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, 2025

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 31, 2024, the aggregate market value of common stock held by non-affiliates of the registrant was $7,238,109 based on the last reported sales price of $1.70 as quoted on the Nasdaq Capital Market on such date.

As of September 15, 2025, there were 9,911,913 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required by Items 10, 11, 12, 13 and 14 of Part III of this report is incorporated by reference from portions of the registrant's Definitive Proxy Statement on Schedule 14A relating to its 2026 annual meeting of stockholders, to be filed within 120 days after June 30, 2025.

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, 2025, ("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 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, EXXUA, 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.

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

- 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.
- We are dependent on our relationships and license and commercialization agreements, and we rely on the intellectual property rights granted to us pursuant to the license and commercialization agreements.
- The expiration or loss of patent protection may adversely affect our future net revenue 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 or assets and such acquisitions may not result in the anticipated benefits, as a result, our business, results of operations and/or financial condition may be materially adversely affected.
- In fiscal 2025, the great majority of our gross revenue and gross accounts receivable were due to four 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 us.
- 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 large 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 advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients. We were originally incorporated as Rosewind Corporation on August 9, 2002, in the state of Colorado and re-incorporated as Aytu BioScience, Inc. in the state of Delaware on June 8, 2015. In March 2021, we changed our name to Aytu BioPharma, Inc. Our common stock trades on the Nasdaq Capital Market LLC (the "Nasdaq") 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.

Our strategy is to become a leading pharmaceutical company that improves the lives of patients. We use a focused approach of in-licensing, acquiring, developing and commercializing novel prescription therapeutics in order to continue building our portfolio of revenue-generating products and leveraging our commercial team's expertise to build leading brands within large therapeutic markets. In June 2025, we entered into an Exclusive Commercialization Agreement (the "Commercialization Agreement") with Fabre-Kramer Holdings, Inc. ("Fabre-Kramer") to commercialize EXXUA (gepirone) extended-release tablets ("EXXUA") in the United States. Gepirone is a new chemical entity, and we believe EXXUA to be a novel first-in-class selective serotonin 5HT1a receptor agonist approved by the United States Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD") in adults.

EXXUA has been extensively studied in over 5,000 patients and represents a new class of therapeutics to compete in the over $22 billion United States prescription MDD market. We believe it can become a very important treatment option for the estimated 21 million Americans affected by MDD. Over 340 million antidepressant prescriptions were written in 2024 in the United States, yet significant unmet needs remain considering the unacceptable side effects associated with current therapeutics. Importantly, we believe that EXXUA is the only antidepressant acting on serotonin receptors that does not carry a label warning about the risk of sexual dysfunction. The mechanism of the antidepressant effect of EXXUA is believed to be related to its modulation of serotonin activity and, specifically, its exclusive and strong binding affinity for 5HT1a receptors, which are key regulators of mood and emotion. EXXUA is not a selective serotonin reuptake inhibitor ("SSRI") and has no reuptake inhibition activity. EXXUA also exhibits no significant adverse effects on weight, blood pressure, heart rate or liver function. It is our expectation that EXXUA has the potential to serve as a major growth catalyst for us and we anticipate launching EXXUA in the fourth calendar quarter of 2025 as a centerpiece of our commercial efforts.

In addition, we will continue to focus on commercializing innovative prescription products that address conditions frequently developed or diagnosed in children, including attention deficit hyperactivity disorder ("ADHD"). We are focusing our efforts on accelerating the growth of our commercial business and achieving positive operating cash flows. To achieve these goals, we indefinitely suspended active development of our clinical development programs and have wound down and divested unprofitable operations. In the first quarter of fiscal 2025 we completed the previously announced wind down and divestiture of our Consumer Health business and now operate our business as a single operating and reporting segment. The accounting requirements for reporting the Consumer Health business as a discontinued operation were met when the wind down and divestiture was completed on July 31, 2024. Accordingly, our consolidated financial statements for all periods presented reflect the Consumer Health business as a discontinued operation.

Our business from continuing operations is focused on the upcoming launch of EXXUA and on our current prescription pharmaceutical products sold primarily through third party wholesalers and pharmacies and which primarily consists of two product portfolios. The first primarily consists of two products for the treatment of ADHD: Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets ("Adzenys") and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets ("Cotempla" and Adzenys together with Cotempla the "ADHD Portfolio"). The second primarily consists 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"). During the fourth quarter of fiscal 2024, we successfully completed the transition of all manufacturing of our Adzenys and Cotempla products to a United States-based third-party contract manufacturer to improve the profitability of these products.

We have incurred significant losses in each year since inception. Our net loss was $13.6 million for the year ended June 30, 2025, and as of June 30, 2025, we had an accumulated deficit of $333.5 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 our competitive landscape (i.e., entry of generic competitors, payor 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 management and our Board expect to continue 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 prescription business given the opportunity for EXXUA in the MDD market 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 completed the wind down of operations and divested our Consumer Health business in the first quarter of fiscal 2025.

For fiscal 2025, we recorded net revenue of $66.4 million. During the year, we were able to continue the production of our ADHD medications, Adzenys and Cotempla, without encountering any supply chain interruptions in order to provide patients receiving stimulant prescriptions for the treatment of ADHD with alternative solutions to products that have experienced supply interruptions. As a result, we recorded our second highest prescription levels for both Adzenys and Cotempla during fiscal 2025, even though the ADHD marketplace saw a decrease in supply chain interruptions and a stabilization of ADHD product supply, resulting in $57.6 million of net revenue for our ADHD Portfolio, the second highest achieved in our history. We also saw Pediatric Portfolio growth to $8.8 million, a 20% increase from fiscal 2024, which reflects the positive effects from our recently implemented return-to-growth plan for this portfolio.

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 now closed facility in Grand Prairie, Texas.

As an additional result of focusing on building our portfolio of revenue-generating products and generating profitability, in fiscal 2023 we terminated our license agreements relating to Healight and NT0502 (N-desethyloxybutynin), and we indefinitely suspended active development of our clinical development programs including AR101 (enzastaurin) ("AR101"). In connection with this suspension, we engaged in negotiations with EnzCo, LLC ("EnzCo") and Rumpus VEDS LLC, ("Rumpus VEDS"), Rumpus Therapeutics LLC, ("Rumpus Therapeutics") and Rumpus Vascular LLC, ("Rumpus Vascular" and, together with Rumpus VEDS and Rumpus Therapeutics, "Rumpus") for the repurchase of AR101. On August 5, 2025, we reached terms with Rumpus and EnzCo whereby for mutual consideration and releases, we transferred all of ours and Rumpus' rights, title and interest in AR101 to EnzCo, which extinguished and terminated all of our obligations and Rumpus' obligations under the April 21, 2021, asset purchase agreement by and between us and Rumpus (the "Rumpus Asset Purchase Agreement"). There is no other relationship between us, EnzCo or Rumpus other than as contracting parties to terminate the Rumpus Asset Purchase Agreement, and there are no penalties or remaining obligations for us for terminating the Rumpus Asset Purchase Agreement.

We continue to experience inflationary pressures and economic uncertainty caused by global geopolitical factors and tariffs and our industry is currently encountering supply chain disruptions related to the sourcing of raw materials, increased costs of materials as result of tariffs, energy, logistics and labor for a number of reasons, including ongoing geopolitical events. While we do not have sales or operations in Russia or Ukraine and we do not have significant sales or operations in the Middle East, it is possible that conflicts and trade wars 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. Inflationary pressures, increased costs and supply chain disruptions could be significant across the business throughout fiscal 2026 and into fiscal 2027. Understanding these risks, we have not experienced stock outages for our ADHD products since the launch of those products, and the pediatric product supply has remained adequate to satisfy demand for the preceding four years.

In October 2024, we received a Paragraph IV Certification Notice Letter (the "Notice Letter") from Granules Pharmaceuticals, Inc. ("Granules"), stating that it intends to market a generic version of Adzenys before the expiration of all patents currently listed in the FDA's publication of approved drug products with therapeutic equivalence evaluations (the "Orange Book"). The Notice Letter states that Granules' New Drug Application ("NDA") for the generic version of Adzenys contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic version of Adzenys. We timely filed a patent infringement lawsuit on December 11, 2024, against Granules to trigger a stay precluding the FDA from approving Granules' NDA for a generic version of Adzenys for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. On January 7, 2025, Granules submitted an answer to the complaint. This litigation is ongoing, and a trial has been scheduled to begin on December 7, 2026. We plan to vigorously enforce our intellectual property rights related to Adzenys.

Debt and Equity Financings

Equity Financings

In June 2025, we raised gross proceeds of $16.6 million from the issuance of (i) 2,806,688 shares of our common stock, at a public offering price of $1.50 and 8,233,332 prefunded warrants at a public offering price of $1.4999 to purchase 8,233,332 shares of our common stock at an exercise price of $0.0001 per share (the "June 2025 Prefunded Warrants"). We received $14.8 million in proceeds net of underwriting commissions and offering expenses and intend to use the net proceeds from the offering for working capital, general corporate purposes and to enable us to exclusively commercialize EXXUA.

In June 2024, certain warrants to purchase 2,173,912 shares of our common stock at an exercise price of $1.59 (the "Tranche B Warrants") were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of our common stock and 1,806,434 prefunded warrants to purchase shares of our common stock with an exercise price of $0.0001 per share (the "Tranche B Prefunded Warrants"). We used a portion of these proceeds as part of the $15.0 million term loan repayment described below.

Eclipse Agreement

In June 2025, we and certain of our subsidiaries entered into an Amendment No. 6 to Loan and Security Agreement (the "Eclipse Amendment No. 6") 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 Amendment No. 5 dated June 12, 2024 (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 Agreement, 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 an outstanding principal amount of $13.0 million on the closing date of the Eclipse Amendment No. 6, at an interest rate of the secured overnight financing rate as administered by the SOFR Administrator (the "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 the June 12, 2029, maturity date, as amended. In June 2024, we used the initial proceeds from the Eclipse Term Loan and a portion of the proceeds from the warrant exercises described above to repay in full a $15.0 million term loan.

The Eclipse Revolving Loan has a potential maximum borrowing base of $14.5 million at an interest rate of the SOFR plus 4.5%, which was temporarily increased pursuant to a $1.5 million incremental advance at an interest rate of the SOFR plus 5.5% (the "Eclipse Incremental Advance"), with repayment and permanent reduction of the Eclipse Incremental Advance commencing on August 1, 2025, and continuing on the first day of each calendar month thereafter, in an amount equal to $125,000 per month, until the Eclipse Incremental Advance has been reduced to $0. 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, 2029.

Commercial Business Overview

We operate through one business segment consisting of various prescription pharmaceutical products sold through third parties. We generate net revenue by selling our products through third party intermediaries in our distribution channels as well as directly to our customers. Over the past two years, we have undergone a planned, strategic change to focus on our core prescription business while seeking to acquire differentiated, branded central nervous system ("CNS") products that complement our portfolio and focus. With this focus, we recently signed an exclusive commercialization agreement for EXXUA, which we believe to be a novel first-in-class treatment for MDD that can become an important treatment for MDD in the United States. Further, we believe that EXXUA is a perfect strategic fit and will be a centerpiece of our commercial efforts going forward considering the significant commercial potential, uniqueness of the product, our sales force's CNS focus and alignment with our proprietary Aytu RxConnect patient access platform. We transitioned the manufacturing of Adzenys and Cotempla to a third-party manufacturer during the fourth quarter of fiscal 2024 and continue to use third party manufacturers for all other products.

Our business consists of EXXUA, which we anticipate launching in the fourth calendar quarter of 2025, 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.

EXXUA is an extended-release medication that is FDA-approved for the treatment of MDD with what we believe to be a novel first-in-class oral selective serotonin 5HT1a receptor agonist indicated for the treatment of MDD in adults. EXXUA has also been studied in other psychiatric disorders, including generalized anxiety disorder ("GAD") and hypoactive sexual desire disorder ("HSDD").

Our ADHD products are extended-release stimulant 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. These products serve established pediatric markets and offer distinct clinical features and patient benefits.

We commercialize our business through our internal commercial organization that includes approximately 40 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 over 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, Aytu 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 commercialize Adzenys and Cotempla in Israel and the Palestinian Authority. In September 2024, we entered into an exclusive collaboration, distribution and supply agreement with Lupin Pharma Canada Ltd ("Lupin"), a subsidiary of global pharmaceutical company Lupin Limited, for Lupin to commercialize Adzenys and Cotempla in Canada. We will supply Adzenys and Cotempla to Medomie and Lupin based on forecasts and provide various product commercialization, regulatory and quality assurance resources. Medomie and Lupin are responsible for seeking local regulatory approvals and marketing authorizations for both Adzenys and Cotempla, which is expected to occur over the next 24 months. The agreements with Medomie and Lupin represent our first and second international commercial agreements for Adzenys and Cotempla, respectively.

Strategy

We are a pharmaceutical company focused on advancing innovative medicines for complex CNS diseases to improve the quality of life for patients. We are committed to enhancing the lives of individuals affected by psychiatric conditions with our innovative treatments for MDD and ADHD and ensuring broad access for those who need them most.

Our strategic priorities are to continue to increase net revenue and enhance our financial performance through operational and manufacturing efficiencies and portfolio prioritization. Specifically, we intend to:

- successfully launch EXXUA in the fourth calendar quarter of 2025 as the centerpiece of our commercialization efforts;

- continue to grow our commercial branded, revenue-generating products, by increasing product sales and improving patient access in order to drive net revenue growth of our products already in the marketplace, 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 of our medicines;

- leverage our novel Aytu RxConnect patient support platform, which is designed to reduce access barriers to medicines facing patients and healthcare professionals ("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 staff 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, along with additional margin improvement initiatives.

We believe our history of acquiring companies and in-licensing and acquiring products, 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: EXXUA (Gepirone) Extended-Release for the Treatment of Major Depressive Disorder in Adults

MDD, also known as clinical depression, is a serious mood disorder characterized by persistent feelings of sadness, hopelessness, and loss of interest in activities that once brought pleasure. These symptoms must be present for at least two weeks to warrant a patient's diagnosis. MDD can significantly impact an individual's daily life, affecting their ability to work, socialize, engage in self-care and maintain relationships. It is considered one of the leading causes of disability globally. While the exact causes are not fully understood, factors like genetics, brain chemistry imbalances, stressful life events and certain medical conditions are believed to play a role. Various treatment options, including medication, psychotherapy and lifestyle changes are available and can be effective for many individuals with MDD. However, despite many available treatment options, significant unmet needs remain in MDD given both ineffectiveness of treatments for many patients as well as a high rate of adverse events that affect patient compliance and treatment satisfaction.

The United States MDD market opportunity is significant given the over 340 million prescriptions written annual and the high rate of patient dissatisfaction and resulting high rate of switching MDD medications often attributable to adverse events caused by these medications. The most commonly prescribed treatments for MDD are SSRIs such as Paxil®, Prozac®, Lexapro® and Zoloft® and serotonin-norepinephrine reuptake inhibitors ("SNRIs") such as Cymbalta® and Effexor®, while sometimes effective in treating MDD symptoms, these classes of medications commonly cause adverse events in the form of sexual side effects and weight gain. Greater than 40% of MDD patients switch from these initial therapies, indicating a high level of treatment ineffectiveness and side effects. Up to 70% of MDD patients complain of treatment emergent sexual dysfunction and greater than 65% complain of weight gain. As the only FDA-approved antidepressant acting on serotonin that does not carry a label warning about the risk of sexual dysfunction, we believe EXXUA can serve an important role in MDD treatment for these patients.

EXXUA is a new chemical entity, and we believe it to be a novel first-in-class selective serotonin 5HT1a receptor agonist approved by the FDA for the treatment of MDD in adults. EXXUA has been extensively studied in over 5,000 patients and represents a new class of therapeutics to compete in the over $22 billion United States prescription MDD market. Importantly, we believe that EXXUA is the only antidepressant acting on serotonin receptors that does not carry a label warning about the risk of sexual dysfunction. The mechanism of the antidepressant effect of EXXUA is believed to be related to its modulation of serotonin activity and, specifically, its exclusive and strong binding affinity for 5HT1a receptors, which are key regulators of mood and emotion. EXXUA is not a SSRI and has no reuptake inhibition activity. EXXUA also exhibits no significant adverse effects on weight, blood pressure, heart rate or liver function.

Given the compelling and novel product profile of EXXUA and the unmet needs of MDD patients, we believe EXXUA can become a very important treatment option for the estimated 21 million Americans affected by MDD. Over 340 million antidepressant prescriptions were written in 2024 in the United States, yet significant unmet needs remain considering the unacceptable side effects associated with current therapeutics. We are well positioned to realize the significant market potential of EXXUA while positively impacting the lives of MDD patients.

EXXUA has demonstrated efficacy in treating MDD in two well-controlled clinical trials (and five additional supportive studies) while avoiding sexual dysfunction seen with SSRIs and SNRIs, and no statistically significant weight changes. EXXUA was approved by the FDA in September 2023.

The two pivotal phase three trials established the efficacy and safety of EXXUA for MDD. The first was Study FK-GBE-007 (n = 248) ("Study FK-GBE-007") and the second was Study 134001 (n ≈ 202, ITT population) ("Study 134001"). Both were randomized, double-blind, placebo-controlled and eight-week outpatient studies in adults meeting Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition ("DSM-IV") criteria for MDD. In Study FK-GBE-007, flexible-dose gepirone extended release (20–80 mg/day; mean ≈ 58 mg) produced a mean HAMD-17 reduction of –10.1 vs –7.8 for placebo, with an LS-mean difference of –2.4 (95% CI: –4.4 to –0.3; p = 0.023). In Study 134001, using a similar dosing schedule (mean dose ≈ 70 mg), showed a HAMD-17 change of –9.04 vs –6.75 for placebo (LS-mean difference –2.47; 95% CI: –4.41 to –0.53; p = 0.013).

Both trials demonstrated symptom improvement emerging by week 2–3. Safety findings were consistent across studies, with the most common adverse events being headache, mild-to-moderate dizziness, and nausea; discontinuation rates due to adverse events were low (~3% for dizziness). Importantly, EXXUA showed no significant sexual dysfunction, or weight gain, supporting a favorable tolerability profile.

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 2024, approximately 104 million prescriptions for medications with ADHD labeling were written in the United States, generating $28.6 billion in sales. Approximately 88% 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 and Cotempla, 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.

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 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 Orange Book. In addition, we entered into a settlement agreement with Actavis Laboratories FL, Inc. ("Actavis") (which is now owned by Teva Pharmaceutical Industries Limited), 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.

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 2024. 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, accounting for 6% of 2024 total prescriptions, while non-sedating, second-generation antihistamines accounted for 94% of total prescriptions.

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 is available in 480 mL bottles.

Through a supply and distribution agreement with Tris Pharma, Inc. ("Tris"), we own exclusive rights to commercialize 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 were 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 latest of which expires in March 2029.

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 supplied drinking water 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 2024, 5.9 million multi-vitamin prescriptions were written in the United States. Of those prescriptions, multi-vitamins containing sodium fluoride accounted for 0.6 million total prescriptions. Common multi-vitamin combinations contain vitamins A, B, C, D and E, but no other prescription pediatric multi-vitamin products contain Metafolin or Arcofolin, both of which make the Poly-Vi-Flor and Tri-Vi-Flor product lines distinct, single-source brands with novel ingredients.

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 prescription multi-vitamin market is dominated by generic products, with brands accounting for 6% of the multivitamin plus fluoride market for the calendar year ending December 31, 2024.

Manufacturing

We contract with contract manufacturing organizations ("CMOs") for the manufacture and testing of our products. We have entered into the following key supply agreements for the commercial manufacture and supply of certain of these products:

- EXXUA is purchased through Fabre-Kramer through their manufacturing agreement with a CMO, as part of our exclusive commercialization agreement with Fabre-Kramer. We are obligated to the material terms of Fabre-Kramer's manufacturing agreement in terms of supply prices, minimum order sizes, forecasting provisions and all regulatory and compliance provisions. Fabre-Kramer's manufacturing agreement has an initial term ending in September 2028.

- During fiscal 2024 we completed the process of transferring the manufacturing of our Adzenys and Cotempla products to a United States-based CMO who started manufacturing both Adzenys and Cotempla during the third quarter of fiscal 2024 and will manufacture all of our ADHD products going forward. 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.

- 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 research and development activities in order to focus our resources on our commercialization efforts and as a result, research and development spending has significantly declined. Research and development spending primarily relate to required regulatory filings and maintenance of our intellectual property and regulatory filings.

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, EXXUA, 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 United States Federal Food, Drug, and Cosmetic Act ("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 each considered a "controlled substance" as defined in the Controlled Substances Act of 1970 ("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. EXXUA and all of our pediatric products (Karbinal, Poly-Vi-Flor and Tri-Vi-Flor) are not 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. As we no longer occupy a manufacturing facility, we no longer need a DEA facility registration.

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 manufacturer's 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 June 30, 2025, we employed 83 employees, of which 82 were full-time employees. Of our 83 employees, 5 are involved in operations, 52 are involved in commercialization and 26 are involved in general and administrative activities. All of our colleagues are located in the United States. Of these colleagues, 49% are female and 51% are male. Our colleagues are not represented by a labor union.

Our values – team-oriented, hard-working, relentless determination, 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, 2025, and 2024, was $13.6 million and $15.8 million, respectively. We have not demonstrated the ability to be a profit-generating enterprise to date. Even though we expect to have net revenue growth in the next several fiscal years, it is uncertain that the net 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 net revenue 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 net revenue that is sufficient to achieve profitability.

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

Since our inception, we have had significant operating losses. As of June 30, 2025, we had accumulated deficit of $333.5 million. 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 net revenue sufficient to consistently 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, 2025, our cash and cash equivalents totaled $31.0 million. During the year ended June 30, 2025, we received $14.8 million of net proceeds from our June 2025 public offering and $3.2 million of net proceeds from the Eclipse Amendment No. 6 that was executed in June 2025.

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.

As of June 30, 2025, we have a $13.0 million term loan and up to $16.0 million of secured revolving loans under the Eclipse Agreement, which includes the temporary Eclipse Incremental Advance of $1.5 million. As of June 30, 2025, $9.1 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 Eclipse Agreement subjects 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 lenders. 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 lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

As of June 30, 2025, we had federal net operating loss carryforwards of $516.7 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 $516.7 million of pre-acquisition net operating loss carryovers. As a result, we expect $324.7 million of net operating losses to expire unused by 2037, at which point we will only retain indefinite-lived carryforwards. The ownership changes have resulted in increased future tax liability and are a driver of the change from a zero percent effective tax rate.

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. 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 net 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 flows 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 net revenue 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 net revenue 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 net revenue 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 and we are currently launching EXXUA in the United States. None of our marketed prescription have thus far generated product revenue at levels sufficient for us to consistently 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 business in the first quarter of fiscal 2025, we now operate our business as a single operating and reporting segment. The accounting requirements for reporting the Consumer Health business as a discontinued operation were met when the wind down and divestiture was completed. Accordingly, our consolidated financial statements for all periods presented reflect the Consumer Health business as a discontinued operation and we will not generate revenue from the Consumer Health business 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 net revenue 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 products are or will be differentiated from other 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 an NDA, including a 505(b)(2) application, is approved, the covered product becomes a "listed drug" that, in turn, can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices.

Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product can be lost to the generic version. Accordingly, competition from generic equivalents to our products could materially adversely impact our net revenue, 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 us that Actavis filed an ANDA with the FDA for a generic version of Adzenys. On October 17, 2017, we entered into a Settlement Agreement and a Licensing Agreement with Actavis (which is now owned by Teva Pharmaceutical Industries Limited), pursuant to which we granted Actavis the right to manufacture and market its now approved generic version of Adzenys under the ANDA beginning on September 1, 2025. On October 31, 2017, we received a paragraph IV certification from Teva advising us that Teva filed an ANDA with the FDA for a generic version of Cotempla. 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 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 net revenue 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 continuous 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, or if the prices of the supply increases due to general economic conditions or tariffs, 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 active pharmaceutical ingredients ("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 Adzenys and Cotempla products during fiscal 2024 to a third-party manufacturer based in the United States, to produce commercial quantities of these products. If the third-party is not successful or does not meet our expectations (for example, timeliness of production, quantity of production, maintenance of needed documentation or regulatory compliance), we may have to find a different manufacturer and incur expenses and delays in the process. Manufacturers of our FDA regulated 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, National Medical Products Administration ("NMPA"), European Medicines Agency ("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.

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 ("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.

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, 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 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 against our current and future competitors, our business will not grow, we our financial condition and operations will suffer. 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.

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

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 net 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 net revenue. As we expect to receive significant net revenue from reimbursement of our 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 net revenue 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 European Union (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 net 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 net revenue 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.

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 payors 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 Federal Supply Schedule ("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 False Claims Act ("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 net revenue.

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 commercialize Adzenys and Cotempla in Israel and the Palestinian Authority and the agreement we entered into with Lupin in September 2024 to commercialize Adzenys and Cotempla in Canada. 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 payor, 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 be, 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 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 Health Insurance Portability and Accountability Act ("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

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. As discussed in Part I, Item 3, *Legal Proceedings* of this Annual Report, we are currently subject to intellectual property litigation. It is possible that this litigation or future intellectual property litigation 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.

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 us. 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 net revenue 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.

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 flows 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 businesses or assets and such acquisitions may not result in the anticipated benefits, 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 launch the sale of purchased assets or to integrate acquired products, assets 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 or assets 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 2025, the great majority of our gross revenue and gross accounts receivable were due to four significant customers, the loss of which could materially and adversely affect our results of operations.

Four customers contributed greater than 10% of our gross revenue during the year ended June 30, 2025. During the year ended June 30, 2025, these four customers accounted for 85% of our gross revenue. 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, 2025, four customers accounted for 89% of our gross accounts receivable. Our profitability and cash flows 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 flows. There is no assurance that we will be able to collect all or any of our accounts receivable 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. 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.

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 us.

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. Certain cases in the industry 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 large percentage of our stock and their interests may conflict with yours.

As of June 30, 2025, Nantahala Capital Management, LLC ("Nantahala"), Stonepine Capital Management, LLC and Laurence W. Lytton hold approximately 12.1%, 10.1% and 5.6%, respectively, of our outstanding common stock and hold warrants and/or prefunded 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 for certain of our warrants and prefunded warrants in excess of 19.99% subject to stockholder approval. Accordingly, these stockholders may be able to exert influence over our management and affairs and over matters requiring security holder approval and their interests may conflict with yours.

In addition, in connection with our public offering of securities in June 2023, Nantahala was 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 of Directors, subject to Nasdaq regulations. To date Nantahala only occupies one Board seat. The interests of this stockholder could conflict with the interests of our other stockholders.

Risk Related to Securities Markets and Investment in Our Securities

Our failure to meet the continued listing requirements of the Nasdaq could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of the Nasdaq, 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 October 11, 2024, the SEC approved a Nasdaq proposed rule change that changes how it views reverse stock splits. The new rule allows Nasdaq to 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. Although we have not effectuated a reverse stock split since January 2023, 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 Contract Research Organizations ("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, as amended, and our 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, as amended, or our Amended and Restated 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 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

We are and may become involved in litigation or other proceedings from time to time relating to the enforcement or defense of patent and other intellectual property rights, which could cause us to divert our resources and could put our intellectual property at risk.

To prevent infringement or unauthorized use of our intellectual property, we have in the past, and may in the future, need to file infringement claims. For example, on December 11, 2024, we filed a patent infringement lawsuit in the United States District Court for the District of Delaware against Granules Pharmaceuticals, Inc. (see Part I, Item 3, *Legal Proceedings* in this Annual Report for further detail of this matter). When we pursue litigation to stop another party from using the inventions claimed in any patents we own or control, that party has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. In addition to patent infringement lawsuits, we may decide to file interferences, oppositions, ex parte reexaminations, post-grant review, or inter partes review proceedings before the United States Patent and Trademark Office (the "USPTO") and corresponding foreign patent offices. Litigation and other proceedings relating to intellectual property are unpredictable and expensive and may consume time and resources and divert the attention of managerial and scientific personnel. Such litigations and proceedings could substantially increase our operating losses and reduce the resources available for research, development and other activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings or may be required to divert such resources from our ongoing and planned research and development and other activities. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

There also is a risk that a court or patent office in such proceeding will decide that our patents or the patents of our licensors are not valid or are not enforceable, and that we do not have the right to stop the other party from using the inventions. Additionally, even if the validity of such patents is upheld, the court may refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. If we are not successful in enforcing or defending our intellectual property, our competitors could develop and market products based on our discoveries and technologies, which may reduce the commercial viability of, and demand for, our product candidates and any future products.

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, and some of our vendors utilize artificial intelligence and similar 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 mitigate 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.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets may experience extreme volatility and disruptions (including as a result of actual or perceived changes in interest rates and economic inflation), which include severely diminished liquidity and credit availability, declines in consumer confidence, slower economic growth, high inflation, tariffs, trade wars, uncertainty about economic stability and swings in unemployment rates. The financial markets and the global economy may also be adversely affected by the impact of supply chain disruptions, labor shortages, fluctuations in currency exchange rates, changes in interest rates, military conflict, acts of terrorism or other geopolitical events. Sanctions imposed, and other actions taken, by the United States and other countries in response to geopolitical conflicts continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that a deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, including our ability to purchase necessary supplies on acceptable terms, if at all. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to further delay or abandon clinical development plans, if we were to resume such development. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

The United States government has indicated its intent to alter its approach to international trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the United States government has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain United States goods. It remains unclear what the United States administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers and/or the United States or global economy or certain sectors thereof and, thus, could adversely impact our businesses.

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 2025, 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 various office buildings within the United States, which we continuously review and evaluate 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, 2025:

Location	Leased/Owned	Purpose
Denver, CO	Leased	Corporate headquarters
Berwyn, PA	Leased	Office

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 Annual 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.

Granules Paragraph IV. On October 31, 2024, the Company received the Notice Letter from Granules, stating that it intends to market a generic version of Adzenys before the expiration of all patents currently listed in the Orange Book. The Notice Letter states that Granules' NDA for the generic version of Adzenys contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic version of Adzenys. On December 11, 2024, the Company filed a patent infringement lawsuit against Granules which triggered a stay precluding the FDA from approving Granules' NDA for a generic version of Adzenys for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. On January 7, 2025, Granules submitted an answer to the complaint. This litigation is ongoing, and a trial has been scheduled to begin on December 7, 2026. The Company plans to vigorously enforce its intellectual property rights related to Adzenys.

Revive Investing. The Company had been named as a nominal plaintiff in a lawsuit by two shareholders against Armistice Capital Master Fund, Ltd ("Armistice"), entitled Revive Investing, LLC. et al v. Armistice Master Fund, Ltd. et al, Case 1:20-cv-02849-CMA-TPO, in the United States District Court for the District of Colorado, contending that Armistice was liable for short swing trading profits in violation of Section 16(b) of the Exchange Act for certain trades it made in Company stock in 2019 and 2020 and must disgorge those profits to the Company. That matter proceeded to trial before a jury, which on January 29, 2025, returned a verdict finding no liability. On March 6, 2025, the plaintiffs filed an appeal in the United States Court of Appeals for the Tenth Circuit. As with the original case, regardless of the outcome, this case will not have a materially adverse effect upon the Company's financial condition, results of operations, or cash flows.

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 under the symbol "AYTU" since October 20, 2017. As of September 15, 2025, the closing price as reported on the Nasdaq of our common stock was $2.33, and there were 183 holders of record of our common stock. A substantially greater number of holders of our common stock are beneficial holders, whose shares of record are held by banks, brokers, and other financial institutions.

Equity Compensation Plan Information

We have an equity compensation plan under which options and shares of our common stock are authorized for grant or issuance as compensation to eligible employees, consultants, and members of the Board of Directors. Our stockholders have approved this plan. Refer to *Note 15 - Equity Incentive Plan* in Part II, Item 8 of this Annual Report for further information about the material terms of our equity incentive plan. The following table displays equity compensation plan information as of June 30, 2025, relating to securities reserved for future issuance upon exercise:

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options, Warrants and Rights (Column A)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (Column B)	Number of Securities Remaining Available for Issuance under Equity Compensation Plans (Excluding Securities Reflected in Column A) (Column C)
Equity compensation plans approved by security holders:			
2023 Equity Incentive Plan [1]			
Outstanding stock options [2]	211,618	$ 4.51	
Unvested restricted stock [3]	32,912	N/A	
Total from the 2023 Equity Incentive Plan	244,530		397,409
Equity compensation plans not approved by security holders [4]	4	N/A	—
Total for all plans	244,534		397,409

(1) On May 18, 2023, our stockholders approved the adoption of the Aytu BioPharma, Inc. 2023 Equity Incentive Plan (the "2023 Equity Incentive Plan"), which replaced all previous plans. For the 2023 Equity Incentive Plan, the stockholders approved (a) 200,000 new shares; (b) 87,155 shares "rolled over" to the 2023 Equity Incentive Plan from plans replaced by the 2023 Equity Incentive Plan; and (c) any shares that are returned to us under plans replaced by the 2023 Equity Incentive Plan to be added to the 2023 Equity Incentive Plan. On May 21, 2025, our stockholders approved an amendment (the "Plan Amendment") to the 2023 Equity Incentive Plan. The Plan Amendment increased the number of shares reserved for issuance under the 2023 Equity Incentive Plan by 300,000 shares to bring the total number of shares reserved for issuance under the 2023 Equity Incentive Plan to 500,000 shares, not including unissued shares from available awards under prior plans or any returned shares. The Plan Amendment became effective immediately upon approval by our stockholders and we plan to register the 300,000 shares pursuant to a registration statement on Form S-8 to be filed with the SEC in fiscal 2026.

(2) As of June 30, 2025, there were 100,195 exercisable stock options with a weighted-average exercise price of $7.44 (see *Note 15 - Equity Incentive Plan* in Part II, Item 8 of this Annual Report for further information).

(3) Unvested restricted stock does not have exercise prices associated with them, but rather a weighted-average per unit fair value, which is presented in order to provide additional information regarding the potential dilutive effect of the awards. The weighted-average grant date per unit fair value for unvested restricted stock granted under the 2023 Equity Incentive Plan as of June 30, 2025, was $69.81 (see *Note 15 - Equity Incentive Plan* in Part II, Item 8 of this Annual Report for further information).

(4) As of June 30, 2025, there were four shares of unvested restricted stock that were granted outside of equity compensation plans approved by security holders, which had less than $0.1 million of total unrecognized compensation costs and a remaining weighted-average vesting period of 1.0 years (see *Note 15 - Equity Incentive Plan* in Part II, Item 8 of this Annual Report for further information).

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 in conjunction with our consolidated financial statements and related notes thereto included 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. We are not undertaking any obligation to update any forward-looking statements or other statements we may make in the following discussion or elsewhere in this document even though these statements may be affected by events or circumstances occurring after the forward-looking statements or other statements were made. Therefore, no reader of this document should rely on these statements being current as of any time other than the time at which this document is filed with the SEC.

Objective

The purpose of the Management's 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, 2025, and our financial condition as of June 30, 2025. 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 advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients. Our strategy is to become a leading pharmaceutical company that improves the lives of patients. We use a focused approach of in-licensing, acquiring, developing and commercializing novel prescription therapeutics in order to continue building our portfolio of revenue-generating products and leveraging our commercial team's expertise to build leading brands within large therapeutic markets. In June 2025, we entered into the Commercialization Agreement with Fabre-Kramer to commercialize EXXUA in the United States. Gepirone is a new chemical entity, and we believe EXXUA to be a novel first-in-class selective serotonin 5HT1a receptor agonist approved by the FDA for the treatment of MDD in adults.

EXXUA has been extensively studied in over 5,000 patients and represents a new class of therapeutics to compete in the over $22 billion United States prescription MDD market. We believe it can become a very important treatment option for the estimated 21 million Americans affected by MDD. Over 340 million antidepressant prescriptions were written in 2024 in the United States, yet significant unmet needs remain considering the unacceptable side effects associated with current therapeutics. Importantly, we believe that EXXUA is the only antidepressant acting on serotonin receptors that does not carry a label warning about the risk of sexual dysfunction. The mechanism of the antidepressant effect of EXXUA is believed to be related to its modulation of serotonin activity and, specifically, its exclusive and strong binding affinity for 5HT1a receptors, which are key regulators of mood and emotion. EXXUA is not a SSRI and has no reuptake inhibition activity. EXXUA also exhibits no significant adverse effects on weight, blood pressure, heart rate or liver function. It is our expectation that EXXUA has the potential to serve as a major growth catalyst for us and we anticipate launching EXXUA in the fourth calendar quarter of 2025 as a centerpiece of our commercial efforts.

In addition, we will continue to focus on commercializing innovative prescription products that address conditions frequently developed or diagnosed in children, including ADHD. We are focusing our efforts on accelerating the growth of our commercial business and achieving positive operating cash flows. To achieve these goals, we indefinitely suspended active development of our clinical development programs and have wound down and divested unprofitable operations. In the first quarter of fiscal 2025 we completed the previously announced wind down and divestiture of our Consumer Health business and now operate our business as a single operating and reporting segment. The accounting requirements for reporting the Consumer Health business as a discontinued operation were met when the wind down and divestiture was completed on July 31, 2024. Accordingly, our consolidated financial statements for all periods presented reflect the Consumer Health business as a discontinued operation.

Our business from continuing operations is focused on the upcoming launch of EXXUA and on our current prescription pharmaceutical products sold primarily through third party wholesalers and pharmacies and which primarily consists of two product portfolios. The first, the ADHD Portfolio, primarily consists of two products for the treatment of ADHD: Adzenys and Cotempla. The second, the Pediatric Portfolio, primarily consists of 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. During the fourth quarter of fiscal 2024, we successfully completed the transition of all manufacturing of our Adzenys and Cotempla products to a United States-based third-party contract manufacturer to improve the profitability of these products.

We have incurred significant losses in each year since inception. Our net loss was $13.6 million for the year ended June 30, 2025, and as of June 30, 2025, we had an accumulated deficit of $333.5 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 regularly reviews our performance, prospects and risks such as the potential impact to our business resulting from our competitive landscape (i.e., entry of generic competitors, payor 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 management and our Board expect to continue to evaluate potential strategic transactions and business combinations.

Significant Developments

Business Environment

We continue to experience inflationary pressures and economic uncertainty caused by global geopolitical factors and tariffs and our industry is currently encountering supply chain disruptions related to the sourcing of raw materials, increased costs of materials as result of tariffs, energy, logistics and labor for a number of reasons, including ongoing geopolitical events. While we do not have sales or operations in Russia or Ukraine and we do not have significant sales or operations in the Middle East, it is possible that conflicts and trade wars 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. Inflationary pressures, increased costs and supply chain disruptions could be significant across the business throughout fiscal 2026 and into fiscal 2027. Understanding these risks, we have not experienced stock outages for our ADHD products since the launch of those products, and the pediatric product supply has remained adequate to satisfy demand for the preceding four years.

In October 2024, we received the Notice Letter from Granules, stating that it intends to market a generic version of Adzenys before the expiration of all patents currently listed in the Orange Book. The Notice Letter states that Granules' NDA for the generic version of Adzenys contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic version of Adzenys. We timely filed a patent infringement lawsuit on December 11, 2024, against Granules to trigger a stay precluding the FDA from approving Granules' NDA for a generic version of Adzenys for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. On January 7, 2025, Granules submitted an answer to the complaint. This litigation is ongoing, and a trial has been scheduled to begin on December 7, 2026. We plan to vigorously enforce our intellectual property rights related to Adzenys.

Aytu Business

As part of our ongoing strategic evaluation and go-forward operating plan, we continue to prioritize growing our prescription business given the opportunity for EXXUA in the MDD market and the current market trends supporting our products' growth such as the positive rebound of our Pediatric Portfolio in fiscal 2025. 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 completed the wind down of operations and divested our Consumer Health business in the first quarter of fiscal 2025.

For fiscal 2025, we recorded net revenue of $66.4 million. During the year, we were able to continue the production of our ADHD medications, Adzenys and Cotempla, without encountering any supply chain interruptions in order to provide patients receiving stimulant prescriptions for the treatment of ADHD with alternative solutions to products that have experienced supply interruptions. As a result, we recorded our second highest prescription levels for both Adzenys and Cotempla during fiscal 2025, even though the ADHD marketplace saw a decrease in supply chain interruptions and a stabilization of ADHD product supply, resulting in $57.6 million of net revenue for our ADHD Portfolio, the second highest achieved in our history. We also saw Pediatric Portfolio net revenue growth to $8.8 million, a 20% increase from fiscal 2024, which reflects the positive effects from our recently implemented return-to-growth plan for this portfolio.

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 now closed facility in Grand Prairie, Texas.

As an additional result of focusing on building our portfolio of revenue-generating products and generating profitability, in fiscal 2023 we terminated our license agreements relating to Healight and NT0502 (N-desethyloxybutynin), and we indefinitely suspended active development of our clinical development programs including AR101. In connection with this suspension, we engaged in negotiations with EnzCo and Rumpus for the repurchase of AR101. On August 5, 2025, we reached terms with Rumpus and EnzCo whereby for mutual consideration and releases, we transferred all of ours and Rumpus' rights, title and interest in AR101 to EnzCo, which extinguished and terminated all of our obligations and Rumpus' obligations under the Rumpus Asset Purchase Agreement. There is no other relationship between us, EnzCo or Rumpus other than as contracting parties to terminate the Rumpus Asset Purchase Agreement, and there are no penalties or remaining obligations for us for terminating the Rumpus Asset Purchase Agreement.

Debt and Equity Financings

Equity Financings

In June 2025, we raised gross proceeds of $16.6 million from the issuance of (i) 2,806,688 shares of our common stock, at a public offering price of $1.50 and 8,233,332 prefunded warrants at a public offering price of $1.4999 to purchase 8,233,332 shares of our common stock at an exercise price of $0.0001 per share. We received $14.8 million in proceeds net of underwriting commissions and offering expenses and intend to use the net proceeds from the offering for working capital, general corporate purposes and to enable us to exclusively commercialize EXXUA.

In June 2024, the Tranche B Warrants to purchase 2,173,912 shares of our common stock at an exercise price of $1.59 were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of our common stock and 1,806,434 prefunded warrants to purchase shares of our common stock with an exercise price of $0.0001 per share. We used a portion of these proceeds as part of the $15.0 million term loan repayment described below.

Eclipse Agreement

Under our Eclipse Agreement, we have two loan agreements, the Eclipse Term Loan and the Eclipse Revolving Loan. The Eclipse Term Loan consists of an outstanding principal amount of $13.0 million on the closing date of the Eclipse Amendment No. 6, at an interest rate of the 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 the June 12, 2029, maturity date, as amended. In June 2024, we used the initial proceeds from the Eclipse Term Loan and a portion of the proceeds from the warrant exercises described above to repay in full a $15.0 million term loan. The Eclipse Revolving Loan has a potential maximum borrowing base of $14.5 million at an interest rate of the SOFR plus 4.5%, which was temporarily increased pursuant to the $1.5 million Eclipse Incremental Advance, with repayment and permanent reduction of the Eclipse Incremental Advance commencing on August 1, 2025, and continuing on the first day of each calendar month thereafter, in an amount equal to $125,000 per month, until the Eclipse Incremental Advance has been reduced to $0. 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, 2029.

The One Big Beautiful Bill Act

The enactment of the One Big Beautiful Bill Act (the "OBBBA") on July 4, 2025, may adversely affect our business, financial condition, results of operation and future plans. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the Tax Cuts and Jobs Act (the "TCJA"), allowing for accelerated tax deductions for qualified property and research expenditures, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in calendar year 2025 and others implemented through calendar year 2027. None of the provisions are expected to impact the realizability of our deferred tax assets and liabilities on the consolidated balance sheet as of June 30, 2025. However, because the OBBBA is a wide reaching law, we are currently assessing its potential impact on our business, financial condition, results of operations and future plans and we plan to provide an update in future SEC filings once this assessment is complete.

Results of Operations

The results of operations for the year ended June 30, 2025, compared to the year ended June 30, 2024, is as follows:

	Year Ended June 30,		
	2025	**2024**	**Change**
		(in thousands)	
Net revenue	$ 66,382	$ 65,183	$ 1,199
Cost of goods sold	20,551	16,129	4,422
Gross profit	45,831	49,054	(3,223)
Operating expenses:			
Selling and marketing	20,906	22,083	(1,177)
General and administrative	17,379	19,954	(2,575)
Research and development	1,326	2,769	(1,443)
Amortization of intangible assets	3,683	3,683	—
Restructuring costs	2,101	2,156	(55)
Impairment expense	8,263	—	8,263
Total operating expenses	53,658	50,645	3,013
Loss from operations	**(7,827)**	**(1,591)**	**(6,236)**
Other (expense) income, net	(512)	870	(1,382)
Interest expense	(3,703)	(5,059)	1,356
Derivative warrant liabilities loss	(1,703)	(4,004)	2,301
Loss on extinguishment of debt	—	(594)	594
Loss from continuing operations before income tax expense	**(13,745)**	**(10,378)**	**(3,367)**
Income tax expense	(437)	(2,142)	1,705
Net loss from continuing operations	**(14,182)**	**(12,520)**	**(1,662)**
Net income (loss) from discontinued operations, net of tax	620	(3,324)	3,944
Net loss	$ **(13,562)**	$ **(15,844)**	$ **2,282**

Net Revenue by Product Portfolio

Net revenue disaggregated by product portfolios for the year ended June 30, 2025, compared to the year ended June 30, 2024, is as follows:

	Year Ended June 30,		
	2025	2024	Change
	(in thousands)		
ADHD Portfolio	$ 57,576	$ 57,784	$ (208)
Pediatric Portfolio	8,769	7,280	1,489
Other	37	119	(82)
Total net revenue	$ 66,382	$ 65,183	$ 1,199

During the year ended June 30, 2025, total net revenue increased by $1.2 million, or 2% compared to the year ended June 30, 2024, primarily due to a $1.5M increase in the Pediatric Portfolio, which reflects the positive effects from our recently implemented return-to-growth plan for that portfolio as well as a $3.3 million increase in ADHD Portfolio net revenue in the first quarter of fiscal 2025 related to a decrease in estimated variable consideration as a result of successful negotiations with a vendor offset primarily by increases in savings offers costs impacting net revenue.

Gross Profit

Gross profit and gross profit percentage for the year ended June 30, 2025, compared to the year ended June 30, 2024, were as follows:

	Year Ended June 30,		
	2025	2024	Change
	(in thousands, except gross profit percentage)		
Gross profit	$ 45,831	$ 49,054	$ (3,223)
Gross profit percentage	69%	75%	(6)%

During the year ended June 30, 2025, gross profit decreased by $3.2 million, or 7% compared to the year ended June 30, 2024. Gross profit percentage decreased to 69% for the year ended June 30, 2025, compared to 75% for the year ended June 30, 2024. The decrease in gross profit percentage is primarily related to increased cost of goods sold for our ADHD Portfolio inventory as we sell through self-manufactured inventory burdened with certain fixed costs associated with its manufacture, which were capitalized into inventory costs in prior periods.

Selling and Marketing

During the year ended June 30, 2025, selling and marketing expense decreased by $1.2 million, or 5%, compared to the year ended June 30, 2024, primarily driven by reduced commission expense and variable commercial marketing program fees, partially offset by increases in labor and service costs. We expect selling and marketing expense to increase during fiscal 2026 related to increased commission expense and commercial marketing program fees from anticipated increases in prescription product sales related to our expected commercial launch of EXXUA.

General and Administrative

During the year ended June 30, 2025, general and administrative expense decreased by $2.6 million or 13%, compared to the year ended June 30, 2024. The decrease is primarily a result of continued cost reduction efforts and improved operational efficiencies. We expect general and administrative expense to increase during fiscal 2026 primarily from increased costs associated with the initial launch and ongoing support of EXXUA.

Research and Development

During the year ended June 30, 2025, research and development expense decreased by $1.4 million, or 52%, compared to the year ended June 30, 2024, primarily driven by the previously announced suspension of our development programs to focus on our commercial operations resulting in a decrease in research and development spending. 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 while having minimum research and development expenses related to any required regulatory filings and maintenance of our intellectual property.

Amortization of Intangible Assets

During the year ended June 30, 2025, amortization of intangible assets, excluding amounts included in cost of goods sold, was relatively consistent compared to the year ended June 30, 2024, due to the regularly recurring straight-line amortization expense that was consistent for both fiscal years. However, we expect amortization of intangible assets to increase in the future as our intangible asset related to EXXUA will increase over time when contingent consideration is capitalized as certain contingencies are met, partially offset by a decrease in amortization expense related to impairments of certain intangible assets recorded in fiscal 2025. Refer to *Note 7 - Intangible Assets* in Part II, Item 8 of this Annual Report for further information.

Restructuring Costs

During the years ended June 30, 2025, and 2024, we recognized $2.1 million and $2.2 million, respectively, of restructuring costs, primarily related to the closure of our Grand Prairie, Texas manufacturing site. We do not anticipate any restructuring costs during fiscal 2026 as our restructuring activities were completed during fiscal 2025. See *Note 17 - Restructuring Costs* in Part II, Item 8 of this Annual Report for further information.

Impairment Expense

During the year ended June 30, 2025, we recognized total impairment expense of $8.3 million, which was primarily the result of our increased focus on our commercial efforts for EXXUA and our ADHD Portfolio. See *Note 7 - Intangible Assets* in Part II, Item 8 of this Annual Report for further information.

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 the net income (loss) from discontinued operations, net of tax financial statement line item discussed below.

Other (Expense) Income, Net

During the year ended June 30, 2025, other (expense) income, net decreased by $1.4 million, compared to the year ended June 30, 2024, primarily due to $1.3 million of underwriting commissions and offering expenses from the issuance of the June 2025 Prefunded Warrants, partially offset by other income, net relatively consistent with the prior year. We expect other (expense) income, net to continue to be relatively consistent during fiscal 2026.

Interest Expense

During the year ended June 30, 2025, interest expense decreased by $1.4 million, or 27%, compared to the year ended June 30, 2024, primarily 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 during the fourth quarter of fiscal 2024, and the gradual paydown of the outstanding principal balance of the Eclipse Term Loan throughout the year as well as reductions in our fixed payment arrangement balance during the period. We expect interest expense to decrease during fiscal 2026 primarily due to the paydown of our fixed payment arrangements.

Derivative Warrant Liabilities Loss

The fair value of derivative warrant liabilities, which 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, 2025, we recognized an unrealized loss of $1.7 million from the fair value adjustment primarily driven by an increase in the fair value of the June 2025 Prefunded Warrants from the issuance date until year end, partially offset by a decrease in the fair value of our other warrants and prefunded warrants due to an overall decrease in our stock price during fiscal 2025. For the year ended June 30, 2024, we recognized an unrealized loss of $4.0 million from the fair value adjustment primarily driven by a decrease in our stock price during fiscal 2024.

Loss on Extinguishment of Debt

We recorded no loss on extinguishment of debt during the year ended June 30, 2025. During the year ended June 30, 2024, we recorded a $0.6 million loss on extinguishment of debt due to the extinguishment of our $15.0 million term loan.

Income Tax Expense

For the years ended June 30, 2025, and 2024, there was $0.4 million of income tax expense and $2.1 million of income tax expense from continuing operations, which was an effective tax rate of negative 3.2% and negative 20.6%, respectively. 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.

Net Income (Loss) from Discontinued Operations, Net of Tax

Net income (loss) from discontinued operations, net of tax is related to the wind down and divestiture of our Consumer Health business that was completed in the first quarter of fiscal 2025. See *Note 20 - Discontinued Operations* in Part II, Item 8 of this Annual Report for further information.

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,		
	2025	2024	Change
	(in thousands)		
Net cash used in operating activities	$ (1,937)	$ (1,388)	$ (549)
Net cash used in investing activities	(2,560)	(329)	(2,231)
Net cash provided by (used in) financing activities	15,443	(1,262)	16,705
Net change in cash and cash equivalents	$ 10,946	$ (2,979)	$ 13,925

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, adjustments from discontinued operations and other charges.

During the year ended June 30, 2025, net cash used in operating activities totaled $1.9 million, which was primarily the result of an increase in accounts receivable and prepaid expenses and other current assets, partially offset by positive cash earnings (net loss offset by non-cash items primarily from impairment expense, depreciation, amortization and accretion, stock-based compensation expense, derivative warrant liabilities adjustment, inventory write-down, adjustments from discontinued operations and other certain non-cash adjustments) and increases in inventories, accounts payable, accrued liabilities, other operating assets and liabilities, net, and changes in operating assets and liabilities from discontinued operations.

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 and an increase in inventories, 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, adjustments from discontinued operations and other certain non-cash adjustments). Additionally, these were partially offset by funds from the Employee Retention Credit program recorded in other operating liabilities and a decrease in accounts receivable, net and a net decrease in various other operating assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities is generally related to our merger and acquisitions, cash payments for acquired intangible assets such as EXXUA, as well as purchases of assets to support our operations and disposal of assets related to exit and disposal costs.

Net cash used in investing activities of $2.6 million during the year ended June 30, 2025, was primarily from a $3.0 million cash payment for acquired intangible assets related to the EXXUA Commercialization Agreement and the purchase of various property and equipment, partially offset to cash received from the sale of fixed assets.

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

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities of $15.4 million during the year ended June 30, 2025, was primarily from $14.8 million of net proceeds received from our public offering of common stock and prefunded warrants in June 2025, $6.7 million of net proceeds from our Eclipse Revolving Loan and $1.9 million of proceeds received from borrowings in June 2025 on our Eclipse Term Loan related to the Eclipse Amendment No. 6, partially offset by $6.0 million of payments for fixed payment arrangements and $1.9 million of payments made against the principal balance of our Eclipse Term Loan throughout fiscal 2025.

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 prefunded warrants and $0.9 million of proceeds from our Eclipse Revolving Loan.

Capital Resources

Sources of Liquidity

We have obligations related to our loan agreements, 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 from cash generated from operations.

Shelf Registrations

On September 26, 2024, we filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 15, 2024. This shelf registration statement covers 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 "2024 Shelf"). Through the filing date of this Annual Report, $100.0 million remains available under the 2024 Shelf. This availability is subject to the SEC's "baby shelf" limitation as set forth in SEC Instruction I.B.6 limitation to the Form S-3.

Equity Financings

We have engaged in several different types of equity financings throughout our history. Most recently in June 2025, we raised gross proceeds of $16.6 million from the issuance of (i) 2,806,688 shares of our common stock, at a public offering price of $1.50 and 8,233,332 prefunded warrants at a public offering price of $1.4999 to purchase 8,233,332 shares of our common stock at an exercise price of $0.0001 per share. We received $14.8 million in proceeds net of underwriting commissions and offering expenses and intend to use the net proceeds from the offering for working capital, general corporate purposes and to enable us to exclusively commercialize EXXUA.

In June 2024, the Tranche B Warrants to purchase 2,173,912 shares of our common stock at an exercise price of $1.59 were exercised, generating proceeds of $3.5 million. The Tranche B Warrants were converted into 367,478 shares of our common stock and 1,806,434 prefunded warrants to purchase shares of our common stock with an exercise price of $0.0001 per share. We used a portion of these proceeds as part of a $15.0 million term loan repayment made in June of 2024. For further information on our equity financings and related warrants outstanding, please refer to *Note 14 - Stockholders' Equity* and *Note 16 - Warrants* in Part II, Item 8 of this Annual Report.

Eclipse Agreement

Under our Eclipse Agreement, we have two loan agreements, the Eclipse Term Loan and the Eclipse Revolving Loan. The Eclipse Term Loan consists of an outstanding principal amount of $13.0 million on the closing date of the Eclipse Amendment No. 6, at an interest rate of the 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 the June 12, 2029, maturity date, as amended. In June 2024, we used the initial proceeds from the Eclipse Term Loan and a portion of the proceeds from the warrant exercises described above to repay in full a $15.0 million term loan. The Eclipse Revolving Loan has a potential maximum borrowing base of $14.5 million at an interest rate of the SOFR plus 4.5%, which was temporarily increased pursuant to the $1.5 million Eclipse Incremental Advance, with repayment and permanent reduction of the Eclipse Incremental Advance commencing on August 1, 2025, and continuing on the first day of each calendar month thereafter, in an amount equal to $125,000 per month, until the Eclipse Incremental Advance has been reduced to $0. 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, 2029.

Contractual Obligations, Commitments and Contingencies

As a result of our acquisitions, exclusive commercialization agreement, 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 Part II, Item 8 of this Annual Report 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 we accrued a settlement liability, which as of June 30, 2025, had a remaining balance of $3.1 million accrued in other current liabilities on the consolidated balance sheet payable to Tris, which was paid in full during the first quarter of fiscal 2026.

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, 2025, we have an accrued fixed payment arrangement balance related to these payment obligations of $0.2 million recorded in other current liabilities on the consolidated balance sheet.

In connection with our suspension of active development of AR101, we engaged in negotiations with EnzCo and Rumpus for the repurchase of AR101. On August 5, 2025, we reached terms with Rumpus and EnzCo whereby for mutual consideration and releases, we transferred all of ours and Rumpus' rights, title and interest in AR101 to EnzCo, which extinguished and terminated all of our obligations and Rumpus' obligations under the Rumpus Asset Purchase Agreement. There is no other relationship between us, EnzCo or Rumpus other than as contracting parties to terminate the Rumpus Asset Purchase Agreement, and there are no penalties or remaining obligations for us for terminating the Rumpus Asset Purchase Agreement.

Critical Accounting Estimates

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

While our significant accounting policies are described in more detail in *Note 2 - Summary of Significant Accounting Policies* in the accompanying notes to the consolidated financial statements later 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 net revenue from continuing operations from product sales through our ADHD Portfolio and our Pediatric Portfolio and we expect that we will generate net revenue from continuing operations from EXXUA after its launch, which is currently anticipated to occur in the fourth calendar quarter of 2025. 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 consist of sales of prescription pharmaceutical products, principally to a limited number of wholesale distributors and pharmacies in the United States. Prescription 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, payor 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.* We offer savings programs for our 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 our products by wholesalers.

- *Rebates.* Our products are subject to commercial managed care and government (e.g., 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.* Our products are subject to certain programs with wholesalers whereby pricing on products is discounted below wholesaler list price to participating entities. These entities purchase products through wholesalers at the discounted price, and the wholesalers charge the difference between their acquisition cost and the discounted price back to us 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. We analyze 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.

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. During the year ended June 30, 2025, we incurred an impairment charge of $8.3 million, which was primarily the result of our shifted focus on our commercial efforts for EXXUA and our ADHD Portfolio.

During the years ended June 30, 2025, and 2024, we recorded restructuring costs totaling $2.1 million and $2.2 million, respectively, related to severance costs and the abandonment of our leased manufacturing facility, equipment and other assets as part of our closure of our Grand Prairie, Texas manufacturing facility. These costs have been recorded in the restructuring costs financial statement line item 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

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, 2025, and 2024, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended June 30, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2025, and 2024, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 23, 2025

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

	June 30,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,952	$ 20,006
Accounts receivable, net	31,155	23,526
Inventories	11,434	12,141
Prepaid expenses and other current assets	5,638	5,097
Current assets of discontinued operations	—	1,121
Total current assets	79,179	61,891
Non-current assets:		
Property and equipment, net	532	693
Operating lease right-of-use assets	1,061	829
Intangible assets, net	42,201	52,453
Other non-current assets	1,204	2,185
Non-current assets of discontinued operations	—	44
Total non-current assets	44,998	56,204
Total assets	$ **124,177**	$ **118,095**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 10,601	$ 10,314
Accrued liabilities	38,164	38,143
Revolving credit facility	9,063	2,395
Current portion of debt	1,857	1,857
Other current liabilities	3,379	8,962
Current liabilities of discontinued operations	—	557
Total current liabilities	63,064	62,228
Non-current liabilities:		
Debt, net of current portion	10,895	10,877
Derivative warrant liabilities	26,334	12,745
Other non-current liabilities	4,918	4,529
Total non-current liabilities	42,147	28,151
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; 8,976,913 and 5,972,638 shares issued and outstanding, respectively	1	1
Additional paid-in capital	352,500	347,688
Accumulated deficit	(333,535)	(319,973)
Total stockholders' equity	18,966	27,716
Total liabilities and stockholders' equity	$ **124,177**	$ **118,095**

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,	
	2025	**2024**
Net revenue	$ 66,382	$ 65,183
Cost of goods sold	20,551	16,129
Gross profit	45,831	49,054
Operating expenses:		
Selling and marketing	20,906	22,083
General and administrative	17,379	19,954
Research and development	1,326	2,769
Amortization of intangible assets	3,683	3,683
Restructuring costs	2,101	2,156
Impairment expense	8,263	—
Total operating expenses	53,658	50,645
Loss from operations	**(7,827)**	**(1,591)**
Other (expense) income, net	(512)	870
Interest expense	(3,703)	(5,059)
Derivative warrant liabilities loss	(1,703)	(4,004)
Loss on extinguishment of debt	—	(594)
Loss from continuing operations before income tax expense	**(13,745)**	**(10,378)**
Income tax expense	(437)	(2,142)
Net loss from continuing operations	**(14,182)**	**(12,520)**
Net income (loss) from discontinued operations, net of tax	620	(3,324)
Net loss	$ **(13,562)**	$ **(15,844)**
Basic and diluted weighted-average common shares outstanding	6,279,744	5,537,957
Net (loss) income per share:		
Basic and diluted - continuing operations	$ (2.26)	$ (2.26)
Basic and diluted - discontinued operations, net of tax	$ 0.10	$ (0.60)
Basic and diluted - net loss	$ (2.16)	$ (2.86)

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	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Equity
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
Stock-based compensation expense	21,607	—	576	—	576
Issuance of common stock from exercise of warrants	176,000	—	463	—	463
Issuance of common stock, net of $437 issuance cost	2,806,668	—	3,773	—	3,773
Net loss	—	—	—	(13,562)	(13,562)
Balances, June 30, 2025	8,976,913	$ 1	$ 352,500	$ (333,535)	$ 18,966

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (13,562)	$ (15,844)
Adjustments to reconcile net loss to cash used in operating activities:		
Impairment expense	8,263	—
Depreciation, amortization and accretion	5,377	6,725
Stock-based compensation expense	576	2,373
Derivative warrant liabilities loss	1,703	4,004
Amortization of debt discount and issuance costs	108	597
Inventory write-down	325	1,189
Non-cash loss on extinguishment of debt	—	400
Other non-cash adjustments	752	471
Non-cash adjustments from discontinued operations	254	3,357
Changes in operating assets and liabilities:		
Accounts receivable, net	(7,629)	5,201
Inventories	382	(4,821)
Prepaid expenses and other current assets	(451)	329
Accounts payable	287	(2,076)
Accrued liabilities	886	(9,161)
Other operating assets and liabilities, net	528	3,801
Changes in operating assets and liabilities from discontinued operations	264	2,067
Net cash used in operating activities	**(1,937)**	**(1,388)**
Cash flows from investing activities:		
Cash received from sales of fixed assets	668	—
Cash payments for fixed asset purchases	(228)	(329)
Cash payments for acquired intangible assets	(3,000)	—
Net cash used in investing activities	**(2,560)**	**(329)**
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants	14,840	3,467
Payments made to fixed payment arrangement	(6,016)	(2,566)
Net proceeds from revolving credit facility	6,668	832
Payments made to borrowings	(1,857)	(15,722)
Proceeds from borrowings	1,857	13,000
Payments for debt issuance costs	(49)	(273)
Net cash provided by (used in) financing activities	**15,443**	**(1,262)**
Net change in cash and cash equivalents	10,946	(2,979)
Cash and cash equivalents at beginning of period	20,006	22,985
Cash and cash equivalents at end of period	$ **30,952**	$ **20,006**
Supplemental disclosure of cash flows information:		
Cash payments for interest	$ 2,822	$ 4,039
Cash payments for income taxes	$ 1,419	$ 1,608
Non-cash investing and financing activities:		
Other non-cash investing and financing activities	$ 483	$ 787

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

Note 1 - Nature of Business and Financial Condition

Aytu BioPharma, Inc. ("Aytu," the "Company," "we," "us," or "our"), is a pharmaceutical company focused on advancing innovative medicines for complex central nervous system diseases to improve the quality of life for patients. 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. In March 2021, 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. In June 2025, the Company entered into an Exclusive Commercialization Agreement (the "Commercialization Agreement") with Fabre-Kramer Holdings, Inc. ("Fabre-Kramer") to commercialize EXXUA (gepirone) extended-release tablets ("EXXUA") in the United States. Gepirone is a new chemical entity, and the Company believes EXXUA to be a novel first-in-class selective serotonin 5HT1a receptor agonist approved by the United States Food and Drug Administration ("FDA") for the treatment of major depressive disorder ("MDD") in adults. It is the Company's expectation that EXXUA has the potential to serve as a major growth catalyst for the Company and anticipates launching EXXUA in the fourth calendar quarter of 2025 as a centerpiece of its commercial efforts.

In addition, the Company will continue to focus on commercializing innovative prescription products that address conditions frequently developed or diagnosed in children, including attention deficit hyperactivity disorder ("ADHD"). The Company is focusing its efforts on accelerating the growth of its commercial business and achieving positive operating cash flows. To achieve these goals, the Company indefinitely suspended active development of its clinical development programs and has wound down and divested unprofitable operations.

In the first quarter of fiscal 2025 the Company completed the previously announced wind down of its Consumer Health business and on July 31, 2024, the Company entered into a definitive agreement to divest its Consumer Health 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 encompassed the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities and provided 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. The accounting requirements for reporting the Consumer Health business as a discontinued operation were met when the wind down and divestiture was completed on July 31, 2024. Accordingly, the Company's consolidated financial statements for all periods presented reflect the Consumer Health business as a discontinued operation and the Company determined that its continuing operations now operate in a single operating and reportable segment (see *Note 20 - Discontinued Operations* and the *Segment Information* section within *Note 2 - Summary of Significant Accounting Policies* for further detail).

The Company's business from continuing operations is focused on the upcoming launch of EXXUA and on its current prescription pharmaceutical products sold primarily through third party wholesalers and pharmacies and which primarily consists of two product portfolios. The first primarily consists of two products for the treatment of ADHD: Adzenys XR-ODT (amphetamine) extended-release orally disintegrating tablets ("Adzenys") and Cotempla XR-ODT (methylphenidate) extended-release orally disintegrating tablets ("Cotempla" and Adzenys together with Cotempla the "ADHD Portfolio"). The second primarily consists 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"). During the fourth quarter of fiscal 2024, the Company successfully completed the transition of all manufacturing of its Adzenys and Cotempla products to a United States-based third-party contract manufacturer to improve the profitability of these products.

In July 2023, the Company entered into an exclusive collaboration, distribution and supply agreement with Medomie Pharma Ltd ("Medomie"), a privately owned pharmaceutical company, for Medomie to commercialize Adzenys and Cotempla in Israel and the Palestinian Authority. In September 2024, the Company entered into an exclusive collaboration, distribution and supply agreement with Lupin Pharma Canada Ltd ("Lupin"), a subsidiary of global pharmaceutical company Lupin Limited, for Lupin to commercialize Adzenys and Cotempla in Canada. The Company will supply Adzenys and Cotempla to Medomie and Lupin based on forecasts and provide various product commercialization, regulatory and quality assurance resources. Medomie and Lupin are responsible for seeking local regulatory approvals and marketing authorizations for both Adzenys and Cotempla, which is expected to occur over the next 24 months. The agreements with Medomie and Lupin represent the Company's first and second international commercial agreements for Adzenys and Cotempla, respectively.

Note 2 - Summary of Significant Accounting Policies

Principles of Consolidation

The Company's consolidated financial statements and notes thereto include the accounts of its wholly owned subsidiaries Aytu Therapeutics, LLC and Neos Therapeutics, Inc. ("Neos") and their respective wholly owned subsidiaries, as well as Innovus Pharmaceuticals, Inc. ("Innovus") and its wholly owned subsidiaries prior to the divestiture of Innovus on July 31, 2024. 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").

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 ("ROU") assets and lease liabilities; valuation of financial instruments, warrants and 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. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. The Company periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

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 years ended June 30, 2025, and 2024, or the Company's financial position as of June 30, 2025, or June 30, 2024.

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, net represents 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. The Company has elected the practical expedient to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. 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, 2025, and 2024. The allowance for discounts was $0.5 million and $0.6 million as of June 30, 2025, and 2024, respectively. The allowance for chargebacks was $0.7 million and $1.2 million as of June 30, 2025, and 2024.

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

	Accounts Receivable, Gross
	(in thousands)
Balance, June 30, 2023	$ 31,718
Decrease in accounts receivable, gross	(6,370)
Balance, June 30, 2024	25,348
Increase in accounts receivable, gross	6,995
Balance, June 30, 2025	$ 32,343

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, 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
Reduction of net revenue	3,940	2,782	6,722
Payments	(4,112)	(3,244)	(7,356)
Balances, June 30, 2025	$ 468	$ 720	$ 1,188

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 goods sold 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 ROU assets are recorded based on the present value of lease payments over the expected lease term, including options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. In determining the present value of the lease payments, the Company uses the implicit interest rate when readily determinable and uses the Company's incremental borrowing rate when the implicit rate is not readily determinable based upon the information available at the lease commencement date.

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

Operating leases are included in other liabilities in the Company's consolidated balance sheets. Financing leases are included in property and equipment, net, current portion of 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 net revenue from continuing operations from sales of prescription pharmaceutical products from the Company's ADHD Portfolio and Pediatric Portfolio and the Company expects it will generate net revenue from continuing operations from EXXUA after the launch of EXXUA, which is currently anticipated to occur in the fourth calendar quarter of 2025. Sales are principally to a limited number of wholesale distributors and pharmacies in the United States. 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. Net revenue is recognized at the point in time that control of the product transfers to the customer, which typically aligns with shipping terms (i.e., upon delivery), generally "free-on-board" destination when shipped domestically within the United States, consistent with contractual terms. The Company expenses the incremental costs to obtain a contract as incurred, since they are satisfied within one year.

ADHD Portfolio and Pediatric Portfolio 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, payor 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 Company's products are subject to commercial managed care and government (e.g., 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 Company's 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 does not believe variances between actual and estimated amounts have been material.

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 Gross Accounts Receivable	
	Year Ended June 30,		June 30,	
	2025	2024	2025	2024
Customer A	26%	33%	35%	40%
Customer B	27%	9%	25%	9%
Customer C	16%	20%	15%	29%
Customer D	16%	17%	14%	11%

Cost of Goods Sold

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

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 $0.5 million and $0.7 million for the years ended June 30, 2025, and 2024.

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. The Company capitalizes to the carrying value of intangible assets any contingent payments made that are considered a part of the total consideration paid for an asset acquisition and which are not within the scope of derivative guidance once the contingencies related to these payments are resolved and the Company adjusts the carrying value of the intangible asset on a cumulative catch-up basis as if the additional capitalized amount had been capitalized on the same date that the intangible asset was put to use. Finite-lived intangible assets are recorded at cost and amortized on a straight-line basis over the estimated lives of the assets.

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.

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

Operating segments are identified as components that 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") 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. After the previously announced successful wind down and divestiture of the Consumer Health business in the first quarter of fiscal 2025, the Company determined that its continuing operations operate in a single operating and reportable segment. The Company's CODM is its Chief Executive Officer, who manages operations and regularly reviews the financial information of the Company's continuing operations as a single operating segment for the purposes of allocating resources and evaluating its financial performance. The results of the Consumer Health business have been reported as discontinued operations (see *Note 20 - Discontinued Operations* for further detail).

The CODM reviews net income or loss as a measure of segment profit or loss in assessing performance and allocating resources. Segment revenues, expenses and profit or loss is reported on the consolidated statements of operations, with particular emphasis on net revenue by product portfolio (see *Note 3 - Revenue* for net revenue disaggregated by product portfolio). Additionally, the measure of segment assets is reported on the Company's balance sheet as total assets, with particular emphasis on the Company's available liquidity and working capital, including its cash and cash equivalents, accounts receivables, net, inventories and current liabilities. As of June 30, 2025, and June 30, 2024, all long-lived assets were domiciled within the United States.

Paragraph IV Litigation Costs

Legal costs incurred by the Company in the enforcement of the Company's intellectual property rights are charged to expense in the general and administrative financial statement line item in the consolidated statement of operations.

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 accounted 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 (expense) income, net 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.

Earnings Per Share

Basic net income or loss per share is calculated by dividing net income or loss available to common stockholders by the basic weighted-average number of common shares outstanding for the respective period. Diluted net income or loss per share is calculated by dividing adjusted net income or loss by the diluted weighted-average number of common shares outstanding, which includes the effect of potentially dilutive securities. Potentially dilutive securities for this calculation consist of warrants to purchase common stock that are either liability classified or equity classified (see *Note 16 - Warrants*); stock options (see *Note 15 - Equity Incentive Plans*); unvested restricted stock (see *Note 15 - Equity Incentive Plans*); and unvested restricted stock units (see *Note 15 - Equity Incentive Plans*). For the years ended June 30, 2025, and 2024, if the Company's adjusted net loss from continuing operations divided by the diluted weighted-average number of common shares outstanding decreased the net loss from continuing operations per share, then the Company did not include common equivalent shares in the computation of diluted net loss from continuing operations per share; diluted net income (loss) from discontinued operations, net of tax; or diluted net loss per share because the effect would have been anti-dilutive.

The following table sets forth securities that could be considered anti-dilutive, and therefore are excluded from the calculation of diluted weighted-average common shares outstanding and related per share calculations:

		June 30,	
		2025	**2024**
Warrants to purchase common stock - liability classified	(Note 16)	3,821,115	3,821,115
Warrants to purchase common stock - equity classified	(Note 16)	15,571	18,114
Prefunded warrants to purchase common stock - liability classified	(Note 16)	10,293,983	2,236,651
Outstanding stock options	(Note 15)	211,618	146,539
Unvested restricted stock	(Note 15)	32,916	25,360
Unvested restricted stock units	(Note 15)	—	1,775
Total		14,375,203	6,249,554

Recently Adopted Accounting Pronouncements

Debt - Debt with Conversion and Other Options

In August 2020, the FASB issued Accounting Standards Update ("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 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. ASU 2023-07 also requires all annual disclosures currently required by ASC Topic 280, *Segment Reporting* to be included in interim periods. The Company adopted ASU 2023-07 on June 30, 2025, on a retrospective basis and updated its disclosures to conform to the new segment disclosure requirements. Refer to the *Segment Information* section within *Note 2 - Summary of Significant Accounting Policies* for additional discussion.

Recent Accounting Pronouncements Not Yet Adopted

Disaggregation of Income Statement Expenses

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The amendments in ASU 2024-03 require public business entities to disclose in the notes to the financial statements, among other things, specific information about certain costs and expenses including purchases of inventory; employee compensation; and depreciation, amortization and depletion expenses for each caption on the income statement where such expenses are included. ASU 2024-03 is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted, and the amendments may be applied prospectively to reporting periods after the effective date or retrospectively to all periods presented in the financial statements. The Company is currently evaluating the provisions of this guidance and assessing the potential impact on the Company's consolidated financial statements and disclosures.

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, 2025, and through the filing of this report.

Note 3 - Revenue

The Company disaggregates its net revenue from continuing operations by product portfolio, which for the years ended June 30, 2025, and 2024, includes the ADHD Portfolio, comprised primarily of Adzenys and Cotempla; and the Pediatric Portfolio, comprised primarily of Karbinal, Poly-Vi-Flor and Tri-Vi-Flor. The Company's disaggregation of revenue is consistent with its operating segment.

Net Revenue by Product Portfolio

Net revenue disaggregated by product portfolios for the years ended June 30, 2025, and 2024, were as follows:

	Year Ended June 30,	
	2025	2024
	(in thousands)	
ADHD Portfolio	$ 57,576	$ 57,784
Pediatric Portfolio	8,769	7,280
Other	37	119
Total net revenue	$ 66,382	$ 65,183

Other includes net revenue from various discontinued or deprioritized products. The Consumer Health business was divested in the first quarter of fiscal 2025 and is reported within discontinued operations (see *Note 20 - Discontinued Operations*).

Net Revenue by Geographic Location

The Company's net revenue is predominately within the United States, with insignificant international sales.

Note 4 - Inventories

Inventories consist of the following:

	June 30,	
	2025	2024
	(in thousands)	
Raw materials	$ 1,115	$ 266
Work in process	1,381	5,725
Finished goods	8,938	6,150
Inventories	$ 11,434	$ 12,141

The Company incurred inventory write-downs from continuing operations of $0.3 million and $1.2 million during the years ended June 30, 2025, and 2024, respectively, 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,	
	2025	2024
	(in thousands)	
Manufacturing and lab equipment	$ 808	$ 1,838
Office equipment, furniture and other	274	945
Leasehold improvements	164	35
Property and equipment, gross	1,246	2,818
Less: accumulated depreciation and amortization	(714)	(2,125)
Property and equipment, net	$ 532	$ 693

Depreciation expense from continuing operations was $0.2 million and $0.9 million during the years ended June 30, 2025, and 2024, respectively. During the year ended June 30, 2025, the Company recognized a gain of $0.5 million on the disposal of equipment and during the year ended June 30, 2024, the Company did not record a material gain or loss on disposal of equipment.

Note 6 - Leases

The Company's operating leases are for its offices and these leases have original lease periods expiring between 2029 and 2030. Most leases include option provisions under which the parties may extend the lease term. The Company's lease agreements generally do not contain any material residual value guarantees or material restrictive covenants. The Company had no finance leases recorded as of June 30, 2025, and June 30, 2024.

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 was renting that same space under a sublease arrangement. The Company 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. 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 recorded an operating lease ROU asset of $0.5 million and a lease liability of $0.5 million at lease commencement. The ROU asset and lease liability will be recorded at present value using an incremental borrowing rate of 12.3%. See *Note 18 - Commitments and Contingencies* for further detail.

In May 2023, the Company entered into an operating lease agreement to relocate its principal office to Denver, Colorado. The initial lease termination date is March 31, 2029, and under the lease agreement the Company has one five-year renewal option to extend the lease through March 2034. Undiscounted minimum monthly rent payments average approximately $15,500 over the initial term of the lease. Variable lease payments will be expensed as incurred.

During the fourth quarter of fiscal 2024, as part of the previously announced wind down of the Consumer Health business and the closure of the Grand Prairie, Texas manufacturing site, the Company ceased using its leased Oceanside, California warehouse and its Grand Prairie, Texas manufacturing facility. As a result, the Company wrote off the remaining related operating lease ROU assets in the fourth quarter of fiscal 2024. The lease for the Oceanside, California warehouse was set to expire on December 31, 2026, however, in March 2025, the Company terminated this lease with the landlord and recorded a net gain on lease termination of $0.1 million in general and administrative expense in the consolidated statement of operations. The lease for the Grand Prairie, Texas manufacturing site expired on December 31, 2024.

The components of lease costs for continuing operations are as follows:

	Year Ended June 30,		
	2025	2024	Statement of Operations Classification
	(in thousands)		
Lease cost:			
Operating lease cost	$ 469	$ 1,986	Operating expenses
Short-term lease cost	182	94	Operating expenses
Finance lease cost:			
Amortization of leased assets	—	53	Cost of goods sold
Interest on lease liabilities	—	3	Interest expense
Total lease cost	$ 651	$ 2,136	

Supplemental balance sheet information related to leases is as follows:

	June 30,		
	2025	2024	Balance Sheet Classification
	(in thousands)		
Assets:			
Non-current: operating leases	$ 1,061	$ 829	Operating lease right-of-use assets
Liabilities:			
Current: operating leases	$ 137	$ 712	Other current liabilities
Non-current: operating leases	985	577	Other non-current liabilities
Total lease liabilities	$ 1,122	$ 1,289	

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

	June 30,	
	2025	2024
Weighted-average remaining lease term (years):		
Operating lease right-of-use assets	4.3	2.7
Weighted-average discount rate:		
Operating lease right-of-use assets	11.3%	10.0%

Supplemental cash flows information related to leases is as follows:

	Year Ended June 30,	
	2025	2024
	(in thousands)	
Cash flows classification of lease payments:		
Operating cash flows from operating leases	$ 754	$ 1,723
Operating cash flows from finance leases	$ —	$ 3
Financing cash flows from finance leases	$ —	$ 85

As of June 30, 2025, the Company's estimated future minimum lease payments were as follows:

	Operating
	(in thousands)
2026	$ 309
2027	331
2028	386
2029	358
2030	230
Thereafter	20
Total lease payments	1,634
Less: imputed interest	(386)
Less: tenant improvement allowance	(126)
Lease liabilities	$ 1,122

Note 7 - Intangible Assets

A summary of the Company's intangible assets, all of which are definite-lived intangible assets, as of June 30, 2025, and June 30, 2024, is as follows:

	June 30, 2025			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life [2]
		(in thousands)		(in years)
Product technology rights [1]	$ 22,200	$ (5,592)	$ 16,608	12.7
Technology rights	30,200	(7,607)	22,593	12.7
Commercialization rights	3,000	—	3,000	N/A
Total intangible assets	$ 55,400	$ (13,199)	$ 42,201	12.7

(1) In June 2025, the Company recorded an impairment to its product technology rights intangible asset of $8.3 million. Accordingly, $19.1 million of gross carrying amount and $10.8 million of related accumulated amortization have been removed from this table as of June 30, 2025.

(2) The commercialization rights intangible asset will be considered placed in service upon the launch of EXXUA, which the Company currently anticipates launching in the fourth calendar quarter of 2025, and the initial estimated useful life of the commercialization rights is expected to be through September 2030.

	June 30, 2024			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted-Average Remaining Life
		(in thousands)		(in years)
Product technology rights	$ 41,268	$ (13,184)	$ 28,084	10.7
Technology rights	30,200	(5,831)	24,369	13.8
Total intangible assets	$ 71,468	$ (19,015)	$ 52,453	12.0

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. Renewal periods generally 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 from continuing operations included in the consolidated statements of operations for the years ended June 30, 2025, and 2024, are set forth in the below table:

	Year Ended June 30,	
	2025	2024
	(in thousands)	
Statement of operations classification:		
Cost of goods sold	$ 1,306	$ 1,306
Operating expenses	3,683	3,683
Total amortization of intangible assets expense	$ 4,989	$ 4,989

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)
2026	$ 3,489
2027	3,692
2028	3,692
2029	3,692
2030	3,692
Thereafter	23,944
Total estimated future amortization expense	$ 42,201

Product Technology Rights

The product technology rights are related to the rights to production, supply and distribution agreements of various products.

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. As a result of the Company's shifted focus of its commercial efforts on EXXUA and its ADHD Portfolio the Company recorded a full impairment of these intangible assets in June 2025, resulting in impairment expense of $2.7 million being recognized. Please refer to *Note 12 - Fair Value Measurements* for further discussion on the fair value measurement of intangible assets.

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. As a result of the Company's shifted focus of its commercial efforts on EXXUA and its ADHD Portfolio the Company recorded a full impairment of these intangible assets in June 2025, resulting in impairment expense of $5.6 million being recognized. Please refer to *Note 12 - Fair Value Measurements* for further discussion on the fair value measurement of intangible assets.

ADHD Portfolio

The Company has developed product technology rights related to the production and sale of Adzenys and Cotempla. The formulations for the ADHD products are protected by patented technology. The estimated remaining economic life of these proprietary product technology rights is 12.6 years.

Technology Rights

TRRP Proprietary Technology

The Company has 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. The estimated remaining economic life of these proprietary technology rights is 12.6 years.

Commercialization Rights

As part of the Commercialization Agreement for the exclusive commercialization rights of EXXUA in the United States, the Company capitalizes to the carrying value of intangible assets any contingent payments made that are considered a part of the Commercialization Agreement's total consideration and which are not within the scope of derivative guidance once the contingencies related to these payments are resolved. Once the commercialization rights are considered placed in service on the launch date of EXXUA, the Company will amortize the commercialization rights on a straight-line basis over the estimated life of the asset and the Company will adjust the carrying value of the commercialization rights on a cumulative catch-up basis as if the additional capitalized amount had been capitalized on the same date that the intangible asset was placed in service. As of June 30, 2025, the commercialization rights were not placed in service and as a result, no amortization expense was recorded for this intangible asset. The Company currently anticipates launching EXXUA in the fourth calendar quarter of 2025, and the initial estimated useful life of the commercialization rights is expected to be through September 2030.

Note 8 - Accrued Liabilities

Accrued liabilities consist of the following:

	June 30,	
	2025	2024
	(in thousands)	
Accrued savings offers	$ 16,092	$ 11,054
Return reserve	6,811	4,832
Accrued program liabilities	5,678	9,964
Accrued customer and product related fees	4,556	5,395
Accrued employee compensation	3,132	4,603
Other accrued liabilities	1,895	2,295
Total accrued liabilities	$ 38,164	$ 38,143

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. The return reserve represents the Company's accrual for estimated product returns. 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. 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, 2023	$ 5,683
Reduction of net revenue	5,838
Payments	(6,689)
Balance, June 30, 2024	4,832
Reduction of net revenue	8,563
Payments	(6,584)
Balance, June 30, 2025	$ 6,811

Note 9 - Other Liabilities

Other liabilities consist of the following:

	June 30,	
	2025	2024
	(in thousands)	
Fixed payment arrangements	$ 3,223	$ 8,337
Employee retention credit	3,759	3,759
Operating lease liabilities	1,122	1,289
Other	193	106
Total other liabilities	8,297	13,491
Less: current portion of other liabilities	(3,379)	(8,962)
Total other liabilities, non-current	$ 4,918	$ 4,529

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 the Company accrued a settlement liability, which as of June 30, 2025, had a remaining balance of $3.1 million accrued in other current liabilities on the consolidated balance sheet payable to Tris, which was paid in full during the first quarter of fiscal 2026.

The Tris Karbinal Agreement grants the Company 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. As of June 30, 2025, the Company has an accrued fixed payment arrangement balance related to these payment obligations of $0.2 million recorded in other 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, 2025, represents the proceeds the Company received from the ERC program during the first quarter of fiscal 2025. 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. Please refer to *Note 6 - Leases* for further detail.

Other

Other consists of taxes payable, deferred cost, 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 20, 2025, the Company and certain of its subsidiaries entered into an Amendment No. 6 to Loan and Security Agreement (the "Eclipse Amendment No. 6") 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 Amendment No. 5 dated June 12, 2024 (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 Agreement, the Company has 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 - Debt*.

The Eclipse Revolving Loan has a potential maximum borrowing base of $14.5 million at an interest rate of the secured overnight financing rate as administered by the SOFR Administrator (the "SOFR") plus 4.5%, which was temporarily increased by Eclipse Amendment No. 6. pursuant to a $1.5 million incremental advance at an interest rate of the SOFR plus 5.5% (the "Eclipse Incremental Advance"), with repayment and permanent reduction of the Eclipse Incremental Advance commencing on August 1, 2025, and continuing on the first day of each calendar month thereafter, in an amount equal to $125,000 per month, until the Eclipse Incremental Advance has been reduced to $0. 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 the Eclipse Revolving Loan remains subject to a borrowing base and reserve, and availability blockage requirements. The maturity date, as amended, is June 12, 2029, and the effective interest rate of the Eclipse Revolving Loan and the Eclipse Incremental Advance was 8.9% and 9.9%, respectively, as of June 30, 2025.

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, 2026, (ii) 1.0% of the Eclipse Revolving Loan commitment if such event occurs after June 12, 2026, but on or before June 12, 2027, and (iii) 0.5% of the Eclipse Revolving Loan commitment if such event occurs after June 12, 2027, but on or before June 12, 2029. The Company may also be required to pay an early termination fee related to the Eclipse Term Loan as further described in *Note 11 - 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 Eclipse 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, 2025, 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 to the Eclipse Revolving Loan as a result of Eclipse Amendment No. 6, bringing to the total unamortized debt issuance costs related to the Eclipse Revolving Loan as of June 30, 2025, 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 $0.2 million and $0.1 million for the years ended June 30, 2025, and 2024, respectively. As of June 30, 2025, and 2024, the outstanding amounts drawn on the Eclipse Revolving Loan were $9.1 million and $2.4 million, respectively. The unused Eclipse Revolving Loan amount as of June 30, 2025, was less than $0.1 million.

Note 11 - Debt

On June 20, 2025, the Company and certain of its subsidiaries entered into Eclipse Amendment No. 6, which provided for among other things, an increase in the Eclipse Term Loan principal amount of $13.0 million on the closing date of the Eclipse Amendment No. 6 and an extension of the maturity date of the Eclipse Term Loan to June 12, 2029, as well as certain amendments to the Eclipse Revolving Loan described further in *Note 10 - Revolving Credit Facility*.

The Eclipse Term Loan incurs interest at a rate of the SOFR plus 7.0%, with a four-year term maturing, as amended, on June 12, 2029, 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 the maturity date of June 12, 2029. The Company used proceeds from the Eclipse Term Loan and a portion of the proceeds from the exercise of warrants to repay a $15.0 million term loan in full, which resulted in the Company recording a loss on extinguishment of debt of $0.6 million in the fourth quarter of fiscal 2024. The Company incurred interest expense on the $15.0 million term loan including debt discount amortization of $3.4 million for the year ended 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, 2026, (ii) 2.0% of the Eclipse Term Loan if such event occurs after June 12, 2026, but on or before June 12, 2027, (iii) 1.0% of the Eclipse Term Loan if such event occurs after June 12, 2027, but on or before June 12, 2028, and (iv) 0.5% of the Eclipse Term Loan if such event occurs after June 12, 2028, but on or before June 12, 2029. 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 Eclipse 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, 2025, the Company was in compliance with the covenants under the Eclipse Agreement.

The Company recorded debt discount and allocated debt issuance costs of less than $0.1 million to the Eclipse Term Loan as a result of Eclipse Amendment No. 6, bringing to the total unamortized debt discount and debt issuance costs related to the Eclipse Term Loan as of June 30, 2025, to $0.2 million, 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 $1.5 million and $0.1 million for the years ended June 30, 2025, and 2024, respectively. The effective interest rate on the Eclipse Term Loan was 11.4% as of June 30, 2025.

Debt consists of the following:

	June 30,	
	2025	2024
	(in thousands)	
Term loan principal amount	$ 13,000	$ 13,000
Unamortized debt discount and issuance costs	(248)	(266)
Total debt	12,752	12,734
Less: current portion of debt	(1,857)	(1,857)
Total debt, net of current portion	$ 10,895	$ 10,877

Future principal payments of debt are as follows:

	June 30, (in thousands)
2026	$ 1,857
2027	1,857
2028	1,857
2029	7,429
Total future principal payments	13,000
Less: unamortized debt discount and issuance costs	(248)
Less: current portion of debt	(1,857)
Total debt, net of current portion	$ 10,895

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 the Company 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, 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, 2025, and 2024, by level within the fair value hierarchy:

	Fair Value at June 30, 2025	Fair Value Measurements at June 30, 2025		
		(Level 1)	(Level 2)	(Level 3)
		(in thousands)		
Liabilities:				
Derivative warrant liabilities	$ 26,334	$ —	$ —	$ 26,334
Total	$ 26,334	$ —	$ —	$ 26,334

	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

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, 2025, and 2024, 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. See *Note 9 - Other Liabilities* for further information on fixed payment arrangements.

Based on the Company's impairment analyses for fiscal 2025 and 2024, the Company recorded an impairment charge of $8.3 million on intangible assets for the year ended June 30, 2025, and the Company did not record an impairment charge on intangible assets during the year ended June 30, 2024. 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 2 - Summary of Significant Accounting Policies* and *Note 7 - Intangible Assets*, for further discussion of the Company's 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 periods presented:

	Derivative Warrant Liabilities
	(in thousands)
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
Issued [2]	12,349
Settlements [3]	(463)
Included in earnings	1,703
Balance as of June 30, 2025	$ 26,334

(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 prefunded 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.

(2) Relates to the June 2025 issuance of 8,233,332 prefunded warrants at a public offering price of $1.4999 to purchase 8,233,332 shares of the Company's common stock at an exercise price of $0.0001 per share (see *Note 14 - Stockholders' Equity* and *Note 16 - Warrants* for further detail).

(3) Relates to the exercise of 176,000 prefunded warrants during the first quarter of fiscal 2025, which were liability classified and exercised at a price of $0.0001 per share.

Level 3 Inputs

Significant assumptions as of June 30, 2025, used in valuing the derivative warrant liabilities, marked to market, were as follows:

	June 2023 Tranche A Warrants	Warrants Other [1]
	Monte Carlo & Black-Scholes	*Black-Scholes*
Aytu closing stock price	$ 2.18	$ 2.18
Equivalent term (years)	2.9	1.6 - 2.2
Expected volatility	85.8%	75.4% - 78.1%
Risk-free rate	3.7%	3.7%
Dividend yield	0%	0%

(1) Includes all liability classified warrants and prefunded warrants except the June 2023 Tranche A Warrants (see *Note 16 - Warrants* for further information).

Note 13 - Income Taxes

For the years ended June 30, 2025, and 2024, there was $0.4 million of income tax expense and $2.1 million of income tax expense from continuing operations, which was an effective tax rate of negative 3.2% and negative 20.6%, respectively. This income tax expense was primarily driven by Section 382 limitation of the IRC on pre-Tax Cuts and Jobs Act (the "TCJA") and post-TCJA net operating loss ("NOL") utilization, as further described below, coupled with existing valuation allowances. As of June 30, 2025, and 2024, the Company had $0.3 million and $0.8 million of deferred tax assets ("DTAs"), net of valuation allowance from continuing operations, respectively, included in other non-current assets and $0.3 million and $0.8 million of deferred tax liabilities ("DTLs") from continuing operations, respectively, included in other non-current liabilities. As of June 30, 2025, and 2024, the Company had $1.1 million of prepaid income taxes included in prepaid expenses and other current assets and $0.3 million of accrued income taxes payable, respectively, recorded in the Company's 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 $9.3 million of disallowed recognized built-in loss that was carried forward as a net operating loss as of June 30, 2024. For fiscal 2025, an additional $3.6 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 $516.7 million as of June 30, 2025, which are subject to limitation (as described above). Of the available federal net operating losses, $190.0 million can be carried forward indefinitely, and $324.7 million will completely expire in 2037 as a result of the ownership change. As of June 30, 2025, the Company had research and development credits of $2.9 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, 2025, 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,	
	2025	2024
	(in thousands)	
Current:		
Federal	$ (215)	$ 1,886
State	652	256
Income tax expense	$ 437	$ 2,142

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 consolidated 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,			
	2025		2024	
	(in thousands, except tax rate)			
Tax at statutory rate	$ (2,897)	21.0%	$ (2,179)	21.0%
State income taxes, net of federal benefit	26	(0.2)%	(906)	8.7%
Stock-based compensation expense	22	(0.1)%	19	(0.2)%
Change in valuation allowance	2,465	(17.9)%	5,172	(49.8)%
Other	821	(6.0)%	36	(0.3)%
Income tax expense	$ 437	(3.2)%	$ 2,142	(20.6)%

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,	
	2025	2024
	(in thousands)	
Deferred tax assets:		
Net operating loss carry forward	$ 119,782	$ 119,170
Interest	5,101	4,845
Accrued rebates	4,478	3,819
Research and development credits	2,416	2,416
Stock-based compensation expense	1,362	1,259
Intangible assets	1,187	—
Accrued expenses	642	1,027
Section 174 capitalization	864	780
Inventory	557	256
Lease liability	266	305
Fixed assets	62	99
Warrant derivatives	—	3,061
Other	87	975
Total deferred tax assets	136,804	138,012
Less: valuation allowance	(136,552)	(137,250)
Deferred tax assets, net of valuation allowance	252	762
Deferred tax liabilities:		
Intangibles	—	(563)
ROU asset	(252)	(199)
Total deferred tax liabilities	(252)	(762)
Net deferred tax liabilities	$ —	$ —

The Company has recorded a valuation allowance of $136.6 million and $137.3 million as of June 30, 2025, and 2024, 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, as of June 30, 2025, and 2024 the Company had gross unrecognized tax benefits related to uncertain tax positions of $0.5 million and $1.3 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,	
	2025	2024
	(in thousands)	
Beginning balances	$ 1,313	$ 2,948
Decrease resulting from current period tax positions	(795)	(1,996)
Increase resulting from current period tax positions	—	361
Ending balances	$ 518	$ 1,313

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, 2024. Additionally, certain of the Company's acquired legal entities 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.

The income tax expense (benefit) allocated to continuing operations and discontinued operations for the years ended June 30, 2025, and 2024, were as follows:

	Year Ended June 30,	
	2025	2024
	(in thousands)	
Continuing operations income tax expense	$ 437	$ 2,142
Discontinued operations income tax benefit	(17)	(374)
Income tax expense	$ 420	$ 1,768

See *Note 20 - Discontinued Operations* for further detail on the Company's discontinued operations related to the wind down and divestiture of its Consumer Health business.

The One Big Beautiful Bill Act

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was enacted in the United States. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the TCJA, allowing for accelerated tax deductions for qualified property and research expenditures, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in calendar year 2025 and others implemented through calendar year 2027. None of the provisions are expected to impact the realizability of the Company's deferred tax assets and liabilities on the consolidated balance sheet as of June 30, 2025. However, because the OBBBA is a wide-reaching law, the Company is currently assessing its potential impact on its business, financial condition, results of operations and future plans and the Company plans to provide an update in future SEC filings once this assessment is complete. See *Note 21 - Subsequent Events* for further detail.

Note 14 - Stockholders' Equity

The Company has 50.0 million shares of preferred stock authorized with a par value of $0.0001 per share and no preferred shares issued and outstanding. The Company has 200.0 million shares of common stock authorized with a par value of $0.0001 per share and as of September 15, 2025, June 30, 2025, and June 30, 2024, the Company had 9,911,913, 8,976,913 and 5,972,638 shares of common stock issued and outstanding, respectively. As of June 30, 2025, included in common stock outstanding are 32,916 shares of unvested restricted stock issued to directors, executives and employees.

On September 26, 2024, the Company filed a shelf registration statement on Form S-3, which was declared effective by the SEC on October 15, 2024. This shelf registration statement covers 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"). Through the filing date of this report, $100.0 million remains available under the 2024 Shelf. This availability is subject to the SEC's "baby shelf" limitation as set forth in SEC Instruction I.B.6 limitation to the Form S-3.

In June 2025, the Company raised gross proceeds of $16.6 million from the issuance of (i) 2,806,688 shares of its common stock, at a public offering price of $1.50 (the "June 2025 Common Stock"), and 8,233,332 prefunded warrants at a public offering price of $1.4999 to purchase 8,233,332 shares of its common stock at an exercise price of $0.0001 per share (the "June 2025 Prefunded Warrants"). The Company received $14.8 million in proceeds net of underwriting commissions and offering expenses and intends to use the net proceeds from the offering for working capital, general corporate purposes and to enable the Company to exclusively commercialize EXXUA. From July 2025 through the filing of this report, a total of 935,000 of the June 2025 Prefunded Warrants were exercised to 935,000 shares of common stock. See *Note 16 - Warrants* for further detail.

Note 15 - Equity Incentive Plan

2023 Equity Incentive Plan

On May 18, 2023, the Company's stockholders approved the adoption of the Aytu BioPharma, Inc. 2023 Equity Incentive Plan (the "2023 Equity Incentive Plan"), which replaced all previous plans. For the 2023 Equity Incentive Plan, the stockholders approved (a) 200,000 new shares; (b) 87,155 shares "rolled over" to the 2023 Equity Incentive Plan from plans replaced by the 2023 Equity Incentive Plan; and (c) any shares that are returned to the Company under plans replaced by the 2023 Equity Incentive Plan to be added to the 2023 Equity Incentive Plan. On May 21, 2025, the Company's stockholders approved an amendment (the "Plan Amendment") to the 2023 Equity Incentive Plan. The Plan Amendment increased the number of shares reserved for issuance under the 2023 Equity Incentive Plan by 300,000 shares to bring the total number of shares reserved for issuance under the 2023 Equity Incentive Plan to 500,000 shares, not including unissued shares from available awards under prior plans or any returned shares. The Plan Amendment became effective immediately upon approval by the Company's stockholders and the Company plans to register the 300,000 shares pursuant to a registration statement on Form S-8 to be filed with the SEC in fiscal 2026. With the approval of the 2023 Equity Incentive Plan, no additional awards will be granted under any previous 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 and previous plans typically have contractual terms of 10 years or less from the grant date and a vesting period ranging from one to four years. The restricted stock and restricted stock units granted under the 2023 Equity Incentive Plan typically have a vesting period of three to four years and restricted stock and restricted stock units granted from previous plans typically have a vesting period ranging from four to 10 years and four years, respectively. As of June 30, 2025, the Company had 397,409 shares available for grant under the 2023 Equity Incentive Plan.

Stock Options

During the year ended June 30, 2025, 87,500 stock options were granted. The weighted-average grant date fair value of options granted during the year ended June 30, 2025, was $1.83. As of June 30, 2025, there was $0.1 million of total unrecognized compensation cost adjusted for estimated forfeitures, related to non-vested stock options granted by the Company, which is expected to be recognized over a weighted-average period of 2.0 years.

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. As of June 30, 2024, there was $0.2 million of total unrecognized compensation cost adjusted for estimated forfeitures, related to non-vested stock options granted by the Company.

Stock option activity during the year ended June 30, 2025, is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years
Outstanding at June 30, 2024	146,539	$ 6.18	8.8
Granted	87,500	$ 1.83	8.3
Forfeited/cancelled	(17,343)	$ 1.87	—
Expired	(5,078)	$ 15.46	—
Outstanding at June 30, 2025	211,618	$ 4.51	8.3
Exercisable at June 30, 2025	100,195	$ 7.44	7.4

The following table details the options outstanding as of June 30, 2025, 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
$1.69	3,000	$ 1.69	9.6	—	$ —
$1.73	87,453	$ 1.73	8.0	59,901	$ 1.73
$1.84	79,000	$ 1.84	9.4	2,500	$ 1.84
$2.53 - $290.00	42,165	$ 15.49	6.6	37,794	$ 15.49
	211,618	$ 4.51	8.3	100,195	$ 7.44

Restricted Stock

During the year ended June 30, 2025, the Company granted a total of 20,000 shares of restricted stock, with certain accelerated vesting conditions, to members of its non-employee directors and its management team pursuant to the 2023 Equity Incentive Plan, that vest between one year and three years from the grant date, subject to continuing service to the Company through each vesting date. These restricted stock grants have a weighted-average grant date fair value of $1.79 per share. As of June 30, 2025, there was $0.7 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 1.9 years.

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.

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, 2024	24,105	$ 100.34
Granted	20,000	$ 1.79
Vested	(11,193)	$ 14.02
Unvested at June 30, 2025	32,912	$ 69.81

As of June 30, 2025, there were four shares of unvested restricted stock that were granted outside of equity compensation plans approved by security holders, which had less than $0.1 million of total unrecognized compensation costs and a remaining weighted-average vesting period of 1.0 years.

Restricted Stock Units

For the years ended June 30, 2025, and 2024, the Company did not grant any restricted stock units and there were no remaining unvested restricted stock units as of June 30, 2025. Restricted stock unit activity is as follows:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested at June 30, 2024	1,775	$ 24.14
Vested	(1,608)	$ 23.93
Forfeited/cancelled	(167)	$ 26.20
Unvested at June 30, 2025	—	$ —

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

	Year Ended June 30,	
	2025	2024
	(in thousands)	
Cost of goods sold	$ 2	$ 2
Research and development	11	6
Selling and marketing	61	—
General and administrative	502	2,365
Net income (loss) from discontinued operations, net of tax	—	540
Total stock-based compensation expense	$ 576	$ 2,913

Note 16 - Warrants

The Company has engaged in several different types of equity financings throughout its history, some of which have resulted in the Company issuing warrants and prefunded 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.

The number of warrants and prefunded warrants outstanding as of June 30, 2025, is as follows:

Description	Number Outstanding	Exercise Price	Remaining Contractual Life in Years [7]	Type	Classification
December 2020 Warrants [1]	15,571	$ 150.00	0.5	Warrant	Equity
January 2022 Warrants [1]	122,092	$ 8.60	1.6	Warrant	Liability
March 2022 Warrants [1]	333,300	$ 26.00	2.2	Warrant	Liability
August 2022 Warrants [1]	1,191,811	$ 2.32	2.1	Warrant	Liability
June 2023 Tranche A Warrants [2]	2,173,912	$ 1.59	3.0	Warrant	Liability
June 2023 Tranche B Prefunded Warrants [3]	1,630,434	$ 0.0001	N/A	Prefunded Warrant	Liability
June 2023 Prefunded Warrants [4]	430,217	$ 0.0001	N/A	Prefunded Warrant	Liability
June 2025 Prefunded Warrants [5][6]	8,233,332	$ 0.0001	N/A	Prefunded Warrant	Liability
Total outstanding June 30, 2025 [6]	14,130,669				

(1) Each of these warrants is exercisable at any time for one share of the Company's common stock on a one-for-one basis under the terms of the agreements between the Company and the investors.

(2) In June 2023, the Company issued these tranche A warrants to purchase 2,173,912 shares of common stock (the "Tranche A Warrants"), which may be exercised on a one-for-one basis at any time subject to certain limitations as defined in the agreements between the Company and the investors, for either shares of common stock at an exercise price of $1.59 per share or for prefunded warrants at an exercise price of $1.5899 per prefunded warrant to purchase common stock at a future exercise price of $0.0001 per share. The Tranche A Warrants will expire upon the earlier of June 2028 or 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.

(3) In June 2024, certain warrants were exercised, generating proceeds of $3.5 million, into 367,478 shares of common stock and 1,806,434 prefunded warrants to purchase shares of common stock with an exercise price of $0.0001 per share (the "Tranche B Prefunded Warrants"), and may be exercised at any time subject to certain limitations as defined in the agreements between the Company and the investors on a one-for-one basis. The Tranche B Prefunded 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.

(4) Each of these prefunded warrants is exercisable at any time for one share of the Company's common stock on a one-for-one basis under the terms of the agreements between the Company and the investors.

(5) In June 2025, the Company raised gross proceeds of $16.6 million from the issuance of the June 2025 Common Stock the June 2025 Prefunded Warrants. The June 2025 Prefunded Warrants may be exercised on a one-for-one basis at any time subject to certain limitations as defined in the agreements between the Company and the investors. The June 2025 Prefunded Warrants had a fair value of approximately $12.3 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. There was $1.3 million of issuance costs allocated to the June 2025 Prefunded Warrants, which were recorded in other (expense) income in the consolidated statement of operations. See *Note 12 - Fair Value Measurements* and *Note 14 - Stockholders' Equity* for further detail.

(6) From July 2025 through the filing of this report, a total of 935,000 of the June 2025 Prefunded Warrants were exercised to 935,000 shares of common stock. See *Note 14 - Stockholders' Equity* for further detail.

(7) All of the Company's prefunded warrants do not have an expiration date.

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 Measurements* for further detail).

A summary of warrant activity, excluding prefunded warrants, during the year ended June 30, 2025, is as follows:

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life in Years
Outstanding June 30, 2024 [1]	3,839,229	$ 4.95	3.6
Warrants expired	(2,543)	N/A	N/A
Outstanding June 30, 2025 [2]	3,836,686	$ 4.76	2.6

(1) The number of warrants, excluding prefunded warrants, outstanding as of June 30, 2024, is comprised of 3,821,115 liability classified warrants and 18,114 equity classified warrants.

(2) The number of warrants, excluding prefunded warrants, outstanding as of June 30, 2025, is comprised of 3,821,115 liability classified warrants and 15,571 equity classified warrants.

A summary of prefunded warrant activity during the year ended June 30, 2025, is as follows:

	Number of Prefunded Warrants	Weighted-Average Exercise Price
Outstanding June 30, 2024	2,236,651	$ 0.0001
Prefunded warrants issued [1][2]	8,233,332	$ 0.0001
Prefunded warrants exercised	(176,000)	$ 0.0001
Outstanding June 30, 2025 [2]	10,293,983	$ 0.0001

(1) Relates to the issuance of the June 2025 prefunded warrants.

(2) From July 2025 through the filing of this report, a total of 935,000 of the June 2025 Prefunded Warrants were exercised to 935,000 shares of common stock. See *Note 14 - Stockholders' Equity* for further detail.

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 business and the closure of the Grand Prairie, Texas manufacturing site, 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. Restructuring costs associated with the Consumer Health business are recorded within the net income (loss) from discontinued operations, net of tax in the consolidated financial statement of operations (see Note 20 - Discontinued Operations).

The expense associated with the closure of the Grand Prairie, Texas manufacturing site such as severance and employee benefits and exit and disposal activities are included in restructuring costs in the consolidated statements of operations. There have been no inventory write-downs associated with this closure. During the years ended June 30, 2025, and 2024, the Company incurred $2.1 million and $2.2 million, respectively, of costs associated with exit and disposal activities related to its previously announced operational realignment and related costs. The Company does not expect to incur additional significant restructuring costs.

Note 18 - Commitments and Contingencies

EXXUA Exclusive Commercialization Agreement

On June 5, 2025, the Company, entered into the Commercialization Agreement with Fabre-Kramer, pursuant to which the Company acquired certain rights and obligations in connection with the commercialization of EXXUA in the United States. As consideration for the Commercialization Agreement, the Company made an upfront cash payment of $3.0 million to Fabre-Kramer in June 2025, which was capitalized as a definite-lived intangible asset (see *Note 7 - Intangible Assets* for further detail). Within 45 days of the one-year anniversary of the first product launch EXXUA in the United States, the Company has agreed to make a second $3.0 million payment (the "Second Payment"). The Second Payment may be increased to $5.0 million if first year EXXUA net sales meet or exceed $35.0 million. Additionally, the Company has agreed to pay Fabre-Kramer certain milestone payments ranging from $5.0 million to over $100.0 million per year based on sales milestones after a certain level of net sales are achieved with a threshold of $100.0 million in net sales and the Company will pay 10% of net sales exceeding $1.0 billion. The Company has also agreed to pay royalty fees throughout the term of the Commercialization Agreement based on the Company's net sales of EXXUA as follows: (i) initially 28% of net sales and increasing to 39% if net sales exceed $300.0 million in any year during the term until such net sales reach a reduced royalty trigger; and (ii) after reaching such royalty trigger, 24.5% and increasing to 35.5% if net sales exceed $300.0 million in any year during the term. The Company will also pay a supply price of 3% of net sales less its cost of goods sold, increasing to 4% of net sales if annual net sales exceed $300.0 million. The Commercialization Agreement also contains customary clauses for pharmaceutical commercialization agreements, including, among others, post-marketing trials and obligations, regulatory matters, and indemnification.

The Commercialization Agreement can be terminated at any time upon mutual agreement between the Company and Fabre-Kramer. Either party can terminate the Commercialization Agreement at any time upon written notice for a material default or breach if the material default or breach is not cured within (1) 90 days after written notice or (2) in the case of a breach that cannot be cured within 90 days, within a reasonable period not exceeding 120 days after written notice. Additionally, either party can terminate the Commercialization Agreement at any time upon writing notice if (1) either party withdraws EXXUA from the market in the United States for safety reasons or (2)(i) the FDA materially restricts the indications for EXXUA, or (ii) federal or state pricing controls are imposed that would result in obvious or substantial loss of sales for EXXUA.

Pediatric Portfolio

The Tris Karbinal Agreement grants the Company 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. As of June 30, 2025, the Company has an accrued fixed payment arrangement balance related to these payment obligations of $0.2 million recorded in other current liabilities on the consolidated balance sheet.

Operating Leases

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 was renting that same space under a sublease arrangement. The Company 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. Variable lease payments will be expensed as incurred.

In May 2023, the Company entered into an operating lease agreement to relocate its principal office to Denver, Colorado. The initial lease termination date is March 31, 2029, and under the lease agreement the Company has one five-year renewal option to extend the lease through March 2034. Undiscounted minimum monthly rent payments average approximately $15,500 over the initial term of the lease. Variable lease payments will be expensed as incurred.

Legal Matters

Granules Paragraph IV

On October 31, 2024, the Company received a Paragraph IV Certification Notice Letter (the "Notice Letter") from Granules Pharmaceuticals, Inc. ("Granules"), stating that it intends to market a generic version of Adzenys before the expiration of all patents currently listed in the FDA's publication of approved drug products with therapeutic equivalence evaluations (the "Orange Book"). The Notice Letter states that Granules' NDA for the generic version of Adzenys contains a Paragraph IV certification alleging that these patents are not valid, not enforceable, and/or will not be infringed by the commercial manufacture, use or sale of the generic version of Adzenys. On December 11, 2024, the Company filed a patent infringement lawsuit against Granules which triggered a stay precluding the FDA from approving Granules' NDA for a generic version of Adzenys for up to 30 months or entry of judgment holding the patents invalid, unenforceable, or not infringed, whichever occurs first. On January 7, 2025, Granules submitted an answer to the complaint. This litigation is ongoing, and a trial has been scheduled to begin on December 7, 2026. The Company plans to vigorously enforce its intellectual property rights related to Adzenys.

Revive Investing

The Company had been named as a nominal plaintiff in a lawsuit by two shareholders against Armistice Capital Master Fund, Ltd ("Armistice"), entitled Revive Investing, LLC. et al v. Armistice Master Fund, Ltd. et al, Case 1:20-cv-02849-CMA-TPO, in the United States District Court for the District of Colorado, contending that Armistice was liable for short swing trading profits in violation of Section 16(b) of the Securities Exchange Act of 1934, as amended, for certain trades it made in Company stock in 2019 and 2020 and must disgorge those profits to the Company. That matter proceeded to trial before a jury, which on January 29, 2025, returned a verdict finding no liability. On March 6, 2025, the plaintiffs filed an appeal in the United States Court of Appeals for the Tenth Circuit. As with the original case, regardless of the outcome, this case will not have a materially adverse effect upon the Company's financial condition, results of operations, or cash flows.

Note 19 - License Agreements

Teva

On December 21, 2018, the Company and Teva Pharmaceuticals USA, Inc. ("Teva") entered into an agreement granting Teva a non-exclusive license to certain patents owned by Neos by which Teva has the right to manufacture and market its generic version of Cotempla 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 Laboratories FL, Inc. ("Actavis") (which is now owned by Teva Pharmaceutical Industries Limited) 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. The ANDA was approved by the FDA on June 22, 2023.

Note 20 - Discontinued Operations

On July 31, 2024, after the wind down of operations, the Company entered into a definitive agreement to divest its Consumer Health business to a private, e-commerce focused company. The divested business encompassed the established e-commerce platform, certain inventory and associated consumer brands, intellectual property, external workforce and contracts, and provided for the Company to receive contingent consideration payments on certain future sales of former Consumer Health business products.

The accounting requirements for reporting the Consumer Health business as a discontinued operation were met when the wind down and divestiture was completed on July 31, 2024. Accordingly, the accompanying consolidated financial statements for all periods presented reflect this business as a discontinued operation and certain assets and liabilities of discontinued operations have been reclassified to the current assets of discontinued operations; non-current assets of discontinued operations; and current liabilities of discontinued operations financial statement line items on the accompanying consolidated balance sheets as of June 30, 2025, and 2024. The Company elected to record the contingent consideration portion of the arrangement when the consideration is determined to be realizable and, therefore, the Company did not record a contingent consideration asset at the transaction date and any subsequent proceeds will not be recognized until the contingent consideration asset is realizable, at which point the Company will recognize it to income (loss) from discontinued operations.

The key components of income (loss) from discontinued operations, net of tax for the years ended June 30, 2025, and 2024, were as follows:

	Year Ended June 30,	
	2025	**2024**
	(in thousands)	
Net revenue	$ 717	$ 15,819
Cost of goods sold	(358)	(10,287)
Selling and marketing	(155)	(4,875)
General and administrative	(7)	(2,560)
Research and development	—	(22)
Amortization of intangible assets	—	(1,529)
Restructuring costs	—	(209)
Non-operating other expense, net	—	(35)
Recognized contingent consideration	660	—
Loss on divestiture	(254)	—
Income (loss) from discontinued operations before income taxes	**603**	**(3,698)**
Income tax benefit	17	374
Net income (loss) from discontinued operations, net of tax	$ **620**	$ **(3,324)**

The key components of assets and liabilities of discontinued operations as of June 30, 2025, and 2024, were as follows:

	June 30, 2024
	(in thousands)
ASSETS	
Current assets of discontinued operations:	
Accounts receivable, net	$ 91
Inventories	492
Prepaid expenses and other current assets	538
Total current assets of discontinued operations	1,121
Non-current assets of discontinued operations:	
Other non-current assets	44
Total current assets of discontinued operations	44
Total current and non-current assets of discontinued operations	$ 1,165
LIABILITIES	
Current liabilities of discontinued operations:	
Accounts payable	$ 126
Accrued liabilities	431
Total current liabilities of discontinued operations	$ 557

Note 21 - Subsequent Events

The One Big Beautiful Bill Act

The enactment of the OBBBA on July 4, 2025, may adversely affect the Company's business, financial condition, results of operation and future plans. The OBBBA includes significant provisions, such as the permanent extension of certain expiring provisions of the TCJA, allowing for accelerated tax deductions for qualified property and research expenditures, and the restoration of favorable tax treatment for certain business provisions. The legislation has multiple effective dates, with certain provisions effective in calendar year 2025 and others implemented through calendar year 2027. None of the provisions are expected to impact the realizability of the Company's deferred tax assets and liabilities on the consolidated balance sheet as of June 30, 2025. However, because the OBBBA is a wide-reaching law, the Company is currently assessing its potential impact on its business, financial condition, results of operations and future plans and the Company plans to provide an update in future SEC filings once this assessment is complete. See *Note 13 - Income Taxes* for further detail.

Termination of AR101 Rumpus Asset Purchase Agreement

As previously disclosed in its SEC filings, the Company suspended its clinical development of AR101 (enzastaurin) ("AR101"). In connection with this suspension, the Company has been engaged in negotiations with EnzCo, LLC ("EnzCo") and Rumpus VEDS LLC, ("Rumpus VEDS"), Rumpus Therapeutics LLC, ("Rumpus Therapeutics") and Rumpus Vascular LLC, ("Rumpus Vascular" and, together with Rumpus VEDS and Rumpus Therapeutics, "Rumpus") for the repurchase of AR101. On August 5, 2025, the Company, Rumpus and EnzCo reached terms whereby for mutual consideration and releases, the Company transferred all of its and Rumpus' rights, title and interest in AR101 to EnzCo, which extinguished and terminated all obligations of the Company and Rumpus under the April 21, 2021, asset purchase agreement by and between the Company and Rumpus (the "Rumpus Asset Purchase Agreement"). There is no other relationship between the Company, EnzCo or Rumpus other than as contracting parties to terminate the Rumpus Asset Purchase Agreement, and there are no penalties or remaining obligations to the Company for terminating the Rumpus Asset Purchase Agreement.

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, 2025. 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, 2025, 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.

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 been no changes to our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the fourth quarter of fiscal 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

MANAGEMENT'S ANNUAL REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

The Company's 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework* (2013 framework).

Based on management's assessment and those criteria, management concluded that the Company maintained effective internal control over financial reporting as of June 30, 2025.

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

ITEM 9B. OTHER INFORMATION

Rule 10b5-1 Trading Plans

During the quarter ended June 30, 2025, 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 information required by this Item is incorporated by reference to the information provided in the Company's Definitive Proxy Statement on Schedule 14A for the 2026 annual meeting of stockholders, to be filed within 120 days from June 30, 2025.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the information provided in the Company's Definitive Proxy Statement on Schedule 14A for the 2026 annual meeting of stockholders, to be filed within 120 days from June 30, 2025.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item is incorporated by reference to the information provided in the Company's Definitive Proxy Statement on Schedule 14A for the 2026 annual meeting of stockholders, to be filed within 120 days from June 30, 2025.

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

The information required by this Item is incorporated by reference to the information provided in the Company's Definitive Proxy Statement on Schedule 14A for the 2026 annual meeting of stockholders, to be filed within 120 days from June 30, 2025.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the information provided in the Company's Definitive Proxy Statement on Schedule 14A for the 2026 annual meeting of stockholders, to be filed within 120 days from June 30, 2025.

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:

(b) Exhibits

Exhibit No.	Description	Registrant's Form	Date Filed	Exhibit Number
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
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.	10-K	09/26/24	3.6

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 Prefunded Common Stock Purchase Warrant.	8-K	03/04/22	4.1
4.2	Form of Common Stock Purchase Warrant.	8-K	03/04/22	4.2
4.3	Form of Pre-Funded Warrant.	8-K	08/10/22	4.1
4.4	Form of Common Warrant.	8-K	08/10/22	4.2
4.5	Form of Pre-Funded Warrant.	S-1/A	06/05/23	4.10
4.6	Form of Tranche A Warrant.	S-1/A	06/05/23	4.11
4.7	Description of Securities.	10-K	09/27/22	4.9
4.8	Form of Prefunded Warrant.	S-1	06/02/25	4.13
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	10/03/19	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	03/22/21	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	02/14/22	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	05/11/23	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	06/18/24	10.1
10.7	Term Loan Note dated June 12, 2024.	8-K	06/18/24	10.2
10.8	Second Amended and Restated Revolving Note dated June 12, 2024.	8-K	06/18/24	10.3
10.9&	Amendment No. 6 to Loan and Security Agreement dated June 20, 2025, between the Borrowers and lenders party thereto and Eclipse Business Capital LLC as agent.	8-K	06/23/25	10.1
10.10&	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
10.11	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
10.12	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	First Amendment to Asset Purchase Agreement with Cerecor, Inc., dated November 1, 2019.	8-K	11/04/19	10.1
10.19	Waiver and Amendment to the July 29, 2019 Amended and Restated License and Supply Agreement, dated November 29, 2019.	8-K	12/02/19	10.1

10.20&	Asset Purchase Agreement, dated July 1, 2020, by and between Aytu BioPharma, Inc. and UAB "Caerus Biotechnologies."	10-K	09/28/21	10.79
10.21&	Termination Agreement, dated June 29, 2021 by and between Aytu BioPharma, Inc. and Avrio Genetics, LLC.	10-K	09/28/21	10.80
10.22#&	Settlement and Termination of License Agreement between the registrant and TRIS Pharma, Inc., dated May 12, 2022.	10-Q	05/16/22	10.1
10.23&	Commercial Manufacturing Services Agreement by and between the Company and Halo Pharmaceutical, Inc., dated November 13, 2023.	10-Q	02/14/24	10.1
10.24&*	Exclusive Commercialization Agreement between the Company and Fabre-Kramer Holdings, Inc., dated June 5, 2025.			
10.25†	2015 Stock Option and Incentive Plan, as amended on July 26, 2017.	8-K	07/27/17	10.1
10.26†	Aytu BioPharma, Inc. 2023 Equity Incentive Plan.	S-8	06/23/23	10.1
10.27†	Amendment to the Aytu BioPharma, Inc. 2023 Equity Incentive Plan.	8-K	05/21/25	10.1
10.28	Form of Indemnification Agreement.	8-K	07/01/22	10.1
10.29†	Restricted Stock Award Agreement between Aytu BioPharma, Inc. and Mark Oki, effective January 17, 2022.	10-Q	02/14/22	10.2
10.30†	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
10.31†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Ryan J. Selhorn dated November 11, 2024.	8-K	11/13/24	10.1
10.32†	Amended and Restated Employment Agreement by and between Aytu BioPharma, Inc. and Jarrett T. Disbrow dated March 20, 2023.	10-K	09/26/24	10.42
10.33†	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
10.34†	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
10.35†	Separation and Release Agreement by and between Aytu BioPharma, Inc. and Mark K. Oki dated December 1, 2024.	10-Q	02/12/25	10.2

19.1	Statement of Insider Trading Policy.	10-K	09/26/25	19.1
21.1*	List of Subsidiaries.			
23.1*	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm.			
24.1*	Power of Attorney (contained on signature page hereto).			
31.1*	Certificate of the Chief Executive Officer of Aytu BioPharma, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certificate of the Chief Financial Officer of Aytu BioPharma, Inc. pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
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.	10-K	09/26/25	97.1
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.			
101 SCH*	Inline XBRL Taxonomy Schema Linkbase Document.			
101 CAL*	Inline XBRL Taxonomy Calculation Linkbase Document.			
101 DEF*	Inline XBRL Taxonomy Definition Linkbase Document.			
101 LAB*	Inline XBRL Taxonomy Labels Linkbase Document.			
101 PRE*	Inline XBRL Taxonomy Presentation Linkbase Document.			
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).			

† 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.
* Filed herewith.
** 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 23, 2025

By: /s/ Joshua R. Disbrow
Joshua R. Disbrow
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 Ryan J. Selhorn, 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 23, 2025.

Signature	**Title**
/s/ Joshua R. Disbrow Joshua R. Disbrow	Chief Executive Officer and Director *(Principal Executive Officer)*
/s/ Ryan J. Selhorn Ryan J. Selhorn	Chief Financial Officer *(Principal Financial and Accounting Officer)*
/s/ John A. Donofrio, Jr. John A. Donofrio, Jr.	Chairman
/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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