of our common stock, preferred stock, debt securities, warrants, rights and units (the "2024 Shelf").

On June 8, 2020, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on June 17, 2020. This shelf registration statement covered the offering, issuance, and sale by us of up to an aggregate of $100.0 million of our common stock, preferred stock, debt securities, warrants, rights and units (the "2020 Shelf"). In June 2020, under the 2020 Shelf, we initiated an at-the-market offering program ("ATM"), which allowed us to sell and issue shares of our common stock from time-to-time. On June 2, 2021, we terminated our "at-the-market" sales agreement with a sales agent, and on June 4, 2021, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the "ATM Sales Agreement") with a sales agent, pursuant to which we agreed to sell up to $30.0 million of our common stock from time to time in "at-the-market" offerings under the 2020 Shelf. During the year ended June 30, 2023, we issued 699,929 shares of common stock under the ATM Sales Agreement, with total net proceeds of $2.9 million. The 2020 Shelf expired in June 2023 and the ATM Agreement was terminated in July 2023.

Underwriting & Placement Agency Agreements

On June 8, 2023, we entered into a securities purchase agreement with certain institutional investors named therein and a placement agency agreement with Maxim Group LLC, pursuant to which the Company agreed in a best efforts offering to issue and sell to investors in the offering an aggregate of 1,743,695 shares of the Company's common stock, pre-funded warrants in lieu of shares to purchase 430,217 shares of common stock at an exercise price of $0.0001, accompanying Tranche A warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche A Warrants"), and accompanying Tranche B warrants to purchase 2,173,912 shares of common stock at an exercise price of $1.59 (the "Tranche B Warrants"). The Tranche A Warrants and the Tranche B Warrants may be exercised for either shares of common stock or pre-funded warrants to purchase common stock at a future exercise price of $0.0001 per share in the same form as the pre-funded warrant. The gross proceeds were $4.0 million, and net proceeds were $3.4 million after deducting offering expenses. The offering closed on June 13, 2023. In June 2024, the Tranche B Warrants were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of common stock and 1,806,434 pre-funded warrants to purchase shares of common stock with an exercise price of $0.0001 per share (the "Tranche B Pre-Funded Warrants"). We used a portion of these proceeds as part of the $15.0 million term loan repayment that occurred in the fourth quarter of fiscal 2024.

On August 11, 2022, we closed an underwritten public offering, pursuant to which we sold an aggregate of (i) 1,075,290 shares of our common stock, (ii), pre-funded warrants to purchase 87,500 shares of our common stock, and (ii) accompanying warrants to purchase 1,265,547 shares of our common stock. The shares of common stock (or pre-funded warrants) and the accompanying common warrants were issued separately but could only be purchased together. The combined public offering price for each share of common stock and accompanying common warrant was $8.60, and the combined offering price for each pre-funded warrant and accompanying common warrant is $8.58, which equals the public offering price per share of the common stock and accompanying common warrant, less the $0.001 per share exercise price of each pre-funded warrant. The pre-funded warrants were exercised in full in August 2022. The common warrants are exercisable at any time after the date of issuance for a period of five years from the date such common warrants are first exercisable. The number of shares of common stock issuable upon exercise of the common warrants is subject to adjustment in certain circumstances, including a stock split of, stock dividend on, or a subdivision, combination or recapitalization of the common stock. The Company received gross proceeds of $10.0 million and net proceeds were $9.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Avenue Capital Agreement

On January 26, 2022, we entered into the Avenue Capital Agreement, pursuant to which the Company received $15.0 million term loan. In the fourth quarter of fiscal 2024, we repaid this term loan in full with proceeds from the Eclipse Term Loan and a portion of the proceeds from the exercise of the Tranche B Warrants.

Eclipse Agreement

In June 2024, we and certain of our subsidiaries entered into the Eclipse Amendment No. 5, with the Eclipse Lender. Under the Eclipse Agreement No. 5, we have two loan agreements, the Eclipse Term Loan and the Eclipse Revolving Loan.

The Eclipse Term Loan consists of a principal amount of $13.0 million, at an interest rate of SOFR plus 7.0%, with a four-year term and a straight-line loan amortization period of seven years, which would provide for a loan balance at the end of the four-year term of $5.6 million to be repaid on June 12, 2028, the maturity date. We used the proceeds of the Eclipse Term Loan and a portion of the proceeds from warrant exercises described below to repay in full a $15.0 million term note.

The Eclipse Revolving Loan allows us to borrow up to $14.5 million at an interest rate of SOFR plus 4.5%. In addition, we are required to pay an unused line fee of 0.5% of the average unused portion of the maximum Eclipse Revolving Loan amount during the immediately preceding month. The ability to make borrowings and obtain advances of the Eclipse Revolving Loan remains subject to a borrowing base and reserve, and availability blockage requirements and the maturity date, as amended, is June 12, 2028.

Contractual Obligations, Commitments and Contingencies

As a result of our acquisitions and licensing agreements, we are contractually and contingently obliged to pay, when due, various fixed and contingent milestone payments. See *Note 18 – Commitments and Contingencies* in the accompanying notes to the consolidated financial statements for further information.

In May 2022, we entered into an agreement with Tris to terminate the License, Development, Manufacturing and Supply Agreement dated November 2, 2018, related to Tuzistra (the "Tuzistra License Agreement"). Pursuant to such termination, as of June 30, 2024, we have accrued a settlement liability of $6.2 million payable to Tris, with a provision that allows us to pay interest on any principal amounts due but remaining unpaid past July 2024.

Upon closing of the acquisition of a line of prescription pediatric products from Cerecor, Inc. in October 2019, we assumed payment obligations that require us to make fixed and product milestone payments. As of June 30, 2024, up to $2.1 million of fixed and product milestone payments remain to be paid through 2026 and are expected to be paid from the revenue generated by Karbinal.

In connection with our acquisition of the assets from Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, Rumpus Vascular, LLC (collectively, "Rumpus"), and only if we resume and ultimately complete clinical development of AR101 and gain regulatory clearances to commercialize the product in multiple markets around the world, we may be required to pay up to $67.5 million in regulatory and commercial-based earn-out payments to Rumpus, which are primarily paid against commercial milestone achievements. Under the licensing agreement with Denovo Biopharma LLC ("Denovo"), we made a payment of $0.6 million for a license fee in April 2022. In addition, upon the achievement of regulatory and commercial milestones, we may be required to pay up to $101.7 million. Under the licensing agreement with Johns Hopkins University ("JHU"), upon achievement of regulatory and commercial milestone, we may be required to pay up to $1.6 million to JHU. In fiscal 2022, two milestones payable to Rumpus were achieved totaling $4.0 million, which were paid in 109,447 shares of common stock and $2.6 million in cash. The Company also assumed the responsibility for royalties of 3.0% of net revenue from the product, with a minimum of $20,000 per year, and upon the achievement of certain regulatory and commercial milestones, up to $1.6 million. With clinical development currently suspended, only if and when we resume and ultimately complete clinical development of AR101, are substantially all milestones payable to these parties.

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 Part II, Item 8, *Note 2 – Summary of Significant Accounting Policies* in this Annual Report, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements and notes thereto.

Revenue Recognition

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

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

We make estimates of the net sales price, including estimates of variable consideration to be incurred on the respective product sales (known as "Gross to Net" adjustments). Significant judgement is required in estimating Gross to Net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

The Gross to Net adjustments includes:

- *Savings offers.* The Company offers savings programs for its patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted.

- *Prompt payment discounts.* Prompt payment discounts are based on standard provisions of wholesalers' services.

- *Wholesale distribution fees.* Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers.

- *Rebates.* The Rx Portfolio products are subject to commercial managed care and government (i.e. Medicaid) programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals are estimated based on historical information from third-party providers.

- *Wholesaler chargebacks.* 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 following the product purchases of the wholesalers' end customers.

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

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

A 10% increase or decrease in these estimates impacts net revenue by a corresponding increase or decrease of approximately $2.9 million. The estimates related to returns and savings offers have the most significant impact on our Gross to Net adjustment calculation.

We generate Consumer Health Segment product revenue from sales of various consumer health products through e-commerce platforms and direct mail. Revenue is generally recognized "free-on-board" shipping point, as those are the agreed-upon contractual terms. Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction that are collected by us from a customer are excluded from revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of sale. We completed the wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025.

Impairment of Long-lived Assets

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

Our strategy is to continue building our portfolio of revenue-generating products by leveraging our commercial team's expertise to build leading brands within large therapeutic markets. As a result of focusing on building the portfolio of revenue-generating prescription products, we decided to abandon active development of our NT0502 (N-desethyloxybutynin), a new chemical entity that is being developed for the treatment of sialorrhea, which is excessive salivation or drooling. During the year ended June 30, 2023, we incurred an impairment charge of $2.6 million related to NT0502 and have terminated the licensing agreement. We also terminated the license agreement with Cedars-Sinai Medical Center surrounding the Healight technology platform as an additional result of terminating the development of the Healight program. Further, the acquired product distribution rights from Innovus was impaired by $3.0 million due to discontinuance of products in the Consumer Health Segment.

During the year ended June 30, 2024, related to our wind down of our Consumer Health Segment we recorded an inventory write-down of $0.7 million and restructuring costs totaling $0.2 million related primarily to severance costs and the abandonment of our leased warehouse facility, equipment and other assets. Also, during the year ended June 30, 2024, related to the closure of our Grand Prairie, Texas manufacturing facility we recorded restructuring costs totaling $2.2 million related to severance costs and the abandonment of our leased manufacturing facility, equipment and other assets. The inventory write-down was recorded in cost of sales and restructuring costs have been recorded in restructuring costs on the consolidated statements of operations.

Warrants

Equity classified warrants are valued using a Black-Scholes option pricing model at issuance and are not remeasured. Liability classified warrants are carried at fair value using either the Black-Scholes option pricing model or the Monte Carlo simulation model. Changes in the fair value of liability classified warrants in subsequent periods are recorded as a gain or loss on remeasurement and reported as a component of cash flows from operations.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO THE CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Aytu BioPharma, Inc. (a Delaware corporation) and subsidiaries (the "Company") as of June 30, 2024, and 2023, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended June 30, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2024, and 2023, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

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

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

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

Critical audit matter

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

Variable consideration related to certain gross to net adjustments

As described further in Note 2 to the financial statements, the Company estimates adjustments to the transaction price of certain product sales ("Gross to Net" adjustments). Certain Gross to Net adjustments involve the use of significant assumptions and judgments to develop the estimate. The most significant assumption used in the ADHD Portfolio savings offers Gross to Net adjustment is the inventory levels in the distribution channel as of the balance sheet date. We identified the ADHD Portfolio savings offerings Gross to Net adjustment as a critical audit matter.

The principal considerations for our determination that the ADHD Portfolio savings offerings Gross to Net adjustment is a critical audit matter are (a) the inherent limitations over management's visibility and insight into the underlying details of the source data, which requires management to depend and rely on external data from multiple sources and (b) the extent to which the external data is used by management to develop the estimate of the ADHD Portfolio savings offerings Gross to Net adjustment.

Our audit procedures related to this critical audit matter included the following, among others:

(i) We evaluated the relevance and reliability of the external data used by management to develop the estimate of inventory levels in the distribution channel as of the balance sheet date.

(ii) We evaluated the reasonableness of the identified significant assumption related to inventory levels in the distribution channel to determine the ADHD Portfolio savings offers Gross to Net adjustment by comparing to external data.

(iii) We tested the overall reasonableness of the ADHD Portfolio savings offers Gross to Net adjustment as of the balance sheet date by developing an expectation for comparison to actual subsequent payments.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2022.

Denver, Colorado
September 26, 2024

AYTU BIOPHARMA, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	June 30,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,006	$ 22,985
Accounts receivable, net	23,617	28,937
Inventories	12,633	11,995
Prepaid expenses and other current assets	5,635	7,162
Total current assets	61,891	71,079
Non-current assets:		
Property and equipment, net	693	1,815
Operating lease right-of-use assets	829	2,054
Intangible assets, net	52,453	58,970
Other non-current assets	2,229	2,545
Total non-current assets	56,204	65,384
Total assets	$ **118,095**	$ **136,463**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,440	$ 13,478
Accrued liabilities	38,574	46,799
Revolving credit facility	2,395	1,563
Current portion of debt	1,857	85
Other current liabilities	8,962	7,090
Total current liabilities	62,228	69,015
Non-current liabilities:		
Debt, net of current portion	10,877	14,713
Derivative warrant liabilities	12,745	6,403
Other non-current liabilities	4,529	6,975
Total non-current liabilities	28,151	28,091
Commitments and contingencies (note 18)		
Stockholders' equity		
Preferred stock, par value $.0001; 50,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, par value $.0001; 200,000,000 shares authorized; 5,972,638 and 5,517,174 shares issued and outstanding, respectively	1	1
Additional paid-in capital	347,688	343,485
Accumulated deficit	(319,973)	(304,129)
Total stockholders' equity	27,716	39,357
Total liabilities and stockholders' equity	$ **118,095**	$ **136,463**

The accompanying notes to the consolidated financial statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended June 30,	
	2024	**2023**
Net revenue	$ 81,002	$ 107,399
Cost of sales	26,416	40,767
Gross profit	54,586	66,632
Operating expenses:		
Selling and marketing	26,958	41,448
General and administrative	22,514	28,630
Research and development	2,791	4,095
Amortization of intangible assets	5,212	4,788
Restructuring costs	2,365	—
Impairment expense	—	5,705
Gain from contingent consideration	—	(969)
Total operating expenses	59,840	83,697
Loss from operations	**(5,254)**	**(17,065)**
Other income, net	568	184
Interest expense	(4,792)	(4,963)
Derivative warrant liabilities (loss) gain	(4,004)	4,793
Loss on extinguishment of debt	(594)	—
Loss before income tax	**(14,076)**	**(17,051)**
Income tax expense	(1,768)	—
Net loss	$ **(15,844)**	$ **(17,051)**
Basic and diluted weighted-average common shares outstanding	5,537,957	3,339,906
Basic and diluted net loss per share	$ (2.86)	$ (5.11)

The accompanying notes to the consolidated financial statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balances, June 30, 2022	1,928,941	$ —	$ 331,386	$ (287,078)	$ 44,308
Stock-based compensation expense	(18,180)	—	6,046	—	6,046
Issuance of common stock, net of $1,004 issuance cost	3,606,413	1	6,053	—	6,054
Net loss	—	—	—	(17,051)	(17,051)
Balances, June 30, 2023	5,517,174	1	343,485	(304,129)	39,357
Stock-based compensation expense	14,250	—	2,913	—	2,913
Issuance of common stock from exercise of warrants	441,214	—	1,290	—	1,290
Net loss	—	—	—	(15,844)	(15,844)
Balances, June 30, 2024	5,972,638	$ 1	$ 347,688	$ (319,973)	$ 27,716

The accompanying notes to the consolidated financial statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (15,844)	$ (17,051)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation, amortization and accretion	8,272	8,815
Stock-based compensation expense	2,913	6,046
Derivative warrant liabilities loss (gain)	4,004	(4,793)
Amortization of debt discount and issuance costs	597	559
Inventory write-down	2,270	2,351
Impairment expense	—	5,705
Gain from contingent consideration	—	(969)
Non-cash loss on extinguishment of debt	400	—
Other non-cash adjustments	660	7
Changes in operating assets and liabilities:		
Accounts receivable, net	5,320	(7,153)
Inventories	(2,908)	(3,609)
Prepaid expenses and other current assets	1,527	846
Accounts payable	(2,879)	2,384
Accrued liabilities	(9,567)	3,605
Other operating assets and liabilities, net	3,847	(1,872)
Net cash used in operating activities	**(1,388)**	**(5,129)**
Cash flows from investing activities:		
Other investing activities	(329)	(117)
Net cash used in investing activities	**(329)**	**(117)**
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants	3,467	15,575
Payment made to fixed payment arrangement	(2,566)	(4,266)
Net proceeds (payments) made on revolving credit facility	832	(2,250)
Payments made to borrowings	(15,722)	(96)
Proceeds from borrowings	13,000	—
Payment for debt issuance costs	(273)	(92)
Net cash (used in) provided by financing activities	**(1,262)**	**8,871**
Net change in cash and cash equivalents	(2,979)	3,625
Cash and cash equivalents at beginning of period	22,985	19,360
Cash and cash equivalents at end of period	$ **20,006**	$ **22,985**
Supplemental disclosure of cash flows information:		
Cash paid for interest	$ 4,039	$ 3,812
Cash paid for income taxes	$ 1,608	$ —
Non-cash investing and financing activities:		
Other non-cash investing and financing activities	$ 787	$ 147

The accompanying notes to the consolidated financial statements are an integral part of this statement.

AYTU BIOPHARMA, INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 - Nature of Business and Financial Condition

Aytu BioPharma, Inc. ("Aytu," the "Company," "we," "us," or "our"), is a pharmaceutical company focused on commercializing novel therapeutics. The Company was originally incorporated as Rosewind Corporation on August 9, 2002, in the state of Colorado and was re-incorporated as Aytu BioScience, Inc. in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. ("Neos") in March 2021 (the "Neos Acquisition"), the Company changed its name to Aytu BioPharma, Inc.

The Company's strategy is to become a leading pharmaceutical company that improves the lives of patients. The Company uses a focused approach of in-licensing, acquiring, developing, and commercializing novel prescription therapeutics in order to continue building its portfolio of revenue-generating products and leveraging its commercial team's expertise to build leading brands within large therapeutic markets. The Company's primary focus is on commercializing innovative prescription products that address conditions frequently developed or diagnosed in childhood, including attention deficit hyperactivity disorder ("ADHD"). The Company operates through two business segments: (i) the Rx segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers (the "Rx Segment") and (ii) the consumer health segment, which consists of various consumer healthcare products sold directly to consumers through certain e-commerce platforms (the "Consumer Health Segment").

The Rx Segment primarily consists of two product portfolios. The first consists of Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets ("Adzenys") and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets ("Cotempla") for the treatment of attention deficit hyperactivity disorder ("ADHD") (the "ADHD Portfolio"). The second consists primarily of Karbinal® ER (carbinoxamine maleate extended-release oral suspension) ("Karbinal"), an extended-release first-generation antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions, and 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 (the "Pediatric Portfolio").

The Consumer Health Segment consisted of multiple consumer health products competing in large healthcare categories including allergy, hair regrowth, diabetes support, digestive health, sexual and urological health and general wellness, which was commercialized through direct mail and e-commerce marketing channels. The Company began to wind down the Consumer Health Segment in fiscal 2024. During the first quarter of fiscal 2025, the Company completed the wind down of operations and entered into a definitive agreement to divest the Consumer Health Segment to a private, e-commerce focused company (the "Consumer Health Divestiture"). The divested business encompasses the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for the Company to receive up to $0.5 million of revenue-based royalty payments and recovery of cost on certain future sales of former Consumer Health business products.

During the fourth quarter of fiscal 2024, the Company concluded that it had alleviated the Company's previously disclosed substantial doubt about its ability to continue as a going concern. This was primarily the result of the extinguishment of its $15.0 million term loan that was due in January 2025, while entering into a new $13.0 million term loan on more favorable terms to the Company with a maturity date of June 2028. Further, the Company maintained and extended the maturity date of its revolving credit facility to June 2028 and had $5.6 million of remaining availability to draw upon as of June 30, 2024 (see *Note 10 – Revolving Credit Facility* and *Note 11 – Long-Term Debt* for further detail). In addition, during fiscal 2024 the Company received $3.5 million of net proceeds from the exercise of warrants, was in compliance with all of its debt covenants as of June 30, 2024, and through the filing of this Annual Report on Form 10-K for the year ended June 30, 2024 ("Form 10-K" or "Annual Report"). The Company has implemented and continues to implement plans to achieve operating profitability and increase cash flows, including various margin improvement initiatives, the wind down and divestiture of the Company's unprofitable Consumer Health Segment, and the indefinite suspension of certain research and development activities. Considering these factors, management has concluded that as of the filing of this Form 10-K, substantial doubt about the Company's ability to continue as a going concern did not exist.

The Company's consolidated financial Statements and notes thereto have been prepared assuming that the Company will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business within one year after the date the consolidated financial statements and notes thereto are available to be issued.

Note 2 - Summary of Significant Accounting Policies

Principals of Consolidation

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

Going Concern Determination

In connection with the preparation for each annual and interim financial reporting period, management evaluates whether there are events that, in the aggregate, raise substantial doubt about the Company's ability to continue as a going concern within one year after the financial statements are available to be issued. The evaluation is based on relevant conditions and events that are known and reasonably knowable within one year after the date that the financial statements are available to be issued. Recurring operating losses or year over year negative cash flows from operating activities are considered negative trends. See *Note 1 – Nature of Business and Financial Condition* for further detail on the evaluation performed by the Company.

Use of Estimates

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

Prior Period Reclassification.

Certain prior year amounts in the Company's consolidated financial statements and the notes thereto have been reclassified to conform to the current year presentation. These reclassifications did not impact operating results or cash flows for the fiscal years ended June 30, 2024, and 2023, or its financial position as of June 30, 2024, or June 30, 2023.

Previously Reported Prepaid Expenses Information

During the year ended June 30, 2024, the Company identified that certain of the Company's prepaid expenses totaling $1.8 million that were previously reported as current assets as of June 30, 2023, should have been classified as non-current assets as of June 30, 2023. The Company assessed the materiality of this omission on the previously issued interim and annual consolidated financial statements in accordance with the United States Securities and Exchange Commission ("SEC") Staff Accounting Bulletin No. 99, "Materiality" and concluded that the omission was not material to any of the previously issued consolidated financial statements and began reporting the prepaid expenses as non-current within this Form 10-K.

Cash and Cash Equivalents

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 cash balances in bank deposits are subject to the Federal Deposit Insurance Corporation ("FDIC") insurance limits, and cash balances in the money market funds are not FDIC insured. The Company considers all highly liquid instruments purchased with an original maturity of three months or less to be cash equivalents.

Accounts Receivable, Net

Accounts receivable represent amounts due from customers less allowances for credit losses, discounts and pricing chargebacks. An allowance for credit losses, when needed, is based on the best estimate of the amount of probable credit losses in existing accounts receivable, which is determined from the Company's historical write-off experience and expected future default probabilities based on ongoing evaluations of Company's customers' financial condition; payment history; collections experience on other accounts; and economic factors or events expected to affect future collections. An allowance for credit losses, when needed, consists of an amount identified for specific customers and an amount based on overall estimated exposure. Accounts receivable are customer obligations due under normal trade terms. Recovery of bad debt amounts which were previously written off are recorded as a reduction of bad debt expense in the period the payment is collected. If the Company's actual collection experience changes, revisions to the Company's allowance for credit losses may be required. After attempts to collect a receivable have failed, the receivable is written off against the allowance for credit losses. The allowance for credit losses was zero for both years ended June 30, 2024, and 2023. The allowance for discounts was $0.6 million and $1.8 million as of June 30, 2024, and 2023, respectively. The allowance for chargebacks was $1.2 million at both June 30, 2024, and 2023.

The table below presents the opening and closing balances of accounts receivable, gross from customers.

	Accounts Receivable, Gross
	(in thousands)
Balance, June 30, 2022	$ 24,219
Increase in accounts receivable, gross	7,708
Balance, June 30, 2023	31,927
Decrease in accounts receivable, gross	(6,488)
Balance, June 30, 2024	$ 25,439

The table below details the change in allowance for discounts and allowance for chargebacks for the periods presented.

	Allowance for Discounts	Allowance for Chargebacks	Total Allowance
		(in thousands)	
Balances, June 30, 2022	$ 1,301	$ 1,206	$ 2,507
Reduction of net revenue	9,074	4,554	13,628
Payments	(8,597)	(4,548)	(13,145)
Balances, June 30, 2023	1,778	1,212	2,990
Reduction of net revenue	4,886	3,812	8,698
Payments	(6,024)	(3,842)	(9,866)
Balances, June 30, 2024	$ 640	$ 1,182	$ 1,822

Inventories

Inventories consist of raw materials, work in process and finished goods and are recorded at the lower of cost or net realizable value, with cost determined on a first-in, first-out basis. Prior to regulatory approval, before economic benefit is probable, pre-launch inventories are expensed as research and development.

The Company periodically reviews the composition of its inventories in order to identify obsolete, slow-moving or otherwise unsaleable items. In the event that such items are identified and there are no alternate uses for the inventory, the Company will record a charge to cost of sales to reduce the value of the inventory to net realizable value in the period the impairment is identified.

Property and Equipment

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

Leases

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

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

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

Fair Value of Financial Instruments

Acquisitions

In an acquisition of a business or a group of assets, the Company uses the acquisition method of accounting which identifies, recognizes, and measures the identifiable assets acquired, liabilities assumed and any non-controlling interest at their acquisition date fair values. Any excess of the purchase consideration over the fair values of the net identifiable assets acquired is recorded as goodwill. If the Company determines the assets acquired do not meet the definition of a business, the transaction is accounted for as an acquisition of assets, which records the assets acquired at the purchase price and does not result in goodwill.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common shares and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding. Liability and equity classified warrants are valued using a Black-Scholes option pricing model or Monte Carlo simulation model at issuance and for each reporting period when applicable.

Revenue Recognition

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

Rx Segment

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

within the United States and "free-on-board" shipping point when shipped internationally consistent with the contractual terms. The Company expenses the incremental costs to obtain a contract as incurred, since they are satisfied within one year.

Rx Segment net revenue is recognized net of consideration paid to the Company's customers and other adjustments to the transaction price (known as "Gross to Net" adjustments). Significant judgement is required in estimating Gross to Net adjustments considering legal interpretations of applicable laws and regulations, historical experience, payer channel mix, current contract prices under applicable programs, unbilled claims, processing time lags and inventory levels in the distribution channel.

The Gross to Net adjustments include:

- *Savings offers.* The Company offers savings programs for its patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted.

- *Prompt payment discounts.* Prompt payment discounts are based on standard provisions of wholesalers' services.

- *Wholesale distribution fees.* Wholesale distribution fees are based on definitive contractual agreements for the management of the Company's products by wholesalers.

- *Rebates.* The Rx Portfolio products are subject to commercial managed care and government (i.e. Medicaid) programs whereby discounts and rebates are provided to participating managed care organizations and federal and/or state governments. Calculations related to rebate accruals are estimated based on historical information from third-party providers.

- *Wholesaler chargebacks.* 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 following the product purchases of the wholesalers' end customers.

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

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

Consumer Health Segment

The Consumer Health Segment, which was divested of in the first quarter of fiscal 2025, had net revenue which was from sales of various consumer health products through e-commerce platforms and direct-to-consumer marketing channels. Revenue was generally recognized "free-on-board" shipping point, as those were 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 were excluded from net revenue. Shipping and handling costs associated with outbound freight after control over a product had transferred to a customer were accounted for as a fulfillment cost and were included in cost of sales. The Company expensed the incremental costs to obtain a contract as incurred, since they are satisfied within one year.

Concentration of Credit Risk.

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

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

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

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

	Percentage of Gross Revenue		Percentage of Accounts Receivable	
	June 30,		June 30,	
	2024	2023	2024	2023
Customer A	33%	43%	40%	50%
Customer B	20%	18%	29%	19%
Customer C	17%	17%	11%	14%

Costs of Sales

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

Stock-Based Compensation Expense

The Company accounts for stock-based payment compensation expense using a fair value based model. Restricted stock and restricted stock unit grants are valued based on the estimated grant date fair value of the Company's common stock and recognized ratably over the requisite service period. Stock option grants are valued using the Black-Scholes option pricing model and compensation costs are recognized ratably over the period of service using the graded method. The Black-Scholes option pricing model requires the Company to estimate the expected term of the award, the expected volatility, the risk-free interest rate, and the expected dividends. The expected term is determined using the "simplified method," which is the midpoint between the vesting date and the end of the contractual term and is utilized by the Company as it does not have sufficient historical data to determine a more reliable expected term estimate. The risk-free interest rate is based on the United States Treasury yield in effect at the time of the grant for the expected term of the award. The Company does not anticipate paying any dividends in the near future. Forfeitures are recognized as they occur.

Employee Benefits Plan

The Company has a 401(k) plan ("Aytu 401(k) Plan"), which allows participants to contribute a portion of their salary, subject to eligibility requirements and annual Internal Revenue Service ("IRS") limits. The Aytu 401(k) Plan matches 100% of the first 3% contributed by employees and matches 50% of the next 4% and 5% contributed by employees. The Company's match for the Aytu 401(k) Plan was $0.7 million for both of the years ended June 30, 2024, and 2023.

Research and Development

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

Intangible Assets

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

Impairment of Long-lived Assets

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

Contingent Consideration

The consideration for the Company's acquired businesses and licenses often includes future payments that are contingent upon the occurrence of a particular event or events. The Company records an obligation for such contingent payments at fair value on the acquisition date. Changes in the fair value of contingent consideration obligations are recognized in the consolidated statements of income, which resulted in a gain from contingent consideration of zero and $1.0 million for the years ended June 30, 2024, and 2023, respectively. The Company did not have any contingent consideration recorded on its consolidated balance sheets as of June 30, 2024, and 2023.

Advertising and Direct Marketing Costs

Advertising and direct marketing costs consist of the direct marketing activities related to the Consumer Health Segment. The Company expenses all advertising costs as incurred. The Company incurred $4.9 million and $17.2 million of advertising costs for the years ended June 30, 2024, and 2023, respectively.

Income Taxes

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

The Company recognizes the effect of income tax positions only if those positions are more likely than not to be sustained upon an examination. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense in the consolidated statements of operations.

Debt Discount and Issuance Costs

Debt issuance costs reflect fees paid to lenders and third parties directly related to issuing debt. Debt discount and issuance costs related to term loans are reported as direct deductions to the outstanding debt and amortized over the term of the debt using the effective interest method as an addition to interest expense. Debt issuance costs related to a revolving credit facility are classified as assets and subsequently amortized using the straight-line method over the term of the revolving credit facility as additional interest expense.

Segment Information

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

Paragraph IV Litigation Costs

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

Business Combinations

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.

Employee Retention Credit

On March 27, 2020, the United States government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") to provide certain relief as a result of the COVID-19 pandemic. The CARES Act provides tax relief, along with other stimulus measures, including a provision for an Employee Retention Credit ("ERC"), which allows for employers to claim a refundable payroll tax credit against the employer share of Social Security tax equal to 70% of the qualified wages paid to employees after December 31, 2020, through September 30, 2021. The ERC was designed to encourage businesses to keep employees on the payroll during the COVID-19 pandemic.

As there is no authoritative guidance under U.S. GAAP on accounting for government assistance to for-profit business entities, the Company will account for the ERC by analogy to International Accounting Standard ("IAS") 20, Accounting for Government Grants and Disclosure of Government Assistance ("IAS 20"). In accordance with IAS 20, the Company recorded a $3.8 million ERC accrual in other non-current liabilities, which represents the proceeds the Company received from the ERC program during the first quarter of fiscal 2024. Further in accordance with IAS 20, when management determines it has reasonable assurance that the Company has substantially met all eligibility requirements of the ERC and following any adjustments from its regulatory audit or upon further clarifications from the Internal Revenue Code of 1986, as amended (the "IRC"), the ERC accrual shall be recognized as a benefit in other income in the consolidated statement of operations. The associated vendor fee of $0.4 million was expensed as incurred in the first quarter of fiscal 2024.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) available to the common stockholders by the weighted average number of common shares outstanding during that period. Diluted net income (loss) per share reflects the potential of securities that could share in the net income (loss) of the Company. For the years ended June 30, 2024, and 2023, the Company incurred a net loss and did not include common equivalent shares in the computation of diluted net loss per share because the effect would have been anti-dilutive.

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

		June 30,	
		2024	**2023**
Warrants to purchase common stock - liability classified	(Note 16)	6,057,766	6,498,980
Warrants to purchase common stock - equity classified	(Note 16)	18,114	39,072
Employee stock options	(Note 15)	146,539	52,762
Employee unvested restricted stock	(Note 15)	25,360	40,996
Employee unvested restricted stock units	(Note 15)	1,775	4,963
Total		6,249,554	6,636,773

Recently Adopted Accounting Pronouncements

Financial Instruments - Credit Losses

In June 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-13, *Financial Instruments—Credit Losses* ("ASU 2016-13"), which requires the measurement of expected credit losses for financial instruments held at the reporting date based on historical experience, current conditions and reasonable forecasts. The main objective of ASU 2016-13 is to provide additional information about the expected credit losses on financial instruments and other commitments to extend credit. The standard was effective for interim and annual reporting periods beginning after December 15, 2019. However, in October 2019, the FASB approved deferral of the adoption date for smaller reporting companies for fiscal periods beginning after December 15, 2022. The effective dates for the amendments in ASU 2022-02 align with those of ASU 2016-13. The Company adopted ASU 2016-13 and ASU 2019-05 on July 1, 2023. The Company evaluated the impact of adoption of ASUs 2016-13, 2019-05, and 2022-02 and concluded that the application of the new standards did not have a material impact on the Company's consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

Debt - Debt with Conversion and Other Options

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)—Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for convertible instruments by removing major separation models currently required. Consequently, more convertible debt instruments will be reported as a single liability instrument with no separate accounting for embedded conversion features. The amendments in this update are effective for public entities that are smaller reporting companies, as defined by the SEC, for the fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted through a modified retrospective or full retrospective method. The Company adopted the guidance on July 1, 2024, and the adoption of the standard did not have a material impact on the Company's consolidated financial statements.

Segment Reporting

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"). ASU 2023-07 was issued to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The guidance should be applied retrospectively unless it is impracticable to do so. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods in fiscal years beginning after December 15, 2024. Early adoption is permitted, including in an interim period. The Company is currently evaluating the provisions of this guidance and assessing the potential impact on the Company's consolidated financial statements and disclosures.

Other than the application of IAS 20 for the ERC, there have been no significant changes to the Company's significant accounting policies and there is no other accounting guidance has been issued and not yet adopted that is applicable to the Company and that the Company expects would have a material effect on the Company's consolidated financial statements and related disclosures as of June 30, 2024, and through the filing of this Form 10-K.

Note 3 - Revenue

The Company disaggregates its revenue into two segments, the Rx Segment and the Consumer Health Segment. The Rx Segment includes the ADHD Portfolio, comprised of Adzenys and Cotempla; and the Pediatric Portfolio, comprised of Karbinal, Poly-Vi-Flor and Tri-Vi-Flor. The Company completed its wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025. The Consumer Health Segment was comprised of over ten consumer health products.

Revenues by Segment

Net revenue disaggregated by segment for the years ended June 30, 2024, and 2023, were as follows:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
Rx Segment net revenue	$ 65,183	$ 73,799
Consumer Health Segment net revenue	15,819	33,600
Total net revenue	$ 81,002	$ 107,399

Revenues by Product Portfolio

Net revenue disaggregated by significant product portfolios in the Rx Segment for the years ended June 30, 2024, and 2023, were as follows:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
ADHD Portfolio net revenue	$ 57,784	$ 46,855
Pediatric Portfolio net revenue	7,280	25,377
Other	119	1,567
Total Rx Segment net revenue	$ 65,183	$ 73,799

Other includes discontinued and deprioritized products in the Rx Segment. The Consumer Health Segment was comprised of one product portfolio.

Revenues by Geographic Location

Net revenue disaggregated by geographic location as determined by the billing address of the Company's customers for the years ended June 30, 2024, and 2023, were as follows:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
United States net revenue	$ 80,911	$ 106,918
International net revenue	91	481
Total net revenue	$ 81,002	$ 107,399

Note 4 - Inventories

Inventories consist of the following:

	June 30,	
	2024	2023
	(in thousands)	
Raw materials	$ 266	$ 1,301
Work in process	5,725	2,956
Finished goods	6,642	7,738
Inventories	$ 12,633	$ 11,995

The Company incurred inventory write-downs of $2.3 million for the year ended June 30, 2024, primarily a result of unsalable and slow-moving products and a $0.7 million write-down as part of the wind down of the Consumer Health Segment. The Company incurred inventory write-downs of $2.4 million for the year ended June 30, 2023, primarily as a result of unsalable and slow-moving products.

Note 5 - Property and Equipment

Property and equipment, net consist of the following:

	June 30,	
	2024	2023
	(in thousands)	
Manufacturing equipment	$ 1,117	$ 2,433
Office equipment, furniture and other	945	1,125
Lab equipment	721	832
Leasehold improvements	35	999
Assets under construction	—	107
Property and equipment, gross	2,818	5,496
Less accumulated depreciation and amortization	(2,125)	(3,681)
Property and equipment, net	$ 693	$ 1,815

Depreciation expense was $0.9 million and $1.3 million during the years ended June 30, 2024, and 2023, respectively. During the year ended June 30, 2024, the Company did not record a material gain or loss on disposal of equipment and during the year ended June 30, 2023, the Company recognized a gain of $0.1 million on the disposal of equipment.

Note 6 - Leases

The Company's operating leases are for its offices, manufacturing facilities and equipment, and its finance leases were for equipment. These leases have original lease periods expiring between 2022 and 2030. Most leases include option provisions under which the parties may extend the lease term. Certain non-real estate leases also include options to purchase the leased property. The Company's lease agreements generally do not contain any material residual value guarantees or material restrictive covenants. The Company had no remaining finance leases recorded as of June 30, 2024.

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

During the fourth quarter of fiscal 2024, as part of the previously announced wind down of the Consumer Health Segment and the closure of the Grand Prairie, Texas manufacturing site, the Company ceased using the Oceanside, California warehouse and the Grand Prairie, Texas manufacturing facility. As a result, the Company wrote off the remaining related operating lease ROU assets. The lease for the Oceanside, California warehouse and the Grand Prairie, Texas manufacturing site are set to expire on December 31, 2026, and on December 31, 2024, respectively.

In June 2024, the Company entered into a forward-starting operating lease agreement to lease office space in Berwyn, Pennsylvania from the owner of the office space that the Company is currently renting under a sublease arrangement. The Company has determined that it is an operating lease, and that lease commencement occurred in July 2024. The initial lease termination date is July 31, 2030, and under the lease agreement the Company has one five-year renewal option to extend the lease through July 2035. Undiscounted minimum monthly rent payments average approximately $13,000 over the initial term of the lease. The Company has elected to utilize the practical expedient to not separate lease and non-lease components upon recognition and variable lease payments will be expensed as incurred. The Company will record an operating lease ROU asset of $0.5 million and a lease liability of $0.5 million at lease commencement in July 2024. The ROU asset and lease liability will be recorded at present value using an incremental borrowing rate of 12.3%.

In May 2023, the Company entered into a lease agreement to relocate its principal office. The space was made available to the Company in September 2023 (lease commencement) with an initial term of five and a half years. The Company recorded an operating lease ROU asset of $0.8 million and a lease liability of $0.8 million at lease commencement. The ROU asset and lease liability were recorded at present value using an incremental borrowing rate of 10.3%. The Company utilized the practical expedient to not separate lease and non-lease components upon recognition. See *Note 18 – Commitments and Contingencies* for further detail.

The components of lease expenses are as follows:

	Year Ended June 30,		
	2024	2023	Statement of Operations Classification
	(in thousands)		
Lease cost:			
Operating lease cost	$ 2,247	$ 1,402	Operating expenses
Short-term lease cost	94	97	Operating expenses
Finance lease cost:			
Amortization of leased assets	53	66	Cost of sales
Interest on lease liabilities	3	9	Interest expense
Total lease cost	$ 2,397	$ 1,574	

Supplemental balance sheet information related to leases is as follows:

	June 30,		
	2024	2023	Balance Sheet Classification
	(in thousands)		
Assets:			
Operating lease assets	$ 829	$ 2,054	Operating lease right-of-use assets
Finance lease assets	—	159	Property and equipment, net
Total lease assets	$ 829	$ 2,213	
Liabilities:			
Current:			
Operating leases	$ 712	$ 1,258	Other current liabilities
Finance leases	—	85	Current portion of debt
Non-current:			
Operating leases	577	832	Other liabilities
Total lease liabilities	$ 1,289	$ 2,175	

The remaining weighted-average lease term and discount rate used are as follows:

	June 30,	
	2024	2023
Weighted-average remaining lease term (years):		
Operating lease assets	2.7	1.7
Finance lease assets	—	0.9
Weighted-average discount rate:		
Operating lease assets	10.0%	7.8%
Finance lease assets	—%	6.5%

Supplemental cash flow information related to leases is as follows:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
Cash flow classification of lease payments:		
Operating cash flows from operating leases	$ 1,812	$ 1,436
Operating cash flows from finance leases	$ 3	$ 9
Financing cash flows from finance leases	$ 85	$ 96

As of June 30, 2024, the Company did not have any remaining finance leases. As of June 30, 2024, the Company's future minimum operating lease payments, including the new forward-starting operating lease agreement to lease office space in Berwyn, Pennsylvania were as follows:

	Operating
	(in thousands)
2025	$ 970
2026	399
2027	377
2028	386
2029	359
Thereafter	249
Total lease payments	2,740
Less: imputed interest	(555)
Lease liabilities	$ 2,185

Note 7 - Intangible Assets

A summary of the Company's intangible assets as of June 30, 2024, and June 30, 2023, is as follows:

	June 30, 2024			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life
		(in thousands)		(in years)
Acquired product technology rights	$ 41,268	$ (13,184)	$ 28,084	10.5
Acquired technology rights	30,200	(5,831)	24,369	13.8
Total definite-lived intangible assets	$ 71,468	$ (19,015)	$ 52,453	12.0

	June 30, 2023			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life
		(in thousands)		(in years)
Acquired product technology rights	$ 42,176	$ (10,881)	$ 31,295	11.5
Acquired technology rights	30,200	(4,054)	26,146	14.8
Acquired product distribution rights	6,207	(4,678)	1,529	1.0
Total definite-lived intangible assets	$ 78,583	$ (19,613)	$ 58,970	12.7

Gross carrying amounts are net of any impairment charges from prior periods. An intangible asset with zero net carrying amount at the end of a reporting period is not presented in the table of a future reporting period. 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 $6.5 million and $6.1 million for the years ended June 30, 2024, and 2023, respectively.

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

	June 30, (in thousands)
2025	$ 4,989
2026	4,989
2027	4,989
2028	4,989
2029	4,989
Thereafter	27,508
Total future amortization expense	$ 52,453

Acquired 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 acquisition of the Pediatric Portfolio in November 2019 and the Neos Acquisition in March 2021.

Karbinal

The Company acquired and assumed all rights and obligations pursuant to the supply and distribution agreement, as amended, with Tris Pharma, Inc. ("Tris") for the exclusive rights to commercialize Karbinal in the United States (the "Tris Karbinal Agreement"). The Tris Karbinal Agreement's initial term terminates in August of 2033, with an optional initial 20-year extension.

Poly-Vi-Flor and Tri-Vi-Flor

The Company acquired and assumed all rights and obligations pursuant to a supply and license agreement and various assignment and release agreements, including a previously agreed to settlement and license agreements (the "Poly-Tri Agreements") for the exclusive rights to commercialize Poly-Vi-Flor and Tri-Vi-Flor in the United States.

ADHD Portfolio

As part of the Neos Acquisition, the Company acquired developed product technology for the production and sale of Adzenys and Cotempla. The formulations for the ADHD products are protected by patented technology. The estimated economic life of these proprietary technologies is 16 years.

Acquired Technology Right

TRRP Proprietary Technology

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

Acquired Product Distribution Rights

In connection with the acquisition of Innovus Pharmaceuticals, Inc. ("Innovus") in February 2020 (the "Innovus Acquisition"), the Company obtained 35 products with a combination of over 300 registered trademarks and/or patent rights and customer lists. The customer lists are fully amortized. During the fiscal year ended June 30, 2023, this intangible asset was impaired by $3.0 million due to the discontinuance of products in the Consumer Health Segment. As of June 30, 2024, this intangible asset was fully amortized and removed from gross carrying value.

Acquired In-Process R&D

IPR&D – NT0502

As part of the Neos Acquisition, the Company acquired in-process research and development associated with NT0502, a new chemical entity that was being developed for the treatment of sialorrhea, which is excessive salivation or drooling. During the year ended June 30, 2023, the Company terminated its development program of NT0502. As a result, the Company fully impaired the IPR&D of NT0502, recording impairment expense of $2.6 million to its Rx Segment during the second quarter of fiscal 2023.

Note 8 - Accrued liabilities

Accrued liabilities consist of the following:

	June 30,	
	2024	2023
	(in thousands)	
Accrued savings offers	$ 11,054	$ 15,739
Accrued program liabilities	9,964	11,012
Accrued customer and product related fees	5,395	6,579
Accrued compensation	4,935	5,675
Return reserve	4,835	5,777
Other accrued liabilities	2,391	2,017
Total accrued liabilities	$ 38,574	$ 46,799

Accrued savings offers represent programs for the Company's patients covered under commercial payor plans in which the cost of a prescription to such patients is discounted. Accrued program liabilities include government and commercial rebates. Accrued customer and product related fees include accrued expenses and deductions for rebates, wholesaler chargebacks and fees, and other product-related fees and deductions such as royalties for Pediatric Portfolio products, accrued distributor fees, and Medicaid liabilities. Accrued employee compensation includes sales commissions, paid time off earned, accrued payroll and accrued bonus. The return reserve represents the Company's accrual for estimated product returns. Other accrued liabilities consist of various other accruals, none of which individually or in the aggregate represent greater than five percent of total liabilities.

The following table details the change in return reserve for the periods presented:

	Return Reserve
	(in thousands)
Balance, June 30, 2022	$ 5,770
Reduction of net revenue	8,353
Payments	(8,346)
Balance, June 30, 2023	5,777
Reduction of net revenue	6,128
Payments	(7,070)
Balance, June 30, 2024	$ 4,835

Note 9 - Other Liabilities

Other liabilities consist of the following:

	June 30,	
	2024	2023
	(in thousands)	
Fixed payment arrangements	$ 8,337	$ 10,420
Employee retention credit	3,759	—
Operating lease liabilities	1,289	2,090
Other	106	1,555
Total other liabilities	13,491	14,065
Less: current portion of other liabilities	(8,962)	(7,090)
Total other liabilities, non-current	$ 4,529	$ 6,975

Fixed payment arrangements

Fixed payment arrangements represent obligations to an investor assumed as part of the acquisition of products from Cerecor, Inc. in 2019, including fixed and variable payments.

In May 2022, the Company entered into an agreement with Tris to terminate the license, development, manufacturing and supply agreement dated November 2, 2018, related to Tuzistra XR (the "Tuzistra License Agreement"). Pursuant to such termination, as of June 30, 2024, the Company has accrued a settlement liability of $6.2 million in other current liabilities on the consolidated balance sheet payable to Tris, with a provision that allows the Company to pay interest on any principal amounts due but remaining unpaid past July 2024.

The Tris Karbinal Agreement grants the Company exclusive right to distribute and sell the product in the United States. The initial term of the agreement was 20 years. The Company pays Tris a royalty equal to 23.5% of net revenue from the product. The Tris 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 Tris Karbinal Agreement make-whole payment is capped at $2.1 million each year. The annual payment is due in August of each year. The Tris Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $3.0 million based on cumulative net revenue from the product, the first of which is triggered at $40.0 million. As of June 30, 2024, the fixed payment arrangement balance was $1.9 million in other current liabilities, and $0.2 million in other non-current liabilities on the consolidated balance sheet.

Employee Retention Credit

The $3.8 million ERC accrual in other non-current liabilities as of June 30, 2024, represents the proceeds the Company received from the ERC program during the first quarter of fiscal 2024. Please see *Note 2 - Significant of Significant Accounting Policies* for further detail.

Operating Lease Liabilities

The Company has entered into various operating lease agreements for certain of its offices, manufacturing facilities and equipment. Please refer to *Note 6 - Leases* for further detail.

Other

Other consists of taxes payable, deferred cost related to the Company's technology transfer, and various other accruals, none of which individually or in the aggregate represent greater than five percent of total liabilities.

Note 10 - Revolving Credit Facility

On June 12, 2024, the Company and certain of its subsidiaries entered into consent, joinder and amendment No. 5 (the "Eclipse Amendment No. 5") to the loan and security agreement dated October 2, 2019, as amended by amendment No. 1, dated March 19, 2021, amendment No. 2, dated January 26, 2022, amendment No. 3, dated June 1, 2022, amendment No. 4 dated March 24, 2023, and the Eclipse Amendment No. 5 (together the "Eclipse Agreement") with Eclipse Business Capital LLC ("Eclipse"), as agent, and the lenders party thereto (agent and such lenders, collectively, the "Eclipse Lender"). Under the Eclipse Amendment No. 5, which provided for among other things, two loan agreements, a term loan (the "Eclipse Term Loan") and a revolving credit facility (the "Eclipse Revolving Loan"). The Eclipse Term Loan is described further in *Note 11 - Long-Term Debt*. The Eclipse Revolving Loan provides for a maximum amount available under the revolving credit facility provided under the Eclipse Agreement of $14.5 million at an interest rate of the secured overnight financing rate as administered by the SOFR Administrator ("SOFR") plus 4.5%. In addition, the Company is required to pay an unused line fee of 0.5% of the average unused portion of the maximum Eclipse Revolving Loan amount during the immediately preceding month. The ability to make borrowings and obtain advances of revolving loans under the Eclipse Agreement remains subject to a borrowing base and reserve, and availability blockage requirements. The Eclipse Revolving Loan maturity date, as amended, is June 12, 2028, and the effective interest rate was 9.9% as of June 30, 2024.

In the event that, for any reason, all or any portion of the Eclipse Agreement is terminated prior to the scheduled maturity date, in addition to the payment of all outstanding principal and unpaid accrued interest, the Company is required to pay a fee equal to (i) 2.0% of the Eclipse Revolving Loan commitment if such event occurs on or before June 12, 2025, (ii) 1.0% of the Eclipse Revolving Loan commitment if such event occurs after June 12, 2025, but on or before June 12, 2026, and (iii) 0.5% of the Eclipse Revolving Loan commitment if such event occurs after June 12, 2026, but on or before June 12, 2028. The Company may also be required to pay an early termination fee related to the Eclipse Term Loan as further described in *Note 11 - Long-Term Debt*. The Company may permanently terminate the Eclipse Agreement upon written notice to Eclipse.

The Eclipse Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restrict the Company's ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of Eclipse. A failure to comply with these covenants could permit Eclipse to declare the Company's obligations under the Eclipse Agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of June 30, 2024, the Company was in compliance with the covenants under the Eclipse Agreement. The Company's obligations under the Eclipse Agreement are secured by substantially all of the Company's assets, as defined further in the Eclipse Agreement.

The Company allocated debt issuance costs of $0.1 million related to the Eclipse Revolving Loan, bringing to the total debt issuance costs related to the Eclipse Revolving Loan to $0.2 million, which will be amortized straight-line over the term of the loan. Total interest expense on the Eclipse Revolving Loan, including amortization of deferred financing costs, was $0.1 million and $0.7 million for the years ended June 30, 2024, and 2023. As of June 30, 2024, and 2023, the outstanding amounts drawn on the Eclipse Revolving Loan were $2.4 million and $1.6 million, respectively. The unused revolving credit facility amount as of June 30, 2024, was $5.6 million.

Note 11 - Long-Term Debt

Avenue Capital Loan

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

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

On January 26, 2022 ("Issuance Date"), as consideration for entering into the Avenue Capital Agreement, the Company issued warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price equal to $24.20 per share (the "Avenue Capital Warrants"). The Avenue Capital Warrants provided that in the event the Company were to engage in an equity offering at a price lower than $24.20 prior to June 30, 2022, the exercise price would be adjusted to the effective price of such equity offering and the number of shares of common stock to be issued under the Avenue Capital Warrants would be adjusted as set forth in the agreement. The Avenue Capital Warrants were immediately exercisable and expire on January 31, 2027. At inception, the Company accounted for the Avenue Capital Warrants as a derivative warrant liability as the number of warrants was not fixed at the Issuance Date. The fair value of the Avenue Capital Warrants at issuance was approximately $0.6 million.

On March 7, 2022, the Company closed on an equity offering of shares of common stock and warrants, as described in *Note 15 - Stockholders Equity*, at an offering price of $25.00 per share. As this offering precluded the Company from pursuing any equity financing prior to July 7, 2022, and the effective price of the March 7, 2022, offering was more than the exercise price of the Avenue Capital Warrants, the shares of common stock issuable upon exercise of the Avenue Capital Warrants were set at an exercise price of $24.20.

On October 25, 2022, the Company entered into an agreement with Avenue Venture Opportunities Fund, L.P ("Avenue") to extend the interest-only period of its existing senior secure loan facility held with Avenue. The amendment to the original loan agreement, which was executed in January 2022, extended the interest-only period to January 2024. In exchange for this extension of the interest-only period, the Company and Avenue agreed to reset the exercise price of the warrants issued in conjunction with the original loan agreement to $8.60, corresponding to the warrant exercise price associated with the Company's August 2022 equity financing.

On June 13, 2023, in conjunction with the Securities Purchase Agreement described in *Note 16 - Warrants*, the interest-only period of the Avenue Capital Agreement was extended further upon the achievement of both the revenue-based milestone and equity raise-based milestone stipulated in the Avenue Capital Agreement. As a result, the interest-only period was extended to January 26, 2025.

In addition to the debt discount discussed above, the Company also incurred $0.4 million loan origination, legal and other fees. The debt discount and issuance costs were being amortized over the term of the loan, using the effective interest method resulting in an effective rate of 16.6%. Total interest expense on the Avenue Capital loan including debt discount amortization, were $3.4 million and $2.7 million for the years ended June 30, 2024, and 2023.

On June 12, 2024, the Company used proceeds from the Eclipse Term Loan and a portion of the proceeds from the exercise of warrants to repay the Avenue Capital loan in full. Upon early repayment of the Avenue Capital loan, the Company was required to pay Avenue Capital a fee equal to 1.0% of the loan or $0.2 million. In addition, upon the payment in full of the obligations, the Company was required to pay Avenue Capital a fee in the amount of $0.6 million ("Final Payment"). At inception, the Company accounted for the Final Payment as additional obligations on the debt, with the corresponding charge being recorded as debt discount. At retirement, the early termination fee, the Final Payment fee, and the write-off of all remaining related debt discount and deferred financing costs were included in the calculation of loss on extinguishment of debt. The Company recorded a loss on extinguishment of debt of $0.6 million related to the retirement of the Avenue Capital loan in the fourth quarter of fiscal 2024.

Eclipse Term Loan

On June 12, 2024, the Company and certain of its subsidiaries entered into Eclipse Amendment No. 5, which provided for among other things, the Eclipse Term Loan and the Eclipse Revolving Loan described further in *Note 10 - Revolving Credit Facility*. The Eclipse Term Loan consists of a principal amount of $13.0 million, at an interest rate of SOFR plus 7.0%, with a four-year term maturing on June 12, 2028, and a straight-line loan amortization period of seven years, which would provide for a loan balance at the end of the four-year term of $5.6 million to be repaid on June 12, 2028, the maturity date. The Company used the proceeds of the Eclipse Term Loan and a portion of the proceeds from warrant exercises described below to repay in full the Avenue Capital loan. The effective interest rate on the Eclipse Term Loan was 12.4% as of June 30, 2024.

In the event that, for any reason, all or any portion of the Eclipse Agreement is terminated prior to the scheduled maturity date, in addition to the payment of all outstanding principal and unpaid accrued interest, the Company is required to pay a fee equal to (i) 3.0% of the Eclipse Term Loan if such event occurs on or before June 12, 2025, (ii) 2.0% of the Eclipse Term Loan if such event occurs after June 12, 2025, but on or before June 12, 2026, (iii) 1.0% of the Eclipse Term Loan if such event occurs after June 12, 2026, but on or before June 12, 2027, and (iv) 0.5% of the Eclipse Term Loan if such event occurs after June 12, 2026, but on or before June 12, 2028. The Company may also be required to pay an early termination fee related to the Eclipse Revolving Loan as further described in *Note 10 - Revolving Credit Facility*. The Company may permanently terminate the Eclipse Agreement upon written notice to Eclipse. The Company's obligations under the Eclipse Agreement are secured by substantially all of the Company's assets, as further defined in the Eclipse Agreement.

The Eclipse Agreement contains customary affirmative covenants, negative covenants and events of default, as defined in the agreement, including covenants and restrictions that, among other things, require the Company to satisfy certain capital expenditure limitations and other financial covenants, and restricts the Company's ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make certain asset sales without the prior written consent of the Eclipse Lender. A failure to comply with these covenants could permit the Eclipse Lender to declare the Company's obligations under the agreement, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination, as described above. As of June 30, 2024, the Company was in compliance with the covenants under the Eclipse Agreement.

The Company recorded total debt discount and allocated debt issuance costs of $0.3 million related to the Eclipse Term Loan, which will be amortized over the term of the loan. The Company incurred interest expense on the Eclipse Term Loan, including debt discount and issuance costs amortization, of $0.1 million for the year ended June 30, 2024.

Long-term debt consists of the following:

	June 30,	
	2024	2023
	(in thousands)	
Term loan principal amount	$ 13,000	$ 15,000
Unamortized debt discount and issuance costs	(266)	(925)
Final payment fee	—	638
Financing leases	—	85
Total debt	12,734	14,798
Less: current portion of debt	(1,857)	(85)
Total debt, net of current portion	$ 10,877	$ 14,713

Future principal payments of long-term debt are as follows:

	June 30,
	(in thousands)
2025	$ 1,857
2026	1,857
2027	1,857
2028	7,429
Total future term loan principal payments	13,000
Less: unamortized debt discount and issuance costs	(266)
Less: current portion of debt	(1,857)
Total debt, net of current portion	$ 10,877

Note 12 - Fair Value Measurements

The Company determines the fair value of financial and non-financial assets using the fair value hierarchy, which establishes three levels of inputs that may be used to measure fair value as follows:

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

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

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

The Company's financial instruments include cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, derivative warrant liabilities, contingent consideration liabilities, fixed payment arrangements, and current and non-current debt. The carrying amounts of certain short-term financial instruments, including cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. Current and non-current debt are reported at their amortized costs on the Company's consolidated balance sheets. The remaining financial instruments are reported on the Company's consolidated balance sheets at amounts that approximate current fair values. The Company's policy is to recognize transfers in and/or out of fair value hierarchy as of the date in which the event or change in circumstances caused the transfer. There were no transfers between Level 1, Level 2 and Level 3 in the periods presented.

Recurring Fair Value Measurement

The following table presents the Company's financial assets and liabilities that were accounted for at fair value on a recurring basis as of June 30, 2024, and 2023, by level within the fair value hierarchy:

	Fair Value at June 30, 2024	Fair Value Measurements at June 30, 2024		
		(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Liabilities:				
Derivative warrant liabilities	$ 12,745	$ —	$ —	$ 12,745
Total	$ 12,745	$ —	$ —	$ 12,745

	Fair Value at June 30, 2023	Fair Value Measurements at June 30, 2023		
		(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Liabilities:				
Derivative warrant liabilities	$ 6,403	$ —	$ —	$ 6,403
Total	$ 6,403	$ —	$ —	$ 6,403

Cash and cash equivalents in the consolidated balance sheets include bank deposits and money market funds and reflect their fair value at Level 1 in the fair value hierarchy.

Non-Recurring Fair Value Measurement

The Company's financial assets and liabilities that were accounted for at fair value on a non-recurring basis during the years ended June 30, 2024, and 2023, were fixed payment arrangements and intangible assets.

Fixed payment arrangements are recognized at their amortized cost basis using market appropriate discount rates and are accreted up to their notional face value over time. Significant assumptions used in valuing the fixed payment arrangements were discount rates from 10.0% to 15.4% and are classified as Level 3 inputs in the fair value hierarchy. In May 2022, the Company recognized a fixed payment arrangement liability of $7.6 million relating to the termination of the Tuzistra License Agreement. See *Note 9 - Other Liabilities* for further information on fixed payment arrangements.

Based on the Company's impairment analyses for fiscal 2024 and 2023, the Company did not record an impairment charge on intangible assets during the year ended June 30, 2024, and recorded an impairment charge of $5.6 million on intangible assets for the year ended June 30, 2023. Valuation of intangible assets involves significant Level 3 inputs in estimating their fair values. These input assumptions included revenue growth rates, forecasted earnings before interest, taxes, depreciation, and amortization margins, and the selection of a discount rate. These assumptions may be affected by expectations about future market or economic conditions. See *Note 7 - Intangible Assets* and *Note 2 - Summary of Significant Accounting Policies*, for further discussion on the fair value measurement of intangible assets.

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, 2024:

	Derivative Warrant Liabilities
	(in thousands)
Balance as of June 30, 2022	$ 1,796
Issued	10,998
Settlements	—
Included in earnings	(6,391)
Balance as of June 30, 2023	6,403
Issued [(1)]	5,148
Settlements [(1)]	(2,810)
Included in earnings	4,004
Balance as of June 30, 2024	$ 12,745

(1) Primarily relates to warrants to purchase 2,173,912 common shares issued with the Company's June 2023 equity financing that were exercised in June 2024. The warrants were converted into 367,478 shares of common stock ("Settlements") and 1,806,434 pre-funded warrants to purchase shares of common stock with an exercise price of $0.0001 per share ("Issued"). See *Note 14 - Stockholders' Equity* and *Note 16 - Warrants* for further detail.

Level 3 Inputs

Significant assumptions as of June 30, 2024, used in valuing the derivative warrant liabilities, marked to market, were as follows:

	June 2023 Warrants Tranche A	Warrants Other [(1)]
	Monte Carlo & Black-Scholes	*Black-Scholes*
Aytu closing stock price	$ 2.92	$ 2.92
Equivalent term (years)	3.9	2.6 - 3.2
Expected volatility	80.3%	83.2% - 87.5%
Risk-free rate	4.4%	4.5% - 4.6%
Dividend yield	0%	0%

(1) Includes August 2022 Warrants, March 2022 Warrants, Avenue Capital Warrants and Tranche B Pre-Funded Warrants. See *Note 16 - Warrants* for definitions of these terms and further information.

Note 13 - Income Taxes

For fiscal 2024, there was $1.8 million of income tax expense, which was an effective tax rate of negative 12.6%. This was primarily driven by Section 382 limitation of the IRC on post-Tax Cuts and Jobs Act ("TCJA") net operating loss ("NOL") utilization, as further described below, coupled with existing valuation allowances. As of June 30, 2024, the Company had $0.8 million of deferred tax assets ("DTAs"), net of valuation allowance, included in other non-current assets; $0.8 million of deferred tax liabilities ("DTLs") included in other non-current liabilities; and $0.3 million of accrued income taxes payable included in accrued liabilities in the consolidated balance sheets.

For fiscal 2023, there was zero income tax expense with an effective tax rate of zero percent, reflecting the full valuation allowance. As of June 30, 2023, the Company had $1.4 million of DTAs, net of valuation allowance, included in other non-current assets; $1.4 million of DTLs included in other non-current liabilities; and $0.1 million of accrued income taxes payable included in accrued liabilities in the consolidated balance sheets.

Section 382 Limitation

Under the provisions of the IRC, substantial changes in the Company's ownership have resulted in limitations on the amount of NOL carryforwards that can be utilized in future years. NOL 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 part of the Company's Section 382 analysis, an ownership change was determined to have occurred in March 2022 at a point in time when the Company had a net unrealized built-in gain. As such, the NOL generated during that period has been allocated and the post-change NOL (approximately $12 million) was determined to be fully available to offset fiscal 2023 pre-change income subject to the 80% limitation. The Company also determined that an ownership change occurred in June 2023 at a time when the Company was in a net unrealized built-in loss position. As a result of the Section 382 analysis, the Company had $0.3 million of disallowed recognized built-in loss that was carried forward as a net operating loss as of June 30, 2023. For fiscal 2024, an additional $8.8 million of disallowed recognized built-in loss was carried forward as an operating loss. These operating loss carryovers are subject to the June 2023 Section 382 limitation.

The Company had federal net operating losses of $519.6 million as of June 30, 2024, that is subject to limitation (as described above). Of the available federal net operating losses, $186.6 million can be carried forward indefinitely, and $333.0 million will completely expire in 2037. Of the amount set to expire, $329.2 million will expire unused as a result of the ownership change. As of June 30, 2024, the Company had research and development credits of $3.0 million, which will begin to expire in 2025 and are also subject to Section 382 limitation. The available state net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2025 and will completely expire in 2039.

As of June 30, 2024, 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 notes there is diversity in practice regarding the treatment of deductions or loss carryforwards that are expected to expire unutilized. Generally, it is not appropriate to use zero as an applicable tax rate and rather, a DTA should be recorded at the applicable tax rate and a valuation of an equal amount would be provided. However, under certain circumstances it may be appropriate to follow an alternative approach and use a zero rate to write off the asset against the valuation allowance, reducing the valuation allowance and gross DTAs disclosed. The Company considered both accounting viewpoints and determined it would present its NOL carryforwards gross with a full valuation allowance and not apply a zero rate to NOL carryforwards expected to expire unutilized.

In review of the Company's consolidated deferred position, excluding NOLs and other tax attributes, the Company is in a net DTA position and therefore all NOLs are being fully valued and not utilized against a net DTL.

The provision for income taxes consisted of the following:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
Current:		
Federal	$ 1,549	$ 80
State	219	46
Total current tax expense	1,768	126
Deferred:		
Federal	—	(109)
State	—	(17)
Total deferred tax expense	—	(126)
Provision for income taxes	$ 1,768	$ —

Income tax expense resulting from applying statutory rates in jurisdictions in which the Company is taxed (federal and various states) differs from the income tax expense in the financial statements. A reconciliation of the United States federal statutory income tax rates to the Company's effective tax rate is as follows.

	Year Ended June 30,			
	2024		2023	
	(in thousands, except tax rate)			
Tax at statutory rate	$ (2,956)	21.0%	$ (3,581)	21.0%
State income taxes, net of federal benefit	(779)	5.5%	(430)	2.5%
Stock-based compensation expense	19	(0.1)%	—	—%
Contingent consideration	—	—%	(193)	1.2%
Change in valuation allowance	5,447	(38.7)%	4,087	(24.0)%
Other	37	(0.3)%	117	(0.7)%
Net income tax expense	$ 1,768	(12.6)%	$ —	(0.0)%

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:

	June 30,	
	2024	2023
	(in thousands)	
Deferred tax assets:		
Net operating loss carry forward	$ 119,170	$ 113,819
Interest	4,845	4,188
Accrued rebates	3,819	6,994
Warrant derivatives	3,061	1,504
Research and development credits	2,416	2,416
Stock-based compensation expense	1,259	4,250
Accrued expenses	1,027	758
Section 174 capitalization	780	836
Inventory	256	743
Lease liability	305	492
Fixed assets	99	—
Other	975	1,332
Total deferred tax assets	138,012	137,332
Less: valuation allowance	(137,250)	(135,954)
Deferred tax assets, net of valuation allowance	762	1,378
Deferred tax liabilities:		
Intangibles	(563)	(845)
ROU asset	(199)	(483)
Fixed assets	—	(50)
Total deferred tax liabilities	(762)	(1,378)
Net deferred tax liabilities	$ —	$ —

The Company has recorded a valuation allowance of $137.3 million and $136.0 million at June 30, 2024, and 2023, respectively, to reserve its net DTAs. In assessing the realizability of DTAs, management considers whether it is more likely than not that some portion or all of the DTAs will not be realized. The ultimate realization of DTAs 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 that it will realize the benefits of these deductible differences, net of the valuation allowance provided.

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 NOL, 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, 2024, and 2023, the Company had gross unrecognized tax benefits related to uncertain tax positions of $1.3 million and $2.9 million, respectively. Changes in unrecognized benefits in any given year are recorded as a component of deferred tax expense.

A tabular roll-forward of the Company's gross unrecognized tax benefit related to uncertain tax positions is below.

	June 30,	
	2024	2023
	(in thousands)	
Beginning balances	$ 2,948	$ 2,822
Decrease resulting from current period tax positions	(1,996)	(120)
Increase resulting from current period tax positions	361	246
Ending balances	$ 1,313	$ 2,948

The change in the Company's gross unrecognized tax benefits relates to filed method changes with the IRS for the tax return year ending June 30, 2023. Additionally, Neos pre-acquisition tax years are subject to the same general statute of limitations, resulting in its tax years back to 2005 being subject to examination

Note 14 - Stockholders' Equity

The Company has 200.0 million shares of common stock authorized with a par value of $0.0001 per share and 50.0 million shares of preferred stock authorized with a par value of $0.0001 per share. As of June 30, 2024, and 2023, the Company had 5,972,638 and 5,517,174 common shares issued and outstanding, respectively, and no preferred shares issued and outstanding. As of June 30, 2024, included in common stock outstanding are 25,360 shares of unvested 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. On June 4, 2021, the Company entered into a sales agreement with a 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 "ATM Sales Agreement"). During the year ended June 30, 2023, the Company issued 699,929 shares of common stock under the ATM Sales Agreement, with total net proceeds of $2.9 million. The 2020 Shelf expired in June 2023 and the ATM Agreement was terminated in July 2023.

On September 28, 2021, the Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 7, 2021. This shelf registration statement covered the offering, issuance and sale by the Company of up to an aggregate of $100.0 million of its common stock, preferred stock, debt securities, warrants, rights and units (the "2021 Shelf"). As of June 30, 2024, $82.4 million remained available under the 2021 Shelf. This availability is subject to SEC 1.B.6 limitation to the Form S-3. The 2021 Shelf expires in October 2024. Given the upcoming expiration of the 2021 Shelf, concurrent with the filing of this Form 10-K the Company expects to file a new shelf registration statement to cover 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 "2024 Shelf").

On March 7, 2022, the Company closed on an underwritten public offering utilizing the 2021 Shelf, pursuant to which, the Company sold, (i) 151,500 shares of the Company's common stock, (ii) pre-funded warrants to purchase up to 151,500 shares of common stock, and (iii) common stock purchase warrants to purchase up to 333,300 shares of common stock (the "March 2022 Offering"). The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, with one common warrant to purchase 1.1 shares of common stock for each share of common stock or each pre-funded warrant sold. The pre-funded warrants have an exercise price of $0.002 per share of common stock and were exercised in full in April 2022. The common warrants have an exercise price of $26.00 per share of common stock and are exercisable six months after the date of issuance and have a term of five years from the date of exercisability. The Company raised gross proceeds of $7.6 million through the March 2022 Offering before commission and other costs of $0.8 million. The pre-funded and common warrants have a combined fair value of approximately $2.8 million at issuance and are classified as derivative warrant liabilities with the offset in additional paid in capital in stockholders' equity in the Company's consolidated financial statements (see *Note 16 - Warrants*).

On August 11, 2022, the Company closed on an underwritten public offering (the "August 2022 Offering") utilizing the 2021 Shelf, pursuant to which it sold an aggregate of (i) 1,075,290 shares of its common stock; (ii) in lieu of common stock to certain investors that so chose, pre-funded warrants to purchase 87,500 shares of its common stock; and (iii) accompanying warrants to purchase 1,265,547 shares of its common stock. The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, with one common warrant to purchase one share of common stock for each share of common stock or each pre-funded warrant sold. The combined public offering price for each share of common stock and accompanying common warrant was $8.60, and the combined offering price for each pre-funded warrant and accompanying common warrant was $8.58, which equated to the public offering price per share of the common stock and accompanying common warrant, less the $0.02 per share exercise price of each pre-funded warrant. The pre-funded warrants were exercised in full in August 2022. The common warrants have an exercise price of $8.60 per share of common stock and are exercisable for a period of five years from issuance. The Company raised $10.0 million in gross proceeds through the August 2022 Offering before underwriting fees and other expenses of $0.9 million. The pre-funded and common warrants had a combined fair value of approximately $6.0 million at issuance and are classified as derivative warrant liabilities, with the offset in additional paid in capital in stockholders' equity in the Company's consolidated financial statements (see *Note 16 - Warrants*).

On June 8, 2023, using a placement agent, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional investors, pursuant to which the Company issued and sold an aggregate of (i) 1,743,695 shares of the Company's common stock; (ii) pre-funded warrants in lieu of shares to purchase 430,217 shares of common stock (the "June 2023 Pre-Funded Warrants"); (iii) accompanying tranche A warrants to purchase 2,173,912 shares of common stock (the "Tranche A Warrants"); and (iv) accompanying tranche B warrants to purchase 2,173,912 shares of common stock in a best-efforts offering (the "Tranche B Warrants" and the Tranche A Warrants together with the Tranche B Warrants, the "Common Warrants"). The Common Warrants may be exercised for either shares of common stock or pre-funded warrants to purchase common stock at a future exercise price of $0.0001 per share in the same form as the June 2023 Pre-Funded Warrants (the "Exchange Warrants"). Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $0.0001 per share. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The Common Warrants are immediately exercisable at a price of $1.59 per share (or $1.5899 per Exchange Warrant). The Tranche A Warrants will expire upon the earlier of (i) five years after the date of issuance or (ii) 30 days following the closing price of the Company's common stock equaling 200% of the exercise price ($3.18 per share) for at least 40 consecutive trading days. The Tranche B Warrants were exercised in June 2024 as further described below. The Company raised $4.0 million in gross proceeds and net proceeds were $3.4 million after deducting offering expenses. The June 2023 Pre-Funded Warrants do not have an expiration date. The warrants had a combined fair value of approximately $5.0 million at issuance and are classified as derivative warrant liabilities. The resulting offset is recorded in derivative warrant liabilities (loss) gain along with the issuance costs of $0.6 million in the consolidated financial statement of operations (see *Note 16 - Warrants*).

On June 14, 2024, the Tranche B Warrants were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of common stock and 1,806,434 pre-funded warrants to purchase shares of common stock with an exercise price of $0.0001 per share (the "Tranche B Pre-Funded Warrants"). The Tranche B Pre-Funded Warrants had a fair value of approximately $5.1 million at issuance and are classified as derivative warrant liabilities, with the offset in additional paid in capital in stockholders' equity in the Company's consolidated financial statements. The Company used a portion of the proceeds from the Tranche B Warrants exercise as part of the Avenue Capital loan repayment described further in *Note 11 - Long-Term Debt.*

Note 15 - Equity Incentive Plans

2023 Equity Incentive Plan

On May 18, 2023, the Company's stockholders approved the Aytu BioPharma, Inc. 2023 Equity Incentive Plan (the "2023 Equity Incentive Plan"). Prior to the Company's adoption of the 2023 Equity Incentive Plan, the Company awarded equity incentive grants to its directors and employees under the Aytu BioScience, Inc. 2015 Stock Option and Incentive Plan (the "Aytu 2015 Plan") and the Neos Therapeutics, Inc. 2015 Stock Options and Incentive Plan (the "Neos 2015 Plan", and collectively with the Aytu 2015 Plan, the "2015 Plans"). For the 2023 Equity Incentive Plan, the stockholders approved (i) 200,000 new shares; (ii) 87,129 shares available for grant under the 2015 Plans be "rolled over" to the 2023 Equity Incentive Plan; and (iii) any shares that are returned to the Company under the 2015 Plans be added to the 2023 Equity Incentive Plan. With the approval of the 2023 Equity Incentive Plan, no additional awards will be granted under the 2015 Plans. All outstanding awards previously granted under previous stock incentive plans will remain outstanding and subject to the terms of the plans. Stock options granted under the 2023 Equity Incentive Plan have contractual terms of 10 years or less from the grant date and a vesting period ranging from 3 to 4 years. The restricted stock awards and restricted stock units have a vesting period of 3 to 4 years. As of June 30, 2024, the Company had 182,322 shares that are available for grant under the 2023 Equity Incentive Plan.

Aytu 2015 Plan

On June 1, 2015, the Company's stockholders approved the Aytu 2015 Plan, which, as amended in July 2017, provides for the award of stock options, stock appreciation rights, restricted stock, and other equity awards. On February 13, 2020, the Company's stockholders approved an increase to 250,000 total shares of common stock in the Aytu 2015 Plan. The shares of common stock underlying any awards that are forfeited, canceled, reacquired by Aytu prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the Aytu 2015 Plan will be added back to the shares of common stock available for issuance under the 2023 Equity Incentive Plan. Stock options granted under this plan have contractual terms of 10 years from the grant date and a vesting period ranging from 3 to 4 years. The restricted stock awards have a vesting period ranging from 4 to 10 years, and the restricted stock units have a vesting period of 4 years.

Neos 2015 Plan

Pursuant to the Neos Acquisition, the Company assumed 3,486 stock options and 1,786 restricted stock units previously granted under the Neos 2015 Plan. Accordingly, on April 19, 2021, the Company registered 5,272 shares of its common stock under the Neos 2015 Plan with the SEC. The terms and conditions of the assumed equity securities remained the same as they were previously under the Neos 2015 Plan. The Company allocated costs of the replacement awards attributable to pre-combination and post-combination service periods. The pre-combination service costs were included in the consideration 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.

Stock Options

During the year ended June 30, 2024, 113,500 stock options were granted. The weighted-average grant date fair value of options granted during the year ended June 30, 2024, was $1.74. During the year ended June 30, 2024, there was $0.2 million of total unrecognized compensation cost adjusted for estimated forfeitures, related to non-vested stock options granted under the Company's equity incentive plan. During the fiscal year ended June 30, 2023, 49,212 stock options were granted. The weighted-average grant date fair value of options granted during the year ended June 30, 2023, was $4.00. During the year ended June 30, 2023, there was $0.1 million of total unrecognized compensation cost adjusted for estimated forfeitures, related to non-vested stock options granted under the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 1.9 years.

Stock option activity is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years
Outstanding at June 30, 2023	52,762	$ 18.37	9.1
Granted	113,500	$ 1.74	9.2
Forfeited/cancelled	(16,610)	$ 3.20	—
Expired	(3,113)	$ 66.84	—
Outstanding at June 30, 2024	146,539	$ 6.18	8.8
Exercisable at June 30, 2024	25,068	$ 26.06	8.0

The following table details the options outstanding at June 30, 2024, 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
$1.73	102,000	$ 1.73	9.1	—	$ —
$2.53	1,500	$ 2.53	9.6	—	$ —
$4.00 - $290.00	43,039	$ 16.85	8.1	25,068	$ 225.74
	146,539	$ 6.18	8.8	25,068	$ 225.74

Restricted Stock

During the year ended June 30, 2024, the Company granted a total of 12,500 shares of restricted stock, with certain accelerated vesting conditions, to members of its non-employee directors pursuant to the 2023 Equity Incentive Plan, of which 1/3 vest on the grant date and 1/12 on the first day of each quarter thereafter, subject to continuing service to the Company through each vesting date. These restricted stock grants have a weighted average grant date fair value of $1.77 per share.

During the year ended June 30, 2023, as a result of the change in members of the Company's board, the Company accelerated unvested shares for two former members and recorded $1.5 million of non-cash equity compensation expense.

On December 19, 2022, the Company entered into a stipulation of compromise and settlement (the "Stipulation"). As a part of the terms of the Stipulation, the Company agreed to rescind 25% of the aggregate 2021 grants to board members. As a result of the recission of the shares, the Company recorded $0.6 million in non-cash compensation during the year ended June 30, 2023.

During the year ended June 30, 2023, the Company granted a total of 6,825 shares of restricted stock, with certain accelerated vesting conditions, to members of its management team pursuant to the Aytu 2015 Plan, of which 1/3 vest on the grant date and 1/12 on the first day of each quarter thereafter, subject to continuing employment with the Company through each vesting date. These restricted stock grants have a grant date fair value ranging from $3.31 per-share to $13.4 per-share.

Restricted stock activity under the 2023 Equity Incentive Plan is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2023	38,075	$ 142.20
Granted	12,500	$ 1.77
Vested	(25,971)	$ 113.37
Forfeited/cancelled	(499)	$ 147.15
Unvested at June 30, 2024	24,105	$ 100.34

As of June 30, 2024, there was $1.0 million of total unrecognized compensation costs adjusted for estimated forfeitures, related to non-vested restricted stock granted under the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.5 years. The total fair value of restricted stock vested during the year ended June 30, 2024, was $0.1 million.

The Company previously issued 4 shares of restricted stock outside of the Aytu 2015 Plan, which vest in July 2026. On January 17, 2022, the Company granted 5,000 shares of restricted stock to a member of its management team outside of the Aytu 2015 Plan, of which 1/3 vest on January 17, 2023, and 1/12 each quarter thereafter, subject to continuing employment with the Company through each vesting date until January 17, 2025. This restricted stock grant has a grant date fair value of $27.00 per share. As of June 30, 2024, there was $0.2 million total unrecognized costs adjusted for estimated forfeitures, related to non-vested restricted stock outside of the Company's equity incentive plan. The unrecognized compensation cost is expected to be recognized over a weighted average period of 0.6 years.

Restricted Stock Units

For the years ended June 30, 2024, and 2023, the Company did not grant restricted stock units ("RSU"). RSU activity is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at June 30, 2023	4,963	$ 25.62
Vested	(2,249)	$ 24.28
Forfeited/cancelled	(939)	$ 31.60
Unvested at June 30, 2024	1,775	$ 24.14

As of June 30, 2024, there was no material unrecognized compensation costs adjusted for estimated forfeitures, related to non-vested RSUs granted under the Company's equity incentive plans. The unrecognized compensation cost is expected to be recognized over a weighted average period of 0.7 years. The total fair value of RSUs vested during the year ended June 30, 2024, was immaterial.

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

	Year Ended June 30,	
	2024	2023
	(in thousands)	
Cost of sales	$ 2	$ 28
Research and development	6	30
Selling and marketing	—	23
General and administrative	2,905	5,965
Total stock-based compensation expense	$ 2,913	$ 6,046

Note 16 - Warrants

Liability Classified Warrants

The Company accounts for liability classified warrants by recording the fair value of each instrument in its entirety and recording the fair value of the warrant derivative liability. The fair value of liability classified derivative financial instruments was calculated using either the Black-Scholes option pricing model or the Monte Carlo simulation model and is revalued every quarter. Changes in the fair value of liability classified derivative financial instruments in subsequent periods are recorded as unrealized derivative gain or loss in the consolidated statements of operations.

On June 8, 2023, using a placement agent, the Company entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain institutional investors, pursuant to which the Company issued and sold an aggregate of (i) 1,743,695 shares of the Company's common stock; (ii) June 2023 Pre-Funded Warrants in lieu of shares to purchase 430,217 shares of common stock; (iii) accompanying Tranche A Warrants to purchase 2,173,912 shares of common stock; and (iv) accompanying Tranche B Warrants to purchase 2,173,912 shares of common stock in a best-efforts offering (the Tranche A Warrants together with the Tranche B Warrants, the "Common Warrants"). The Common Warrants may be exercised for either shares of common stock or pre-funded warrants to purchase common stock at a future exercise price of $0.0001 per share in the same form as the June 2023 Pre-Funded Warrants (the "Exchange Warrants"). Each pre-funded warrant is exercisable for one share of common stock at an exercise price of $0.0001 per share. The pre-funded warrants are immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. The Common Warrants are immediately exercisable at a price of $1.59 per share (or $1.5899 per Exchange Warrant). The Tranche A Warrants will expire upon the earlier of (i) five years after the date of issuance or (ii) 30 days following the closing price of the Company's common stock equaling 200% of the exercise price ($3.18 per share) for at least 40 consecutive trading days. The Tranche B Warrants were exercised in June 2024 as further described below. The Company raised $4.0 million in gross proceeds and net proceeds were $3.4 million after deducting offering expenses. The June 2023 Pre-Funded Warrants do not have an expiration date. The warrants had a combined fair value of approximately $5.0 million at issuance and are classified as derivative warrant liabilities. The resulting offset is recorded in derivative warrant liabilities (loss) gain along with the issuance costs of $0.6 million in the consolidated financial statement of operations (see *Note 14 - Stockholders' Equity*).

On June 14, 2024, the Tranche B Warrants were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of common stock and 1,806,434 Tranche B Pre-Funded Warrants to purchase shares of common stock with an exercise price of $0.0001 per share. The Tranche B Pre-Funded Warrants, which do not have an expiration date, had a fair value of approximately $5.1 million at issuance and are classified as derivative warrant liabilities, with the offset in additional paid in capital in stockholders' equity in the Company's consolidated financial statements. The Company used a portion of the proceeds from the Tranche B Warrants exercise as part of the Avenue Capital loan repayment described further in *Note 11 - Long-Term Debt*.

On August 11, 2022, the Company closed on the August 2022 Offering, pursuant to which, the Company issued pre-funded warrants to purchase 87,500 shares of its common stock and common warrants to purchase 1,265,547 shares of its common stock. The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, which one common warrant to purchase one share of common stock for each share of common stock or each pre-funded warrant sold. The pre-funded warrants had an exercise price of $0.02 per share of common stock and were exercised in full in August 2022. The common warrants have an exercise price of $8.60 per share of common stock and are exercisable for a period of five years from issuance. The common warrants provide that if there occurs any a stock split, stock dividend stock recapitalization, or similar event (a "Stock Combination Event"), then the warrant exercise price will be adjusted to the greater of the quotient determined by dividing (x) the sum of the VWAP of the common stock for each of the five lowest trading days during the 20 consecutive trading day period ending immediately preceding the 16th trading day after such Stock Combination Event, divided by (y) five; or $2.32 and the number of shares of common stock to be issued would be adjusted proportionately as set forth in the agreement limited to a maximum of 2,325,581 shares. The common warrants also provide that in the event the Company were to engage in an equity offering at a common stock price lower than the warrant exercise price prior to the second anniversary of a Stock Combination Event, the exercise price would be adjusted to the greater of the effective price of such equity offering or $2.32 (see *Note 14 - Stockholders' Equity*).

In November 2022 and throughout the quarter ended December 31, 2022, the Company sold shares through its ATM Sales Agreement. Per the warrant agreement in the August 2022 Offering, these sales qualified as an equity offering and the sales price was less than the current exercise price of $8.60. As a result, the associated common warrants exercise price was adjusted to $3.30. On January 6, 2023, the Company consummated a 20 to 1 reverse stock split. Pursuant to the aforementioned warrant agreement, the Company triggered a Stock Combination Event and the warrant exercise price and number to be issued was adjusted based on the average of each of the lowest five trading days during the twenty-day consecutive trading day period beginning on December 30, 2022. Subsequently, as a result of the Securities Purchase Agreement in June 2023, the common warrants from the August 2022 Offering had an adjusted exercise price of $2.32.

On March 7, 2022, the Company closed on an underwriting agreement, pursuant to which, the Company sold, (i) 151,500 shares of the Company's common stock, (ii) pre-funded warrants to purchase up to 151,500 shares of common stock, and (iii) common warrants to purchase up to 333,300 shares of common stock. The shares of common stock and the pre-funded warrants were each sold in combination with corresponding common warrants, with one common warrant to purchase 1.1 shares of common stock for each share of common stock or each pre-funded warrant sold. The pre-funded warrants have an exercise price of $0.002 per share of common stock and were exercised in full in April 2022. The common warrants have an exercise price of $26.00 per share of common stock and are exercisable six months after the date of issuance and have a term of five years from the date of exercisability (see *Note 14 - Stockholders' Equity*).

On January 26, 2022, as consideration for entering into the Avenue Capital Agreement as described in *Note 11 – Long-Term Debt*, the Company issued warrants to the Avenue Capital Lenders to purchase shares of common stock at an exercise price equal to $24.20 per share (the "Avenue Capital Warrants"). The Avenue Capital Warrants provided that in the event the Company were to engage in an equity offering at a price lower than $24.20 prior to June 30, 2022, the exercise price would be adjusted to the effective price of such equity offering and the number of shares of common stock to be issued under the Avenue Capital Warrants would be adjusted as set forth in the agreement. The Avenue Capital Warrants were immediately exercisable and expire on January 31, 2027. At inception, the Company accounted for the Avenue Capital Warrants as a derivative warrant liability as the number of warrants was not fixed at the issuance (see *Note 11 – Long-Term Debt* for further details).

Outstanding warrants that are classified as derivative warrant liabilities in the consolidated balance sheets are marked to market at each reporting period (see *Note 12 – Fair Value Considerations*).

A summary of warrants is as follows:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life in Years [4]
Outstanding June 30, 2023 [1]	6,538,052	$ 4.42	4.7
Warrants issued [2]	1,806,434	$ 0.0001	N/A
Warrants exercised	(2,247,648)	$ 1.61	—
Warrants expired	(20,958)	$ 300.00	—
Outstanding June 30, 2024 [3]	6,075,880	$ 3.71	3.1

(1) The number of warrants outstanding as of June 30, 2023, is comprised of 6,068,763 liability classified warrants, 430,217 liability classified June 2023 Pre-Funded Warrants and 39,072 equity classified warrants.

(2) The warrants issued during fiscal 2024 were a result of 1,806,434 Tranche B Warrants being exercise to 1,806,434 Tranche B Pre-Funded Warrants.

(3) The number of warrants outstanding as of June 30, 2024, is comprised of 3,821,115 liability classified warrants, 430,217 liability classified June 2023 Pre-Funded Warrants, 1,806,434 liability classified Tranche B Pre-Funded Warrants and 18,114 equity classified warrants.

(4) As pre-funded warrants do not have an expiration date, they have been excluded from the calculation of the weighted average remaining contractual life in years.

Note 17 - Restructuring Costs

As part of the Company's previously announced restructuring activities related to the wind down and divestiture of the Consumer Health Segment and the closure of the Grand Prairie, Texas manufacturing site (Rx Segment), the Company has incurred expenses that qualify as exit and disposal costs under U.S. GAAP. These include severance and employee benefit costs as well as other direct separation benefit costs, right of use asset impairment charges, fixed asset and other asset impairment charges, accelerated depreciation of fixed assets, contract termination costs, and inventory write-downs. Severance and employee benefit costs primarily relate to cash severance.

The expense associated with severance and employee benefits and exit and disposal activities are included in restructuring costs in the consolidated statements of operations and expense associated with inventory write-downs is recorded in cost of sales in the consolidated statements of operations. The Company does not expect to incur any additional significant restructuring costs related to the wind down and divestiture of the Consumer Health Segment and the closure of the Grand Prairie, Texas manufacturing site during fiscal 2025. As of June 30, 2024, the Company did not have any material accruals related to the wind down of the Consumer Health Segment. As of June 30, 2024, the Company had accrued $0.9 million and $0.4 million related to accrued severance and employee benefits and accrued exit and disposal activity costs, respectively, related to the closure of the Grand Prairie, Texas manufacturing facility.

A summary of restructuring costs incurred during the year ended June 30, 2024, is as follows:

	Year Ended June 30, 2024			
	Severance and Employee Benefits [1]	Exit and Disposal Activities [1]	Inventory Write-Down [2]	Total
	(in thousands)			
Wind down of Consumer Health Segment [3]	$ 20	$ 189	$ 730	$ 939
Closure of Grand Prairie, Texas manufacturing site [4]	1,125	1,031	—	2,156
Total	$ 1,145	$ 1,220	$ 730	$ 3,095

(1) Expense associated with severance and employee benefits and exit and disposal activities are included in restructuring costs in the consolidated statements of operations.
(2) Expense associated with inventory write-downs is recorded in cost of sales in the consolidated statements of operations.
(3) Expense associated with the wind down of the Consumer Health Segment is related to the Consumer Health Segment.
(4) Expense associated with the closure of the Grand Prairie, Texas manufacturing site is related to the Rx Segment.

Note 18 - Commitments and Contingencies

Pediatric Portfolio Fixed Payments and Product Milestone

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

On May 29, 2020, the Company entered into an early payment agreement and escrow instruction (the "Early Payment Agreement") pursuant to which the Company agreed to pay $15.0 million to the investor in satisfaction of the Balloon Payment Obligation. The parties to the Early Payment Agreement acknowledged and agreed that the remaining fixed payments other than the Balloon Payment Obligation remained due and payable pursuant to the terms of the agreement, and that nothing in the Early Payment Agreement alters, amends, or waives any provisions or obligations in the waiver or the investor agreement other than as expressly set forth therein. The first fixed obligation was fully paid as of January 2021.

On June 21, 2021, the Company entered into a waiver, release and consent pursuant to which the Company paid $2.8 million to the investor in satisfaction of the second fixed obligation. The Company agreed to pay the remaining fixed obligation of $3.0 million in six equal quarterly payments of $0.5 million over the next six quarters commencing September 30, 2021. The Company accounted for the waiver, release and consent as a debt and remeasured the related liabilities using a discounted cash flow model. This fixed payment arrangement was paid in full by January 2023.

The Company acquired the Tris Karbinal Agreement, under which the Company is granted the exclusive right to distribute and sell Karbinal in the United States. The initial term of the agreement was 20 years. The Company pays Tris a royalty equal to 23.5% of net revenue from the product.

The Tris 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 Tris Karbinal Agreement make-whole payment is capped at $2.1 million each year. The annual payment is due in August of each year. The Tris Karbinal Agreement also has multiple commercial milestone obligations that aggregate up to $3.0 million based on cumulative net revenue from the product, the first of which is triggered at $40.0 million. As of June 30, 2024, the fixed payment arrangement balance was $1.9 million in other current liabilities, and $0.2 million in other non-current liabilities on the consolidated balance sheet.

Operating Lease

In June 2024, the Company entered into a forward-starting operating lease agreement to lease office space in Berwyn, Pennsylvania from the owner of the office space that the Company is currently renting under a sublease arrangement. The Company has determined that it is an operating lease, and that lease commencement occurred in July 2024. The initial is from March 1, 2025, through July 31, 2030, and under the lease agreement the Company has one five-year renewal option to extend the lease through July 2035. Undiscounted minimum monthly rent payments average approximately $13,000 over the initial term of the lease.

In May 2023, the Company entered into an operating lease agreement to relocate its principal office from Englewood, Colorado to Denver, Colorado. The lease has a commencement date of October 1, 2023, with an initial term of five and a half years. Undiscounted minimum monthly rent payments average approximately $15,500 over the initial term of the lease. Variable lease payments will be expensed as incurred. Under the lease agreement, the Company has one five-year renewal option through March 2034.

Legal Matters

Witmer Class-Action Securities Litigation

A stockholder derivative suit was filed on September12, 2022, in the Delaware Chancery Court by Paul Witmer, derivatively and on behalf of all Aytu stockholders, against Armistice Capital, LLC, Armistice Capital Master Fund, Ltd., Steve Boyd (Armistice's Chief Investment Officer and Managing Partner, and a former director of Aytu), and certain other current and former directors of Aytu, Joshua R. Disbrow, Gary Cantrell, John Donofrio, Jr., Michael Macaluso, Carl Dockery and Ketan B. Mehta. Plaintiff amended the complaint on April 5, 2023. The Amended Complaint dropped Mr. Macaluso as a defendant and alleges that (i) Armistice facilitated the sale of assets of Cerecor in 2019 and Innovus in 2020 to Aytu in exchange for convertible securities which it subsequently converted and sold at a profit on the open market; (ii) the Armistice defendants breached their fiduciary duties, were unjustly enriched and wasted corporate assets in connection with these acquisitions; (iii) the Armistice defendants breached their fiduciary duties by engaging in insider trading; and (iv) the other directors breached their fiduciary duties, and aided and abetted the Armistice defendants' breaches of fiduciary duties, in connection with these acquisitions. The Amended Complaint sought unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees. While the Company believes that this lawsuit is without merit and have vigorously defended against it, the Company agreed to settle the matter for various corporate governance modifications and the payment of plaintiff's attorneys' fees. That settlement is subject to court approval, the hearing on which has not yet been scheduled.

Sabby Litigation

A complaint was filed on February 22, 2023, in the Supreme Court of the State of New York by Sabby Volatility Warrant Master Fund LTD ("Sabby") and Walleye Opportunities Master Fund Ltd ("Walleye"), holders of certain warrants to purchase common stock, against the Company. The complaint alleged that the Company improperly adjusted the exercise price of the warrants and miscalculated the number of shares the warrant holders may receive, and that the Company failed to provide prompt notice to the warrant holders of such adjustment. The complaint sought a declaratory judgment of the warrant share calculation, that 575,000 warrant shares be due to Sabby on exercise of its warrants rather than 312,908 shares, and that 100,000 warrant shares be due to Walleye on exercise of its warrants rather than 54,146 shares. In October 2023, the Company entered into a settlement agreement and general release with Sabby and Walleye.

Stein Litigation

Cielo Stein ("Stein"), a former sales specialist, filed a complaint on February 1, 2023, in Jefferson County Circuit Court in Kentucky against the Company and its wholly-owned subsidiary Neos. The complaint alleged that Aytu retaliated against Stein in violation of the Kentucky Civil Rights Act after she opposed what she contends was unwelcome behavior by her supervisor. The complaint also alleged that the Company's response to Stein's subsequent complaint to human resources was inadequate. The complaint sought an award of unspecified compensatory damages, emotional-distress damages, and attorneys' fees and costs. The Company removed the lawsuit to the United States District Court for the Western District of Kentucky. A Section 16 pretrial conference was held on June 3, 2024. During the pretrial conference the parties agreed to settle the matter. The parties entered into a settlement and release agreement on August 5, 2024. The matter has been closed.

Note 19 - License Agreements

Healight

In April 2020, the Company entered into a licensing agreement with Cedars-Sinai Medical Center to secure worldwide rights to various potential esophageal and nasopharyngeal uses of Healight, an investigational medical device platform technology. The agreement with Cedars-Sinai grants the Company a license to all patent and development related technology rights for the intra-corporeal therapeutic use of ultraviolet light in the field of endotracheal and nasopharyngeal applications. The term of the agreement is on a country-by-country basis and will expire on the latest of the date upon which the last to expire valid claim shall expire, ten years after the first bona fide commercial sale of such licensed product in a country, or the expiration of any market exclusivity period granted by a regulatory agency. Pursuant to the terms of the agreement, the Company paid an initial $0.3 million license fee and $0.1 million in earlier patent prosecution fees.

As a result of the Company's focus on the revenue growth of its commercial business, the Company terminated the licensing agreement with Cedars-Sinai Medical Center, effective May 9, 2023.

NeuRx

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

In April 2023, the Company returned the NT0502 rights to NeuRx in exchange for, and to receive a royalty and potential milestone payments on amounts received for future revenue generated by NeuRx (or a future licensee) on NT0502.

Teva

On December 21, 2018, the Company and Teva entered into an agreement granting Teva a non-exclusive license to certain patents owned by Neos by which Teva has the right to manufacture and market its generic version of Cotempla under an abbreviated new drug application ("ANDA") filed by Teva beginning on July 1, 2026, or earlier under certain circumstances. The ANDA was approved by the FDA on June 19, 2020.

Actavis

On October 17, 2017, the Company entered into an agreement granting Actavis a non-exclusive license to certain patents owned by the Company by which Actavis has the right to manufacture and market its generic version of Adzenys under its ANDA beginning on September 1, 2025, or earlier under certain circumstances. The ANDA was approved by the FDA on June 22, 2023.

Shire

In July 2014, Neos entered into a settlement agreement and an associated license agreement (the "2014 License Agreement") with Shire LLC ("Shire") for a non-exclusive license to certain patents for certain activities with respect to Neos' New Drug Application (the "NDA") No. 204326 for an extended-release orally disintegrating amphetamine polistirex tablet. In accordance with the terms of the 2014 License Agreement, following the receipt of the approval from the FDA for Adzenys, 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 during the life of the patents. The settlement agreement expired in May 2023.

Note 20 - Segment Information

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

The Company manages and aggregates its operational and financial information in accordance with two reportable segments: Rx and Consumer Health. The Rx Segment consists of the Company's prescription products. The Consumer Health Segment contained the Company's consumer healthcare products. For purposes of determining operating income or loss by segment, the Company allocates common expenses such as corporate administration, executive and board compensation, insurance, and fees associated with being a publicly traded entity, among others, to the Rx Segment. The Rx Segment also includes pipeline research and development. The CODM does not regularly review asset information by segment, accordingly, asset information is not provided by segment.

Select financial information for these segments is as follows:

	Rx	Consumer Health	Consolidated
		(in thousands)	
Year Ended June 30, 2024			
Net revenue	$ 65,183	$ 15,819	$ 81,002
Loss from operations	$ (1,590)	$ (3,664)	$ (5,254)
Depreciation and amortization	$ 5,909	$ 1,547	$ 7,456
Stock-based compensation expense	$ 2,373	$ 540	$ 2,913
Restructuring costs	$ 2,156	$ 209	$ 2,365
Year Ended June 30, 2023			
Net revenue	$ 73,799	$ 33,600	$ 107,399
Loss from operations	$ (7,358)	$ (9,707)	$ (17,065)
Depreciation and amortization	$ 6,271	$ 1,116	$ 7,387
Stock-based compensation expense	$ 5,722	$ 324	$ 6,046
Impairment expense	$ 2,730	$ 2,975	$ 5,705

Note 21 - Subsequent Events

Wind Down and Subsequent Divestiture of Consumer Health Business

In July 2024, the Company completed the wind down of its Consumer Health Segment and on July 31, 2024, the Company entered into a definitive agreement to divest its Consumer Health (a/k/a Innovus Pharmaceuticals) business to a private, e-commerce focused company affiliated with the Company's former Vice President of Consumer Health, Jonathan Hughes. Pursuant to the definitive agreement, Mr. Hughes resigned from the Company effective July 31, 2024. The divested business encompasses the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for the Company to receive up to $0.5 million of revenue-based royalty payments and recovery of cost on certain future sales of former Consumer Health business products. Upon consummation of this agreement, the Company has completed its wind down of the Consumer Health Segment.

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 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.

As required by Rules 13a-15(e) and 15d-15(e) under the Exchange Act, our management, with the participation of our Chief Executive Officer and Chief Financial Officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of June 30, 2024. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of June 30, 2024, at reasonable assurance levels, in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Accordingly, we believe that the financial statements presented in this Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented herein.

Remediation of Previously Identified Material Weakness

Warrants

As previously disclosed in our September 30, 2022 Form 10-Q/A, we identified a material weakness in internal control over financial reporting related to our accounting for complex warrant issuances and the classification of these issued warrants. This material weakness resulted in the failure to prevent material adjustments in accounting for the warrants as equity classification when the warrants should have been classified as liabilities and marked to market each reporting period. While we have processes to properly identify and evaluate the appropriate accounting technical pronouncements, other literature, and consultation with third-party experts, we did not classify the warrants correctly.

Inventory

As previously disclosed in our Fiscal 2023 Annual Report on Form 10-K, we identified a material weakness in internal control over financial reporting related to our analysis for the accounting for valuation of our inventory. As of June 30, 2023, it was determined that the analysis of over or under absorbed manufacturing costs was not performed, which could have led to material misstatement of our financial statement.

Remediation Efforts

As previously reported in our public reports referred to above, our Audit Committee conducted an internal investigation to identify and determine a plan to remediate the material weaknesses described above and to enhance our overall control environment. We undertook to remediate these deficiencies and strengthen our internal control over financial reporting by enhancing existing controls and establishing additional review and procedure controls over the process of reviewing significant and complex contracts and agreements, and the valuation of inventory, which include the following:

- Identified specific clauses and relevant guidance that could result in liability classification of issued warrants;
- Identified and engaged a firm that specializes in the analysis and technical accounting for the classification of warrants and utilized this firm to assist with the technical accounting analysis for our warrants issued on June 8, 2023, including arriving at the correct conclusion that these warrants should be classified as liabilities and marked to market each reporting period;
- Identified and engaged a firm that specializes in the valuation analysis regarding the fair value of our liability classified warrants to assist us with calculating the necessary mark to market adjustment each reporting period;
- Implemented a new quarterly control and related processes effective for the fourth quarter of fiscal 2023, and operating every quarter thereafter, to perform a detailed analysis of over or under absorbed manufacturing costs, quantify any over or under absorbed manufacturing costs, and have the appropriate level of management review and evaluate the analysis and approve the recording of any adjusting journal entries as necessary;
- Successfully hired additional personnel with the expertise necessary to improve the technical accounting and financial reporting functions; and
- Provided additional guidance, education and training to employees relating to our accounting procedures with a continued focus on warrant classification and inventory valuation.

Given these remediation efforts above and that a sufficient period of time has passed with successful testing performed, management concluded that the material weaknesses set forth above were remediated as of March 31, 2024.

Inherent Limitations on Effectiveness of Internal Controls over Financial Reporting

Our management team, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdown can occur because of simple errors or mistakes. In particular, many of our current processes rely upon manual reviews and processes to ensure that neither human error nor system weakness has resulted in erroneous reporting of financial data.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of fiscal 2024 that have materially affected, or are reasonably likely to materially affected, our internal control over financial reporting.

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). The Company's internal control over financial reporting is designed 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. The Company's internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the Company's assets that have a material effect on the financial statements.

Because of the inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of the changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Based on our management's assessment and those criteria, our management concluded that the Company maintained effective internal control over financial reporting as of June 30, 2024.

Grant Thornton LLP ("Grant Thornton") the independent registered public accounting firm that audited our financial statements included in this Annual Report, was not required to issue an attestation report on our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the quarter ended June 30, 2024, none of our directors or executive officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTION THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The following table sets forth the names and ages of all of our directors and NEOs. 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	49	Chairman and Chief Executive Officer
Mark K. Oki	55	Chief Financial Officer, Corporate Secretary and Treasurer
Jarrett T. Disbrow	49	Chief Business Officer
Greg Pyszczymuka	45	Chief Commercial Officer
John A. Donofrio, Jr.	57	Lead Independent Director
Carl C. Dockery	61	Director
Abhinav "Abi" Jian	33	Director
Vivian H. Liu	62	Director

Biographical Summaries

The following is a biographical summary of the experience of our NEOs and directors during the past five years, and an indication of directorships held by the directors in other companies subject to the reporting requirements under the federal securities law.

Joshua R. Disbrow – Chairman and Chief Executive Officer

Mr. Disbrow has been employed by us since April 16, 2015, and a member of our Board of Directors since January 2016. Prior to the closing of the merger between Luoxis Diagnostics, Inc. ("Luoxis") and Vyrix Pharmaceuticals, Inc. that formed Aytu, Mr. Disbrow was the Chief Executive Officer of Luoxis since January 2013. Mr. Disbrow jointly served as the Chief Operating Officer of Ampio Pharmaceuticals, Inc. ("Ampio"), a public biotechnology company, 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 private specialty pharmaceutical company, from May 2007 through October 2012. He joined Arbor as the company's second full-time employee and led the company's commercial efforts from inception to the company's acquisition in 2010 and growth to over $250 million in net sales in 2012. By the time Mr. Disbrow departed Arbor in late 2012, he had led the growth of the commercial organization that included a nationwide sales force, marketing, sales training, managed care, national accounts, distribution and other commercial functions. Mr. Disbrow has spent 27 years in the pharmaceutical, diagnostic, and medical device industries and has held positions of increasing responsibility in sales, sales management, marketing, commercial operations, commercial strategy, and corporate finance and business development. Prior to joining Arbor, Mr. Disbrow served in sales management 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 began his career in sales. Mr. Disbrow holds an M.B.A. from Wake Forest University School of Business and BS in Management from North Carolina State University. Mr. Disbrow's experience in executive management and commercialization within the pharmaceutical industry, monetizing company opportunities, and corporate finance led to the conclusion that he should serve as a member of our Board of Directors.

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

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

Jarrett T. Disbrow – Chief Business Officer

Mr. Disbrow has served as our Chief Business Officer since November 2022. Until July 2024, he also held the position of President, Consumer Health. Prior to these roles, Mr. Disbrow served as our Executive Vice President, Corporate Operations from April 2021 to November 2022; Executive Vice President, Corporate Development from April 2020 to April 2021; our Executive Vice President, Marketing and Market Access from November 2019 to April 2020; our Chief Operating Officer and Head of Commercial from July 2019 to November 2019; and our Chief Operating Officer from April 2015 to July 2019. Prior to co-founding Aytu BioPharma in April 2015, Mr. Disbrow was the President and Chief Executive Officer of Vyrix Pharmaceuticals, Inc., a specialty pharmaceutical company focused on male sexual dysfunction. Mr. Disbrow's first pharmaceutical start-up was Arbor Pharmaceuticals, LLC ("Arbor"), a privately held company focused initially on pediatrics. As the original founder of Arbor, Mr. Disbrow was responsible for the vision, fundraising, start-up, strategy and growth of the company until its acquisition by a private investor group in 2010. Mr. Disbrow also held various sales and marketing positions with Accentia Biopharmaceuticals, Inc., a publicly held biopharmaceutical company, and GlaxoSmithKline, a publicly held pharmaceutical company. Mr. Disbrow received a B.S. in Business Management from North Carolina State University and a M.S. in Organizational Leadership from the University of Colorado Boulder.

Greg Pyszczymuka – Chief Commercial Officer

Mr. Pyszczymuka has served as our Chief Commercial Officer since January 2022. Prior to joining the Company at the closing of the Company's merger with Neos in March 2021, Mr. Pyszczymuka served as Vice President, Commercial at Neos since June 2020. He previously served as Vice President, Commercial Strategy & Market Access at Neos from November 2018 to June 2020, and as Executive Director of Channel Strategy & Access Programs. Prior to joining Neos, Mr. Pyszczymuka had served in roles of increasing responsibility over a 20-year career including sales management, brand management, channel strategy, managed markets and new products planning. Mr. Pyszczymuka joined Neos most recently from Aqua Pharmaceuticals (an Almirall company), and previously was with Iroko Pharmaceuticals, Zogenix, and Endo Pharmaceuticals. He holds a B.S. from Rutgers University and an M.B.A. from Argosy University.

John A. Donofrio, Jr. – Lead Independent Director

Mr. Donofrio joined our Board of Directors in July 2016. He is a senior pharmaceutical executive with over 30 years of experience in the industry across a broad range of areas, including President, Chief Financial Officer, and Chief Operating Officer positions. Mr. Donofrio has significant finance experience in consolidated financial reporting, international accounting and internal controls, financial systems development and implementation, cost accounting, inventory management, supply chain, transfer pricing, budget and forecast planning, integration of mergers and acquisitions and business development. Since March 2022 Mr. Donofrio has served as Executive Vice President, Chief Operating Officer of Novan Inc., a publicly held specialty dermatology company, and as President of Novan Inc.'s wholly owned subsidiary EPI Health, a specialty pharmaceutical company commercializing products in the dermatology market. From March 2019 until its acquisition by Novan, Inc. in March 2022, Mr. Donofrio served as EPI Health's President. Mr. Donofrio previously served as Chief Financial Officer and Head of Business Development at TrialCard from March of 2018 to March 2019. TrialCard is a technology-driven pharmaceutical services company providing patient access and support programs to the pharmaceutical and biotechnology industries. Prior to joining TrialCard, Mr. Donofrio was the Chief Financial Officer and Head of North American Business Development for Merz North America ("Merz") from August 2013 to March 2018. Merz is a specialty healthcare company that develops and commercializes innovative treatment solutions in aesthetics, dermatology and neurosciences in the United States and Canada. At Merz, Mr. Donofrio was accountable for financial performance, cost management, business development and strategic business planning and analysis for the finance organization in North America. Prior to joining Merz, Mr. Donofrio served as Vice President, Stiefel Global Finance, U.S. Specialty Business and Puerto Rico for Stiefel, a GlaxoSmithKline plc company from July 2009 to July 2013. In that role, Mr. Donofrio was responsible for the financial strategy, management reporting, and overall control framework for the Global Dermatology Business Unit. Mr. Donofrio served as a director of Vyrix from February 2014 to April 2015. Mr. Donofrio holds a degree in Accounting from North Carolina State University. Mr. Donofrio's broad executive leadership experience and financial expertise along with experience in the pharmaceutical industry led to the conclusion that he should serve as a member of our Board of Directors.

Carl C. Dockery – Director

Mr. Dockery joined our Board of Directors in April 2016. Mr. Dockery is a financial executive with over 30 years of experience as an executive in the insurance and reinsurance industry and more recently since 2006 as the founder and president of a registered investment advisory firm, Alpha Advisors, LLC. Mr. Dockery's career as an insurance executive began in 1988 as an officer and director of two related and closely held insurance companies, including serving as Secretary of Crossroads Insurance Co. Ltd. of Bermuda and as Vice President of Gulf Insurance Co. Ltd. of Grand Cayman. Familiar with the London reinsurance market, in the 1990s, Mr. Dockery worked at Lloyd's and the London Underwriting Centre brokering various types of reinsurance placements. From September 2014 through September 2019, Mr. Dockery served as a director of CytoDyn Inc. (OTCQB: CYDY), a publicly traded biotechnology company focused on the development and potential commercialization of humanized monoclonal antibodies for the treatment and prevention of HIV and cancers. Mr. Dockery graduated from Southeastern University with a Bachelor of Arts in Humanities. Mr. Dockery's financial expertise and experience, as well as his experience as a director of a publicly traded biopharmaceutical company led to the conclusion that he should serve as a member of our Board of Directors.

Abhinav "Abi" Jain – Director

Mr. Jain joined our Board of Directors in June 2023. Since July 2019, Mr. Jain has served as an Analyst at Nantahala Capital Management, LLC ("Nantahala") and is focused on investments in various sectors, including specialty and generic pharmaceuticals. From 2015 to 2017, Mr. Jain was an Associate at Angelo, Gordon & Co., an alternative asset manager. At Angelo, Gordon & Co., Mr. Jain focused on private equity and structured credit investments. He graduated from Massachusetts Institute of Technology in 2012 with an S.B. in Chemical-Biological Engineering and from The Wharton School of the University of Pennsylvania in 2019 with a M.B.A. with honors in Finance and Entrepreneurial Management. Mr. Jain's financial expertise and experience led to the conclusion that he should serve as a member of our Board of Directors. Mr. Jain was appointed pursuant to a board designation right granted to Nantahala to appoint one director to our Board of Directors, pursuant to the Securities Purchase Agreement dated June 8, 2023, with Nantahala and other investors.

Vivian H. Liu – Director

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

Family Relationships

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

Involvement in Certain Legal Proceedings

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

None of our other directors or executive officers have 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 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 SEC. These officers, directors and stockholders are required by regulations under the 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, except for one late filing of a Form 4 by Joshua R. Disbrow relating to a rescission of 80,000 shares of restricted common stock on December 20, 2022, which was inadvertently filed one day late on December 23, 2022, and two late filings of Form 4s by Greg Pyszczymuka, one of which related to the conversion of 833 restricted stock units to shares of common stock on April 25, 2023, which was inadvertently filed late on June 20, 2023, and the second of which related to the conversion of 208 restricted stock units to shares of common stock on June 30, 2023, which was inadvertently filed late on July 6, 2023.

Code of Ethics

We have adopted a written code of ethics that applies to our officers, directors, and employees, including our principal executive officer (Joshua R. Disbrow), principal financial officer (Mr. Oki), and principal accounting officer (Mr. Oki). 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. Our Code of Ethics and Business Conduct and our Code of Ethics for Chief Executive Officer and Senior Financial Officers can be found on our website at https://www.aytubio.com under the “Investors—Corporate Governance” section.

Board Committees

Our Board has established an Audit Committee, Compensation Committee and a Nominating and Governance Committee. Our Audit Committee consists of Mr. Donofrio (Chair), Mr. Dockery, Mr. Jain, and Ms. Liu. Our Compensation Committee consists of Ms. Liu (Chair), Mr. Dockery, Mr. Jain, and Mr. Donofrio. Our Nominating and Governance Committee consists of Mr. Dockery (Chair), Mr. Donofrio, Mr. Jain, and Ms. Liu. 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 https://www.aytubio.com under the “Investor Relations—Corporate Governance” section.

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 of stockholders of the Company. 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 of stockholders of the Company, or if no annual meeting of stockholders of the Company was held in the prior year, then the stockholder notice must be no less than the later of (i) 90 days prior to the date of the Annual Meeting or (ii) the 10th day following the date on which the date of the Annual Meeting is first publicly announced or disclosed by us.

Pursuant to the bylaws, a stockholder’s notice must set forth among other things: (i) 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 Exchange Act, and the rules and regulations thereunder; and (ii) as to any other business that the stockholder proposes to bring before the Annual Meeting, a brief description of the business desired to be brought before the Annual Meeting, the reasons for conducting such business at the Annual Meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made.

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

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

In accordance with Item 402 of Regulation S-K promulgated by the SEC, we are required to disclose certain information regarding the makeup of and compensation of our Company's NEOs. In establishing executive compensation, our Board of Directors is guided by the following goals:

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

Compensation of Directors

Our current compensation package for non-employee directors, effective July 1, 2024, consists of: (i) an annual cash retainer of $80,000 for the non-executive Board chair or lead independent director; (ii) $50,000 for each other director; (iii) $20,000 for each Audit Committee and Compensation Committee chair; (iv) $10,000 for Nominating and Governance Committee chair; (v) $10,000 for each other committee member of the Audit and Compensation Committees; (vi) $5,000 for each other committee member of the Nominating and Governance Committee; (vii) a grant of 6,500 restricted shares of stock or restricted stock units upon appointment to the Board; and (viii) an annual grant of 1,500 restricted shares of stock or restricted stock units thereafter.

The following table provides information regarding all compensation paid to non-employee directors of Aytu during the year ended June 30, 2024:

Name	Fees Earned or Paid in Cash	Stock Awards	Total
John A. Donofrio, Jr. [1][2]	$ 105,000	$ 2,595	$ 107,595
Carl C. Dockery [1][2]	$ 70,000	$ 2,595	$ 72,595
Abhinav "Abi" Jian [1][2]	$ 65,000	$ 14,297	$ 79,297
Vivian H. Liu [1][2]	$ 75,000	$ 2,595	$ 77,595

(1) As of June 30, 2024, Mr. Donofrio held 2,262 restricted shares and Mr. Dockery held 9,652 restricted shares, both adjusted for the recission of shares from the Aponowicz and Paguia settlement (for more information, see discussion of the Stipulation in *Note 15 - Equity Incentive Plans* to the notes to the consolidated financial statements included in this Form 10-K). As of June 30, 2024, Mr. Jian held 8,000 restricted shares and Ms. Liu held 8,325 restricted shares.

(2) As of June 30, 2024, the number of vested stock options held by each non-employee director was as follows: (i) 200 vested stock options for Mr. Donofrio and (ii) 200 vested stock options for Mr. Dockery.

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, 2024, and 2023, to each of the following NEOs:

Name and Principal Position	Year	Salary	Stock Awards [1]	Option Awards [1]	Non-Equity Incentive Plan Compensation [2]	All Other Compensation	Total
Joshua R. Disbrow							
Chairman and Chief Executive Officer since December 2012	2024	$ 590,000	$ —	$ 55,017	$ 283,200	$ —	$ 928,217
	2023	$ 590,000	$ —	$ —	$ 118,000	$ —	$ 708,000
Mark K. Oki							
Chief Financial Officer, Corporate Secretary and Treasurer since January 2022	2024	$ 427,450	$ —	$ 20,435	$ 136,784	$ —	$ 584,669
	2023	$ 415,000	$ —	$ —	$ 83,000	$ 24,840	$ 522,840
Jarrett T. Disbrow							
Chief Business Officer since November 2022	2024	$ 386,250	$ —	$ 11,003	$ 144,844	$ —	$ 542,097
	2023	$ 375,000	$ —	$ 17,554	$ 62,438	$ —	$ 454,992
Greg Pyszczymuka							
Chief Commercial Officer since January 2022	2024	$ 389,423	$ —	$ 11,003	$ 115,875	$ —	$ 516,301
	2023	$ 375,000	$ —	$ 15,046	$ 150,000	$ —	$ 540,046

(1) Stock awards and option awards are reported at fair value at the date of grant. Stock awards and options are approved by our Compensation Committee of our Board of Directors.

(2) The amounts reported in this column reflect cash bonuses awarded pursuant to the achievement of our fiscal 2024 and fiscal 2023 corporate objectives, as approved by our Compensation Committee of our Board of Directors.

Our NEOs are reimbursed by us for any out-of-pocket expenses incurred in connection with activities conducted on our behalf. NEOs are reimbursed for business expenses directly related to our business activities, such as travel, primarily for business development as we grow and expand our product lines. On average, each NEO 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 is determined to be the most beneficial to the Company and our stockholders. No interest is paid on amounts reimbursed to the NEOs.

Outstanding Equity Awards at Fiscal Year-End

The following table lists all of the outstanding stock awards held as of June 30, 2024, for each of the following NEOs:

	Option Awards				Stock Awards	
Name	**Number of Securities Underlying Unexercised Options Exercisable**	**Number of Securities Underlying Unexercised Options Unexercisable**	**Option Exercise Price**	**Option Expiration Date**	**Number of Shares or Unites of Stock That Have Not Vested**	**Market Value of Shares or Units of Stock That Have Not Vested [1]**
Joshua R. Disbrow						
Option award	500	—	$ 290.00	6/8/2030	—	$ —
Option award	—	35,000	$ 1.73	8/11/2033	—	$ —
Stock award	—	—	$ —	—	37	$ 108
Stock award	—	—	$ —	—	2,227	$ 6,503
Stock award	—	—	$ —	—	2	$ 6
Mark K. Oki						
Option award	—	13,000	$ 1.73	8/11/2033	—	$ —
Stock award	—	—	$ —	—	1,251	$ 3,653
Jarrett T. Disbrow						
Option award	4,557	3,646	$ 4.00	10/1/2032	—	$ —
Option award	—	7,000	$ 1.73	8/11/2033	—	$ —
Stock award	—	—	$ —	—	25	$ 73
Stock award	—	—	$ —	—	1,687	$ 4,926
Stock award	—	—	$ —	—	917	$ 2,678
Stock award	—	—	$ —	—	2	$ 6
Greg Pyszczymuka						
Option award	3,906	3,125	$ 4.00	10/1/2032	—	$ —
Option award	—	7,000	$ 1.73	8/11/2033	—	$ —
Stock award	—	—	$ —	—	626	$ 1,828
Stock award	—	—	$ —	—	626	$ 1,828

[1] Based on $2.92 per share, which was the closing price of our common stock as quoted on the Nasdaq Capital Market on June 28, 2024, the last trading day of fiscal 2024.

Employment Agreements

Joshua R. Disbrow Agreement

The Company entered into an employment agreement with Joshua R. Disbrow effective April 16, 2015 (the "Initial Disbrow Agreement"), in connection with his employment as Chief Executive Officer. On February 13, 2023, we entered into an amended and restated employment agreement with Joshua R. Disbrow. The agreement supersedes the Initial Disbrow Agreement and any prior employment agreements or amendments with the Company. The agreement was amended to: (i) provide for one-year employment terms with auto-renewal; (ii) modify the acceleration provision in connection with a change of control such that Joshua R. Disbrow would need to be terminated within 12 months following a change of control for "Cause" or resign for "Good Reason;" and (iii) provide associated changes to the "Cause" definition to (a) change material misconduct in connection with his employment to willful malfeasance or willful misconduct; and (b) change material breach of the employment agreement to willful and deliberate breach.

Mark K. Oki Agreement

On January 17, 2022, Mr. Oki was appointed as our Chief Financial Officer pursuant to an employment agreement effective January 17, 2022 (the "Initial Oki Agreement"). On February 13, 2023, we entered into an amended and restated employment agreement with Mr. Oki. The agreement supersedes the Initial Oki Agreement and any prior employment agreements with the Company. The agreement was amended to: (i) modify the equity acceleration provision to conform to Joshua R. Disbrow's agreement relating to the equity awards referenced and acceleration language; and (ii) provide associated changes to the "Cause" definition to (a) change material misconduct in connection with his other agreements with the Company to willful malfeasance or willful misconduct; (b) make conforming changes related to Mr. Oki's unintended but material breach of the agreement instead of a material and repeated breach; and (c) change gross negligence in connection with his employment to willful malfeasance.

Jarrett T. Disbrow Agreement

On March 20, 2023, we entered into an amended and restated employment agreement with Jarrett T. Disbrow. The agreement supersedes any prior employment agreements with the Company. The agreement was amended to: (i) modify the equity acceleration provision to conform to Joshua R. Disbrow's agreement relating to the equity awards referenced and acceleration language; and (ii) provide associated changes to the "Cause" definition to (a) change material misconduct in connection with his other agreements with the Company, to willful malfeasance or willful misconduct; (b) make conforming changes related to Jarrett T. Disbrow's unintended but material breach of the agreement, instead of a material and repeated breach; and (c) change gross negligence in connection with his employment to willful malfeasance.

Greg Pyszczymuka Agreement

On March 21, 2023, we entered into an amended and restated employment agreement with Mr. Pyszczymuka. The agreement supersedes any prior employment agreements with the Company. The agreement was amended to: (i) modify the equity acceleration provision to conform to Joshua R. Disbrow's agreement relating to the equity awards referenced and acceleration language; and (ii) provide associated changes to the "Cause" definition to (a) change material misconduct in connection with his other agreements with the Company, to willful malfeasance or willful misconduct; (b) make conforming changes related to Mr. Pyszczymuka's unintended but material breach of the agreement, instead of a material and repeated breach; and (c) change gross negligence in connection with his employment to willful malfeasance.

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, in the case of Joshua R. Disbrow, (i) a lump sum payment equal to two and one half (2.5) times his base salary in effect at the date of termination; (ii) continued participation in the health and welfare plans for up to two years; and (iii) a pro-rata amount of the target bonus determined by the percentage of time he was employed during the fiscal year. Jarrett T. Disbrow shall receive (i) a lump sum payment equal to two (2) times his base salary in effect at the date of termination; (ii) immediate vesting for the number of awards equal to 1/24th the number of awards multiplied by the number of full months of his employment; and (iii) continued participation in the health and welfare plans for up to two years. Mr. Oki and Mr. Pyszczymuka shall receive, (i) a payment equal to his base salary in effect at the date of termination; (ii) immediate vesting of all stock-based awards; (iii) continued participation in the health and welfare plans for up to 12 months; and (iv) a pro-rata amount of the target bonus determined by the percentage of time he was employed during the fiscal year.

"Cause" means (i) willful malfeasance or willful misconduct in connection with his employment; (ii) 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 infraction which is a misdemeanor; (iii) willful and deliberate violation of a Company policy, (iv) unintended but material breach of any written policy applicable to all employees adopted by the Company which is not cured to the reasonable satisfaction of the Board of Directors within 30 business days after notice thereof; (v) the unauthorized use or disclosure of any proprietary information or trade secrets of the Company or any other party as to which the officer owes an obligation of nondisclosure as a result of the officer's relationship with the Company, or (vi) the willful and deliberate breach of the employment agreement.

"Good Reason" means (i) there is a material reduction of the level compensation (excluding any bonuses) except where there is a general reduction applicable to the management team generally; (ii) there is a material reduction in overall responsibilities or authority, or scope of duties; or (iii) without the officer's written consent, a material change in the principal geographic location at which the officer must perform his services (it being understood that the relocation of the officer to a facility or a location within 40 miles of the State Capitol Building in Denver, Colorado shall not be deemed material for purposes of the employment agreements).

Payments Provided Upon a Change in Control

In the event the NEO's employment is terminated within 12 months 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 NEO will immediately vest and become exercisable. In addition, Joshua R. Disbrow shall be paid a pro-rata amount of the target bonus determined by the percentage of time he was employed during the fiscal year. In addition, Mr. Oki shall receive (i) a payment equal to his base salary in effect at the date of the Change in Control; (ii) continued participation in the health and welfare plans for up to 12 months; and (iii) a pro-rata amount of the target bonus determined by the percentage of time he was employed during the fiscal year.

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

- the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity; or
- a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power and outstanding stock immediately prior to such transaction do not own a majority of the outstanding voting power and outstanding stock or other equity interests of the resulting or successor entity (or its ultimate parent, if applicable) immediately upon completion of such transaction; or
- the sale of all of the stock of the Company to an unrelated person, entity or group thereof acting in concert; or
- any other transaction in which the owners of the Company's outstanding voting power immediately prior to such transaction do not own at least a majority of the outstanding voting power of the Company or any successor entity immediately upon completion of the transaction other than as a result of the acquisition of securities directly from the Company.

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, 2024, for:

- each beneficial owner of 5% or more of our outstanding common stock;
- each of our non-employee directors and NEOs; 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, 2024. The percentage ownership information shown in the table is based upon 6,148,993 shares of common stock outstanding as of August 31, 2024.

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, 2024. 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 is 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 non-employee directors, NEOs and named beneficial owners are in care of Aytu BioPharma, Inc., 7900 East Union Avenue, Suite 920, Denver, Colorado 80237.

	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% or more Beneficial Owners		
Nantahala Capital Management, LLC [1]	1,086,812	17.6%
Stonepine Capital Management, LLC [2]	565,484	9.1%
Non-employee Directors		
John A. Donofrio, Jr. [3]	2,462	*
Carl C. Dockery [4]	9,902	*
Abhinav "Abi" Jain [5]	8,000	*
Vivian H. Liu [6]	8,325	*
Named Executive Officers		
Joshua R. Disbrow [7]	85,595	1.4%
Mark K. Oki [8]	14,516	*
Jarrett T. Disbrow [9]	20,965	*
Greg Pyszczymuka [10]	31,537	*
All directors and executive officers as a group, including those named above (eight persons)	181,302	2.9%

* Represents beneficial ownership of less than 1%.

(1) The number of shares is based on a Form 13D/A filed by Nantahala Capital Management, LLC ("Nantahala") with the SEC on June 18, 2024. Based on such filing, Nantahala are deemed to have the voting and dispositive power with respect to 1,086,812 shares of common stock. Nantahala have their principal business office at 130 Main Street, 2nd Floor, Nan Canaan, CT 06840.

(2) The number of shares is based on a Form 13G/A filed by Stonepine Capital Management, LLC ("Stonepine") with the SEC on February 13, 2024. Based on such filing, Stonepine are deemed to have the voting and dispositive power with respect to 565,484 shares of common stock. Stonepine have their principal business office at 919 NW Bond Street, Suite 204, Bend, OR 97703.

(3) Consists of (i) 495 shares of common stock, (ii) 1,767 unvested restricted shares and (iii) 200 shares of common stock issuable upon the exercise of vested options.

(4) Consists of (i) 7,885 shares of common stock, (ii) 1,767 unvested restricted shares, (iii) 200 shares of common stock issuable upon the exercise of vested options and (iv) 50 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) 2,640 shares of common stock and (ii) 5,360 unvested restricted shares. Mr. Jain is affiliated with Nantahala, however, the 8,000 unvested restricted shares are held by Mr. Jain in his individual capacity.

(6) Consists of (i) 3,961 shares of common stock and (ii) 4,364 unvested restricted shares.

(7) Consists of (i) 69,325 shares of common stock, (ii) 2,266 unvested restricted shares and (iii) 14,004 shares of common stock issuable upon the exercise of vested options. Does not include 116 shares of common stock held by an irrevocable trust for estate planning in which Joshua R. Disbrow is a beneficiary. Joshua R. Disbrow does not have or share investment control over the shares held by the trust, Joshua R. Disbrow is not the trustee of the trust (nor is any member of Joshua R. Disbrow's immediate family) and Joshua R. Disbrow does not have or share the power to revoke the trust. As such, under Rule 16a 8(b) and related rules, Joshua R. Disbrow does not have beneficial ownership over the shares purchased and held by the trust.

(8) Consists of (i) 8,666 shares of common stock, and (ii) 834 shares of unvested restricted shares and (iii) 5,016 shares of common stock issuable upon the exercise of vested options.

(9) Consists of (i) 11,082 shares of common stock, (ii) 1,714 shares of unvested restricted shares and (iii) 8,169 shares of common stock issuable upon the exercise of vested options.

(10) Consists of (i) 22,663 shares of common stock, (ii) 313 shares of unvested restricted shares and (iii) 8,561 shares of common stock issuable upon the exercise of vested options.

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.

Jarrett T. Disbrow, the brother of Joshua R. Disbrow, our Chairman and Chief Executive Officer, is employed by us as Chief Business Officer. His total annual salary and other cash compensation was $531,094, which consists of $386,250 base salary and a $144,844 cash bonus during the year ended June 30, 2024, and he also receives benefits consistent with other employees serving in the same capacity.

On July 31, 2024, we entered into a definitive agreement to divest our Consumer Health (a/k/a Innovus Pharmaceuticals) business to a private, e-commerce focused company affiliated with our former Vice President of Consumer Health, Jonathan Hughes. Pursuant to the definitive agreement, Mr. Hughes resigned from the Company effective July 31, 2024. The divested business encompasses the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for us to receive up to $0.5 million of revenue-based royalty payments and recovery of cost on certain future sales of former Consumer Health business products. Upon consummation of this agreement, we have completed our wind down of the Consumer Health Segment.

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 Business Conduct and Ethics available on our website at https://www.aytubio.com under the “Investors—Corporate Governance” section.

Prior to the adoption of the Audit Committee Charter, and due to the small size of the 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 Exchange Act, 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.

Four of our five directors are independent under the definition of Nasdaq. Joshua R. Disbrow is not independent due to his position as Chief Executive Officer of Aytu

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Grant Thornton has served as our independent auditor since December 12, 2022, and has been appointed by our Audit Committee to continue as our independent auditor for the fiscal year ending June 30, 2024.

The following table presents aggregate fees for professional services rendered by our principal independent registered public accounting firms, Grant Thornton for the years ended June 30, 2024, and 2023, for the audit of our annual financial statements:

	Year Ended June 30,	
	2024	2023
	(in thousands)	
Audit fees	$ 777	$ 940
Audit related fees	—	—
Tax fees	231	—
All other fees	10	—
Total fees	$ 1,018	$ 940

Tax fees of $0.2 million during the fiscal year ended June 30, 2024, represent fees that were pre-approved by our Audit Committee related to analysis of Section 382 of the IRC performed by Grant Thornton.

Policy on Pre-Approval of Services of Independent Registered Public Accounting Firm

Our Audit Committee has responsibility for appointing, setting compensation and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee pre-approves all audit and permissible non-audit services provided by the independent registered public accounting firm, although it has no written policy on this matter. Prior to engagement of the independent registered public accounting firm for the following year's audit, management will submit to the Audit Committee Chair or the full Audit Committee fees in excess of $25,000, for approval. Any fees approved by the Audit Committee Chair will be presented to the full Audit Committee at the following Audit Committee meeting. A description of services expected to be rendered during that year for each of following four categories of services:

- Audit services include audit work performed in audit of the annual financial statements, review of quarterly financial statements, reading of annual, quarterly and current reports, as well as work that generally only the independent auditor can reasonably be expected to provide;

- Audit-related services are for assurance and related services that are traditionally performed by the independent auditor, including the provisions of consents and comfort letters in connection with the filing of registration statements, due diligence related to mergers and acquisitions and special procedures required to meet certain regulatory requirements;

- Tax services consist principally of assistance with tax compliance and reporting, as well as certain tax planning consultations; and

- Other services are those associated with services not captured in the other categories. We generally do not request such services from our independent auditor.

Prior to the engagement, the Audit Committee pre-approves these services by category of service. The fees are budgeted, and the Audit Committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS AND CONSOLIDATED FINANCIAL STATEMENT SCHEDULES

(a)(1) and (a)(2) Financial Statements

The following documents are filed as part of this Annual Report:

	Page
• Report of Independent Registered Public Accounting Firm (PCAOB ID 248)	64
• Consolidated Balance Sheets	66
• Consolidated Statements of Operations	67
• Consolidated Statements of Stockholders' Equity	68
• Consolidated Statements of Cash Flows	69
• Notes to the Consolidated Financial Statements	70

(b) Exhibits

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number	Filed Herewith
2.1	Agreement and Plan of Merger, dated as of September 12, 2019, by and among Aytu BioScience, Inc., Aytu Acquisition Sub, Inc. and Innovus Pharmaceuticals, Inc.	8-K	09/18/19	2.1	
2.2	Asset Purchase Agreement, dated October 10, 2019, by and between Aytu Bioscience, Inc. and Cerecor Inc.	8-K	10/15/19	2.1	
2.3	Agreement and Plan of Merger, dated as of December 10, 2020, by and among Aytu BioScience, Inc., Neutron Acquisition Sub, Inc. and Neos Therapeutics, Inc.	8-K	12/10/20	2.1	
2.4	Asset Purchase Agreement, dated April 12, 2021, by and among Aytu BioPharma, Inc., Rumpus VEDS LLC, Rumpus Therapeutics LLC, Rumpus Vascular LLC, Christopher Brooke and Nathaniel Massari.	10-Q	05/17/21	2.4	
3.1	Certificate of Incorporation effective, June 3, 2015.	8-K	06/09/15	3.1	
3.2	Certificate of Amendment of Certificate of Incorporation, effective June 1, 2016.	8-K	06/02/16	3.1	
3.3	Certificate of Amendment of Certificate of Incorporation, effective June 30, 2016.	8-K	07/01/16	3.1	
3.4	Certificate of Amendment of Certificate of Incorporation, effective August 25, 2017.	8-K	08/29/17	3.1	
3.5	Certificate of Amendment to the Restated of Certificate of Incorporation, effective August 10, 2018.	8-K	08/10/18	3.1	
3.6	Certificate of Amendment to the Restated Certificate of Incorporation, effective May 20, 2020.				X

3.7	Certificate of Amendment to the Restated Certificate of Incorporation, effective December 8, 2020.	8-K	12/08/20	3.1
3.8	Certificate of Amendment of Certificate of Incorporation, effective March 22, 2021.	8-K	03/22/21	3.1
3.9	Certificate of Amendment of Certificate of Incorporation, effective January 6, 2023.	8-K	01/25/23	3.1
3.10	Amended and Restated Bylaws.	8-K	05/09/22	3.1
4.1	Form of Placement Agent Common Stock Purchase Warrant.	8-K	03/13/20	4.2
4.2	Form of Common Stock Purchase Warrant.	8-K	03/13/20	4.1
4.3	Common Stock Purchase Warrant.	8-K	03/20/20	4.1
4.4	Form of Placement Agent Common Stock Purchase Warrant.	8-K	03/20/20	4.2
4.5	Form of Wainwright Warrant.	8-K	07/02/20	4.1
4.6	Form of Prefunded Common Stock Purchase Warrant.	8-K	03/04/22	4.1
4.7	Form of Common Stock Purchase Warrant.	8-K	03/04/22	4.2
4.8	Form of Pre-Funded Warrant.	8-K	08/10/22	4.1
4.9	Form of Common Warrant.	8-K	08/10/22	4.2
4.10	Form of Pre-Funded Warrant.	S-1/A	06/05/23	4.10
4.11	Form of Tranche A Warrant.	S-1/A	06/05/23	4.11
4.12	Description of Securities.	10-K	09/27/22	4.9
10.1	Loan and Security Agreement, by and between Neos Therapeutics, Inc., Neos Therapeutics Brands, LLC, and Neos Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, LLC, and Encina Business Credit, LLC, dated October 2, 2019.	8-K	10/3/19	10.1
10.2	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
10.3	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, LLC, and Encina Business Credit, LLC, dated March 19, 2021.	8-K	3/22/21	10.3
10.4&	Consent, Joinder and Second Amendment to Loan and Security Agreement dated January 26, 2022 between the registrant and Eclipse Business Capital LLC.	10-Q	2/14/22	10.3

10.5	Amendment No. 4 to Loan and Security Agreement by and among Neos Therapeutics, Inc., Neos Therapeutics Brands, LLC, Neos Therapeutics, LP, Neos Therapeutics Commercial, LLC, PharmaFab Texas, LLC, Aytu Therapeutics, LLC, Innovus Pharmaceuticals, Inc., Semprae Laboratories, Inc., Novalere, Inc., Delta Prime Savings Club, Inc. and Eclipse Business Capital LLC, dated March 24, 2023.	10-Q	5/11/23	10.1
10.6#	Consent, Joinder and Amendment No. 5 to Loan and Security Agreement dated June 12, 2024, between Aytu BioPharma, Inc., the Obligors and lenders party thereto and Eclipse Business Capital LLC as agent.	8-K	6/18/24	10.1
10.7	Term Loan Note dated June 12, 2024.	8-K	6/18/24	10.2
10.8	Second Amended and Restated Revolving Note dated June 12, 2024.	8-K	6/18/24	10.3
10.9&	Loan and Security Agreement dated January 26, 2022 between the registrant and the Avenue Capital Lenders and Avenue Capital Agent.	10-Q	02/14/22	10.3
10.10	Second Amendment to Loan Documents by and among Avenue Capital Management II L.P., certain lenders and Aytu BioPharma, Inc., dated March 24, 2023.	10-Q	05/11/23	10.2
10.11	Common Stock Purchase Warrant.	10-Q	02/07/19	10.5
10.12	Registration Rights Agreement dated January 26, 2022 between Aytu and each of the warrant holders.	10-Q	02/14/22	10.5
10.13&	Form of Warrant.	10-Q	02/14/22	10.6
10.14	Form of Placement Agency Agreement.	S-1/A	06/05/23	10.42
10.15	Form of Securities Purchase Agreement.	S-1/A	06/05/23	10.43
10.16	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
10.17&	License, Development, Manufacturing and Supply Agreement, dated November 2, 2018.	10-Q	02/07/19	10.2
10.18#	Amended and restated License and Supply Agreement with Acerus Pharmaceuticals, dated July 29, 2019.	8-K	08/02/19	10.1
10.19	Form of Contingent Value Rights Agreement.	8-K	09/18/19	10.1
10.20	First Amendment to Asset Purchase Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.1

10.21	Waiver and Amendment to the July 29, 2019 Amended and Restated License and Supply Agreement, dated November 29, 2019.	8-K	12/02/19	10.1
10.22	Termination and Transition Agreement between Aytu BioPharma, Inc. and Acerus Pharmaceuticals Corporation, dated March 31, 2021.	10-Q	05/17/21	10.9
10.23	Option Agreement between Rumpus VEDS, LLC and Denovo Biopharma LLC, dated December 21, 2019.	10-Q	05/17/21	10.14
10.24	Exclusive License Agreement between Rumpus VEDS, LLC and Johns Hopkins University, dated December 20, 2019.	10-Q	05/17/21	10.15
10.25&	Asset Purchase Agreement, dated July 1, 2020, by and between Aytu BioPharma, Inc. and UAB "Caerus Biotechnologies."	10-K	09/28/21	10.79
10.26&	Termination Agreement, dated June 29, 2021 by and between Aytu BioPharma, Inc. and Avrio Genetics, LLC.	10-K	09/28/21	10.80
10.27#&	Settlement and Termination of License Agreement between the Registrant and TRIS Pharma, Inc., dated May 12, 2022.	10-Q	05/16/22	10.1
10.28&	Commercial Manufacturing Services Agreement by and between the Company and Halo Pharmaceutical, Inc., dated November 13, 2023.	10-Q	02/14/24	10.1
10.29	Commercial Lease Agreement dated June 10, 1999, between Walstib, L.P. and Pharmafab, Inc.	10-K	10/12/23	10.48
10.30	First Amendment to Lease dated September 1, 2002, between Walstib, L.P. and PFAB, LP.	10-K	10/12/23	10.49
10.31	Second Amendment to Lease dated September 4, 2003, between Teachers Insurance and Annuity Association of America and PFAB, LP.	10-K	10/12/23	10.50
10.32	Third Amendment to Lease dated October 1, 2003, Between TIAA and PFAB, LP.	10-K	10/12/23	10.51
10.33	Fourth Amendment to Lease dated May 1, 2009, between TIAA and Neos Therapeutics, LP (formerly PFAB, LP).	10-K	10/12/23	10.52
10.34	Fifth Amendment to Lease dated April 5, 2010, between TIAA and Neos Therapeutics, LP.	10-K	10/12/23	10.53
10.35	Sixth Amendment to Lease dated August 14, 2013, between Riverside Business Green, LP and Neos Therapeutics, LP.	10-K	10/12/23	10.54

10.36†	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	07/27/17	10.1	
10.37†	Aytu BioPharma, Inc. 2023 Equity Incentive Plan.	S-8	06/23/23	10.1	
10.38	Form of Indemnification Agreement.	8-K	07/01/22	10.1	
10.39†	Restricted Stock Award Agreement between Aytu BioPharma, Inc. and Mark Oki, effective January 17, 2022.	10-Q	02/14/22	10.2	
10.40†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Joshua R. Disbrow dated February 13, 2023.	10-K	10/12/23	10.45	
10.41†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Mark Oki dated February 13, 2023.	10-K	10/12/23	10.46	
10.42†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Jarrett T. Disbrow dated March 20, 2023.				X
10.43†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Greg Pyszczymuka dated March 21, 2023.	10-K	10/12/23	10.55	
19.1	Statement of Insider Trading Policy.				X
21.1	List of Subsidiaries.				X
23.1	Consent of Grant Thornton LLP, 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 BioPharma, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certificate of the Chief Financial Officer of Aytu BioPharma, 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 BioPharma, Inc. pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
97.1	Executive Compensation Clawback Policy.				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 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 SEC pursuant to a confidential treatment request.

& Pursuant to Item 601(b)(10) of Regulation S-K, portions of this exhibit 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.

* Furnished herewith.

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 26, 2024

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., hereby severally constitute and appoint Joshua R. Disbrow and Mark Oki, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, to file any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC, 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 26, 2024.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chairman and Chief Executive Officer *(Principal Executive Officer)*
/s/ Mark K. Oki Mark K. Oki	Chief Financial Officer *(Principal Financial Officer)* *(Principal Accounting Officer)*
/s/ John A. Donofrio, Jr. John A. Donofrio, Jr.	Lead Independent Director
/s/ Carl C. Dockery Carl C. Dockery	Director
/s/ Abhinav Jain Abhinav Jain	Director
/s/ Vivian H. Liu Vivian H. Liu	Director

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