**Risk Factors Comparison 2024-09-26 to 2023-10-12 Form: 10-K**

**Legend:** **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

~~RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION~~ **Risks Related to Our Business and Financial Position** ● We have incurred losses to date and can give no assurance of profitability. **● We have not established sources of ongoing revenue sufficient to cover operating costs. ● We may need to raise additional funding, which may not be available on acceptable terms, or at all. ● We may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. ● The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility. ● We are currently engaged in discussions with various parties regarding potential strategic transactions and there can be no assurance that these discussions will result in the pursuit or consummation of any potential transaction. ● We have indefinitely suspended development of our AR101 (enzastaurin) clinical development program and shifted our strategic focus towards accelerating the growth of our commercial business. If we fail to execute successfully on this reprioritized strategic focus, our business, results of operations and financial condition could be materially and adversely affected. ● We have been and, in the future, may become a defendant in one or more stockholder derivative, class- action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows. Risks Related to Commercialization ● We are heavily dependent on the commercial success of our commercial products. To date, we have not generated sufficient revenues from the sales of these products to achieve companywide profitability and we may never achieve or maintain profitability. ● We rely on third parties to manufacture certain products, and third- party manufacturing risks and inefficiencies may result in costs and delays that prevent us from successfully commercializing products and adversely affect our ability to produce our products. ● If our contract manufacturer fails to manufacture our ADHD products in sufficient quantities and at acceptable quality and pricing levels, or fails to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of these products, or be unable to meet market demand, and may be unable to generate potential revenues. ● Government restrictions on pricing and reimbursement, as well as other healthcare payor cost- containment initiatives, may negatively impact our ability to generate revenues. ● Our financial results will depend on the acceptance among clinicians, third- party payors and the medical community of our products. ● If third- party payors do not reimburse our customers for the products we sell or if reimbursement levels are set too low for us to sell our products at a profit, our ability to sell those products and our results of operations will be harmed. ● Adzenys and Cotempla contain controlled substances, and their manufacture, use, sale, importation, exportation, prescribing and distribution are subject to regulation by the DEA. Risks Related to Our Intellectual Property ● We are dependent on our relationships and license agreements, and we rely on the intellectual property rights granted to us pursuant to the license agreements. ● The expiration or loss of patent protection may adversely affect our future revenues and operating results. ● Our ability to compete may decline if we do not adequately protect or enforce our intellectual property rights. Risks Related to Our Organization, Structure and Operations ● Our efforts to expand and transform our businesses may require significant investments; if our strategies are unsuccessful, our business, results of operations and / or financial condition may be materially adversely affected. ● We may have difficulties integrating acquired businesses and as a result, our business, results of operations and / or financial condition may be materially adversely affected. ● In fiscal 2024, the great majority of our gross revenue and gross accounts receivable were due to three significant customers, the loss of which could materially and adversely affect our results of operations. ● Our accounts receivable subjects us to credit risk. ● Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to the Company. ● Public concern over the abuse of medications that are controlled substances, including increased legislative, legal and regulatory action, could negatively affect our business. ● Certain of our stockholders own a significant percentage of our stock and their interests may conflict with yours. PART I ITEM 1. BUSINESS Company Overview Aytu BioPharma, Inc. (“ Aytu, ” the “ Company, ” “ we, ” “ us, ” or “ our ”) is a pharmaceutical company focused on commercializing novel therapeutics. The Company was originally incorporated as Rosewind Corporation on August 9, 2002, in the state of Colorado and was re-incorporated as Aytu BioScience, Inc. in the state of Delaware on June 8, 2015. Following the acquisition of Neos Therapeutics, Inc. (“ Neos ”) in March 2021 (the “ Neos Acquisition ”), the Company changed its name to Aytu BioPharma, Inc. Our common stock trades on the Nasdaq Capital Market under the ticker symbol “ AYTU. ” Our principal office is located at 7900 East Union Avenue, Suite 920, Denver, Colorado 80237, and our telephone number is (720) 437- 6580. We operate through two business segments: (i) the Rx segment, consisting of prescription pharmaceutical products sold primarily through third party wholesalers (the “ Rx Segment ”) and (ii) the consumer health segment, which consists of various consumer healthcare products sold directly to consumers through certain e-commerce platforms (the “ Consumer Health Segment ”). The Rx Segment primarily consists of two product portfolios. The first consists of Adzenys XR- ODT (amphetamine) extended- release orally disintegrating tablets (“ Adzenys ”) and Cotempla XR- ODT (methylphenidate) extended- release orally disintegrating tablets (“ Cotempla ”) for the treatment of attention deficit hyperactivity disorder (“ ADHD ”) (the “ ADHD Portfolio ”). The second consists primarily of Karbinal ® ER (carbinoxamine maleate extended- release oral suspension) (“ Karbinal ”), an extended- release first- generation**

**antihistamine suspension containing carbinoxamine indicated to treat numerous allergic conditions, and Poly- Vi- Flor and Tri- Vi- Flor, two complementary prescription fluoride- based supplement product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency (the " Pediatric Portfolio "). The Consumer Health Segment consists of multiple consumer health products competing in large healthcare categories, including allergy, hair regrowth, diabetes support, digestive health, sexual and urological health, and general wellness, commercialized through direct mail and e- commerce marketing channels. To date, the Consumer Health Segment has generated negative cash flows. We began to wind down the Consumer Health Segment in fiscal 2024. During the first quarter of fiscal 2025, we completed the wind down of operations and entered into a definitive agreement to divest the Consumer Health Segment to a private, e- commerce focused company (the " Consumer Health Divestiture "). The divested business encompasses the established e- commerce platform, certain inventory and associated consumer brands, intellectual property, contracts and liabilities, and provides for us to receive up to $ 0. 5 million of revenue- based royalty payments on future sales of former Consumer Health Segment products. We expect the savings realized from the strategic shift away from the Consumer Health business, coupled with incremental margin improvements expected from the previously announced closure of our Grand Prairie, Texas manufacturing site, to significantly enhance our operating results and drive stockholder value. We have incurred significant losses in each year since inception. Our net loss was $ 15. 8 million for the year ended June 30, 2024, and as of June 30, 2024, we had an accumulated deficit of $ 320. 0 million. We expect to continue to incur significant expenses in connection with our ongoing activities, although we do expect to become profitable through the continued growth of our commercial business. In light of our own business activities and external developments in the biotechnology and biopharmaceutical industries, Aytu management and our board of directors (the " Board " or the " Board of Directors ") regularly reviews our performance, prospects and risks such as the potential impact to our business resulting from the Company' s competitive landscape (i. e., entry of generic competitors, payer pressures, new branded entrants, etc.). These reviews have included consideration of potential partnerships, collaborations, and other strategic transactions such as acquisitions or divestitures of programs or technology to enhance stockholder value. Aytu' s management and Board continues to evaluate potential strategic transactions and business combinations. Recent Business Development As part of our ongoing strategic evaluation and go- forward operating plan, we continue to prioritize growing our Rx Segment given the encouraging prescription trends for our ADHD Portfolio and the current market trends supporting our products' growth. We believe focusing resources on our most profitable, growing products provides the most effective pathway to achieve companywide profitability and continued growth. As part of our plan, we began winding down the Consumer Health Segment in fiscal 2024 and completed the wind down of operations and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025. For fiscal 2024, our Rx Segment recorded net revenue of $ 65. 2 million. During the year, the ADHD market continued to encounter several supply chain interruptions, causing a shortage of medications for patients receiving stimulant prescriptions for the treatment of ADHD. We were able to continue to increase the production of our ADHD medications, Adzenys and Cotempla, to provide patients with alternative solutions to products that have experienced supply interruptions. As a result, we recorded the highest prescription levels for both Adzenys and Cotempla during fiscal 2024, resulting in $ 57. 8 million of net revenue for our ADHD Portfolio, the highest achieved in our history. We saw a reduction in net revenue from our Pediatric Portfolio products, largely due to payor changes impacting coverage and recusing prescriptions. To reduce the costs associated with the manufacture of Adzenys and Cotempla we transferred the manufacturing of these products to a United States- based third- party manufacturer in the fourth quarter of fiscal 2024. Prior to this, we manufactured these products in our facility in Grand Prairie, Texas. As an additional result of focusing on building the portfolio of revenue-generating products and generating profitability, in fiscal 2023 we indefinitely suspended active development of our clinical development programs including AR101 (enzastaurin) and terminated our license agreements relating to Healight and NT0502 (N- desethyloxybutynin). AR101 is a development- stage asset we had been developing as an investigational treatment for Vascular Ehlers- Danlos Syndrome (" VEDS "), a rare connective tissue disorder for which there are no approved treatments. AR101 has received Orphan Drug Designation from both the United States Food and Drug Administration (" FDA ") and from the European Commission, thus making AR101 eligible for market exclusivity upon product approval. AR101 also received Fast Track Designation from the FDA given the urgent, unmet need in VEDS. We do not expect the development of AR101 to advance until we are able to either fund development through operating cash flows, or through an out- license or sale to a strategic partner as we focus our resources on our commercial operations. Debt and Equity Financings Eclipse Agreement In June 2024, we and certain of our subsidiaries entered into a Consent, Joinder and Amendment No. 5 (the " Eclipse Amendment No. 5 ") to the loan and security agreement dated October 2, 2019, as amended by Amendment No. 1, dated March 19, 2021, Amendment No. 2, dated January 26, 2022, Amendment No. 3, dated June 1, 2022, Amendment No. 4 dated March 24, 2023, and the Eclipse Amendment No. 5 (together the " Eclipse Agreement ") with Eclipse Business Capital LLC (" Eclipse "), as agent, and the lenders party thereto (agent and such lenders, collectively, the " Eclipse Lender "). Under the Eclipse Amendment No. 5, we have two loan agreements, a term loan (the " Eclipse Term Loan ") and a revolving credit facility (the " Eclipse Revolving Loan "). The Eclipse Term Loan consists of a principal amount of $ 13. 0 million, at an interest rate of the secured overnight financing rate as administered by the SOFR Administrator (" SOFR ") plus 7. 0 %, with a four-year term and a straight- line loan amortization period of seven years, which would provide for a loan balance at the end of the four- year term of $ 5. 6 million to be repaid on June 12, 2028, the maturity date. We used the proceeds of the Eclipse Term Loan and a portion of the proceeds from warrant exercises described below to repay in full a $ 15. 0 million term loan. The Eclipse Revolving Loan allows us to borrow up to $ 14. 5 million at an interest rate of SOFR plus**

**4. 5 %. In addition, we are required to pay an unused line fee of 0. 5 % of the average unused portion of the maximum Eclipse Revolving Loan amount during the immediately preceding month. The ability to make borrowings and obtain advances of the Eclipse Revolving Loan remains subject to a borrowing base and reserve, and availability blockage requirements and the maturity date, as amended, is June 12, 2028. In June 2023, we raised gross proceeds of $ 4. 0 million from the issuance of (i) 1, 743, 695 shares of our common stock, and (ii) in lieu of common stock to certain investors that so chose, pre- funded warrants to purchase 430, 217 shares of common stock (the " June 2023 Pre- Funded Warrants ") and (iii), accompanying Tranche A warrants to purchase 2, 173, 912 shares of common stock at an exercise price of $ 1. 59 (the " Tranche A Warrants "), (iv) and accompanying Tranche B warrants to purchase 2, 173, 912 shares of common stock at an exercise price of $ 1. 59 (the " Tranche B Warrants "). We received $ 3. 4 million in proceeds net of underwriting fees and other expenses. In June 2024, the Tranche B Warrants were exercised, generating proceeds of $ 3. 5 million. The Tranche B Warrants were converted into 367, 478 shares of common stock and 1, 806, 434 " pre- funded " warrants to purchase shares of common stock with an exercise price of $ 0. 0001 per share (the " Tranche B Pre- Funded Warrants "). We used a portion of these proceeds as part of the $ 15. 0 million term loan repayment described above. Commercial Business Overview We operate through two business segments (i) the Rx Segment, consisting of various prescription pharmaceutical products sold through third parties, and (ii) the Consumer Health Segment, which consists of various consumer health products sold directly to consumers. We completed the wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025. We generate revenue by selling our products through third party intermediaries in our marketing channels as well as directly to our customers. We transitioned the manufacturing of our ADHD products to a third- party manufacturer during the fourth quarter of fiscal 2024 and continue to use third party manufacturers for all other products. Our Rx Segment consists of our ADHD Portfolio and our Pediatric Portfolio. Our prescription products are sold primarily in the United States and are distributed through multiple channels, including sales to pharmaceutical wholesalers, distributors and pharmacies, using third- party logistics enterprises. Our ADHD products are extended- release (" XR ") medications formulated in patient- friendly, orally disintegrating tablets (" ODT ") that utilize the internally developed microparticle modified- release drug delivery technology platform. Products containing amphetamine or methylphenidate are the most commonly prescribed medications in the United States for the treatment of ADHD. Adzenys (for patients six years of age and above) and Cotempla (for patients six to seventeen years of age) are the first and only FDA- approved amphetamine and methylphenidate extended- release, orally disintegrating tablets, respectively, for the treatment of ADHD. Our prescription Pediatric Portfolio includes Karbinal, an extended- release carbinoxamine (a first- generation antihistamine) suspension indicated to treat numerous allergic conditions for patients two years of age and above and Poly- Vi- Flor ® and Tri- Vi- Flor ®, two complementary prescription fluoride- based multi- vitamin product lines containing combinations of fluoride and vitamins in liquid and chewable tablet form for infants and children with fluoride deficiency (Karbinal, Poly- Vi- Flor and Tri- Vi- Flor are collectively the " Pediatric Portfolio "). These products serve established pediatric markets and offer distinct clinical features and patient benefits. We commercialize our Rx Portfolio through our internal commercial organization that includes approximately forty sales territories for our ADHD Portfolio and approximately five sales territories for our Pediatric Portfolio. Our Aytu RxConnect ™ patient support program operates through a network of approximately 1, 000 pharmacies to offer affordable, predictable copays and hassle- free availability to all commercially insured patients, regardless of their individual insurance plan. In addition, RxConnect seeks to significantly reduce the challenges and frustrations that health care professionals and their office staff can face when prescribing branded medications, including our medications, for their patients. In July 2023, we entered into an exclusive collaboration, distribution and supply agreement with Medomie Pharma Ltd (" Medomie "), a privately owned pharmaceutical company, for Medomie to sell Adzenys and Cotempla in Israel and the Palestinian Authority. We will supply Adzenys and Cotempla to Medomie, who will be responsible for seeking local regulatory approvals and marketing authorizations for each product. This agreement represents Aytu' s first international commercial agreement for Adzenys and Cotempla. Our Consumer Health Segment was dedicated to commercializing safe and effective " over- the- counter " (" OTC ") medicines, personal care products, and dietary supplements to improve health and vitality. Our core products competed in categories such as hair loss, digestive health, urological health, diabetes management, and allergy. The Consumer Health Segment sold directly to consumers primarily in the United States through e- commerce platforms, including branded websites and Amazon. com, which utilized marketing strategies focused on search engine optimization, search marketing and affiliate marketing. Additionally, the segment sold products through direct mail solicitations and advertisements, allowing consumers to purchase directly through business reply mail, through call centers, or online with shipment directly to their homes. In fiscal 2023, we announced we would wind down the Consumer Health Segment. We completed the wind down of the Consumer Health Segment and entered into a definitive agreement to effect the Consumer Health Divestiture in the first quarter of fiscal 2025. Development Portfolio – AR101 In April 2021, we entered into an asset purchase agreement with Rumpus VEDS, LLC, Rumpus Therapeutics, LLC, and Rumpus Vascular, LLC (together " Rumpus ") pursuant to which we acquired commercial global licenses, relating primarily to the pediatric- onset rare disease development asset enzastaurin, or AR101. AR101 is initially being developed for the treatment of VEDS with the potential to treat other connective tissue disorder diseases such as Marfan' s syndrome. AR101 is an orally available investigational first- in- class small molecule, serine / threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways. AR101 has been studied in more than 3, 300 patients across a range of solid and hematological tumor types in trials previously conducted by Eli Lilly & Company. Harry " Hal " C. Dietz III, M. D. developed the first preclinical model that mimics the human condition and recapitulates VEDS, and this model serves as**

**the basis for the plausible clinical benefit and rationale for conducting a clinical trial with AR101 in VEDS. This novel knock- in mouse model has the same genetic mutation most prevalent in VEDS patients and is representative of the human condition in both the timing and location of VEDS- related vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that vascular structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high- throughput RNA sequencing of the aorta displayed a molecular signature for excessive PKC / ERK cell signaling that is the purported driver of disease. PKC inhibitors proved efficacious in multiple pre- clinical and murine models and indeed prevented death due to vascular rupture. We have secured exclusive global rights to AR101 in the field of connective tissue disorders with the initial license covering VEDS. AR101 is protected by a suite of pending patents being pursued in major markets globally which have been licensed from The Johns Hopkins University (" Johns Hopkins ") and have an earliest priority date of March 2017. In December 2021, the FDA granted Orphan Drug Designation (" ODD ") to AR101 for the treatment of EDS, inclusive of VEDS, allowing for seven years of marketing exclusivity in the United States. The FDA has cleared the IND application for AR101, although, we do not expect to advance development of AR101 until we are able to either fund development through operating cash flows or through an out- license or sale to a strategic partner. Strategy Our goal is to become a leading pharmaceutical company that improves the lives of patients. We will do this by employing a focused approach of in- licensing, acquiring, developing, and commercializing novel prescription therapeutics. Our primary focus is on commercializing innovative prescription products that address conditions frequently developed or diagnosed in childhood, including ADHD. Our strategic priorities are to continue to increase revenues from our Rx Segment and enhance our financial performance through operational and manufacturing efficiencies and portfolio prioritization. Specifically, we intend to: ● continue to grow our commercial branded, revenue- generating products, by increasing product sales and improving patient access. Our primary commercial objective is to drive revenue growth of our brands, which consist primarily of Adzenys, Cotempla, Karbinal, Poly- Vi- Flor and Tri- Vi- Flor. We expect to increase market share using our internal commercial organization and leveraging our advanced analytics platform to increase prescribing our medicines; ● leverage our novel Aytu RxConnect patient support platform, which is designed to reduce access barriers to medicines facing patients and HCPs by providing coverage for all commercially insured patients, regardless of their individual insurance plan, thus establishing an affordable and predictable monthly co- pay for patients, and eliminating many of the hassles facing HCPs and their staffs by improving availability of Aytu products at participating pharmacies; and ● improve gross margins for our ADHD product franchise through the manufacturing transfer of Adzenys and Cotempla to a contract manufacturing organization, a transition that was completed in the fourth quarter of fiscal 2024. We believe our history of acquiring companies and in- licensing and acquiring products and pipeline assets, along with our success in building out commercial organizations and executing product growth strategies, is a distinct competitive advantage. Our transactional adeptness and execution orientation enable us to continue to seek growth opportunities through both organic growth and opportunistic in- licensing or strategic acquisitions. Further, our commercial infrastructure and advanced analytics capability is scalable and lends itself to additional on- market assets and future product candidates that fit within our commercial capabilities and infrastructure. As such, in the near term, we may seek to leverage our commercial model and infrastructure by expanding our commercial portfolio with external product opportunities as we have done since our inception. Products and Markets Prescription Products: ADHD Portfolio ADHD Market and Treatment Options ADHD is a neurobehavioral disorder characterized by a persistent pattern of inattention and / or hyperactivity / impulsivity that interferes with functioning and / or development. ADHD can have a profound impact on an individual' s life, causing disruption at school, work, home and in relationships. It is one of the most common developmental disorders in children and often persists into adulthood. The Centers for Disease Control and Prevention (" CDC ") reported that six million children in the United States ages 3 to 17 had previously received an ADHD diagnosis between 2016- 2019, up 36 % since 2003. Current ADHD treatment guidelines recommend a multi- faceted approach that uses medications in conjunction with behavioral interventions. In 2023, approximately 96. 0 million prescriptions for medications with ADHD labeling were written in the United States, generating $ 27. 4 billion in sales. Approximately 89 % of these prescriptions were for stimulant medications, such as amphetamine and methylphenidate, which are and have remained the standard of care for several decades. The market for ADHD medications outside of the United States is less developed, but we believe it will continue to grow as recognition and awareness of the disorder increase. Extended- release, or long- acting, dosage forms of stimulant medications are the standard of care for treating ADHD, making up approximately 59 % of ADHD prescriptions. The most prescribed extended- release medications for ADHD, Adderall XR ® and Concerta ® (and each of their generic equivalents), are long- acting versions of previously short- acting amphetamine and methylphenidate medications, respectively. Most of these extended- release dosage forms allow for once- daily dosing in the morning, which eliminates the need to re- dose during the day. Our products, Adzenys XR- ODT and Cotempla XR- ODT, are extended- release orally disintegrating tablets that allow for once- daily dosing based upon our internally developed proprietary microparticle delivery technology and are the only approved extended- release orally disintegrating tablet formulations of amphetamine and methylphenidate for the treatment of ADHD. There is significant competition in the ADHD market, including from well- established companies, many of whom have substantially greater financial, technical and commercial resources than we do, and entrenched existing ADHD products. For example: ● Extended- release amphetamine products are currently marketed in the United States by (i) Takeda Pharmaceutical Company Limited under the brand names Adderall XR ®, Vyvanse ® and Mydayis ® and (ii) Tris Pharma, Inc. (" Tris "), under the brand names Dyanavel ® XR, Dyanavel ® XR tablets; ● Extended- release methylphenidate products are marketed in the United States by (i) Janssen Pharmaceuticals, Inc. under the brand name Concerta ®, (ii) Tris under the brand**

**names Quillivant XR ® and QuilliChew ER ®, (iii) Rhodes Pharmaceuticals LP under the brand name Aptensio XR ®, (iv) Ironshore Pharmaceuticals Inc. under the brand name Jornay PM ®, (v) Alora Pharmaceuticals under the name Methylphenidate HCl ER 72 mg Tablets, (vi) Novartis under the brand names Focalin XR ® and Ritalin LA ® and (vii) Azstarys ®, a product developed by KemPharm (now Zevra Therapeutics) and sold by Corium; and ● A non- stimulant treatment for ADHD was approved by the FDA and commercially launched by Supernus in the United States in 2021 is being sold under the brand name Qelbree ®. Other branded and generic non- stimulant treatments remain available in the United States but are no longer promoted. Further, makers of branded drugs could also enhance their own formulations in a manner that competes with our enhancements of these drugs. We are also aware of efforts by several pharmaceutical companies with ADHD medications in clinical development, including Cingulate Therapeutics, NLS Pharma, Tris Pharma and Neurovance, a subsidiary of Otsuka Pharmaceutical Co., Ltd. ADHD Product Portfolio Overview Our modified- release drug delivery technology platform has enabled us to create extended- release ODT formulations of amphetamine and methylphenidate. This was achieved by developing an extended- release profile that allows for once daily dosing and an ODT formulation that allows for easier administration and ingestion and twelve- hour duration of action. Adzenys and Cotempla are the first and only XR- ODT products for the treatment of ADHD. These XR- ODT products offer unique attributes to ADHD patients and caregivers, including: ● ease of administration and ingestion because they disintegrate rapidly in the mouth and may be taken without water; ● taste- masking of bitter ADHD medications, with pleasant- tasting flavor; and ● prevention of " cheeking, " the practice of hiding medication in the mouth and later spitting it out rather than swallowing it. Adzenys XR- ODT: Amphetamine XR- ODT for the treatment of ADHD Adzenys is approved by the FDA for the treatment of ADHD in patients six years and older and is the first FDA- approved amphetamine XR- ODT for the treatment of ADHD. The New Drug Application (" NDA ") for Adzenys relies on the efficacy and safety data that formed the basis of FDA approval for the reference listed drug, Adderall XR, 30 mg, together with bioequivalence, bioavailability, and aggregate safety data from the Adzenys clinical program. Adzenys contains amphetamine loaded onto a mixture of immediate- release and polymer- coated delayed- release resin particles, which are formulated and compressed into an ODT along with other tableting excipients using our patented Rapidly Disintegrating Ionic Masking (" RDIM ") technology. The result is amphetamine with an in vivo extended- release profile delivered through a tablet that quickly disintegrates in the mouth without the need for water. Adzenys is available in 30- day supply, child- resistant blister packs. The suite of composition- of- matter patents for Adzenys are scheduled to expire in 2026 and 2032. These patents are listed in the FDA' s publication of approved drug products with therapeutic equivalence evaluations (the " Orange Book "). In addition, we entered into a settlement agreement with Actavis Laboratories FL, Inc. (" Actavis ") (acquired by Teva Pharmaceutical Industries), which resolved all ongoing litigation involving Adzenys patents and Actavis' ANDA with the FDA for a generic version of Adzenys. Under the agreement with Actavis, Actavis has the right to manufacture and market its approved generic version of Adzenys under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. In conjunction with the approval of the Adzenys NDA, the FDA has required us to conduct certain clinical studies in preschool (age four to five years) children with ADHD as a post- marketing requirement. A pharmacokinetic study in this population was completed in 2018, and we are in discussions with the FDA to further clarify the design protocols required to conduct the remaining studies. Cotempla XR- ODT: Methylphenidate XR- ODT for the treatment of ADHD The FDA approved Cotempla for the treatment of ADHD in patients six to seventeen years old. The Cotempla NDA relies on the efficacy and safety data that formed the basis of FDA approval for the reference listed drug, Metadate CD ®, together with bioavailability / bioequivalence data and efficacy / safety data from the Cotempla clinical program. The results of the Cotempla Phase 3 clinical efficacy and safety trial showed a statistically significant improvement in ADHD symptom control compared to placebo across the school day. Onset of effect was observed within one- hour post- dose and persisted through 12 hours. No serious adverse events were reported during the study, and the adverse event profile was consistent with the drug' s mechanism of action. Cotempla contains methylphenidate loaded onto a mixture of immediate- release and polymer- coated delayed- release resin particles, which are formulated and compressed into an ODT along with other tableting excipients using our RDIM technology. The result is methylphenidate with an in vivo extended- release profile delivered through a tablet that quickly disintegrates in the mouth. Cotempla is available in 30- day supply, child- resistant blister packs. Cotempla is the first FDA- approved methylphenidate XR- ODT for the treatment of ADHD. We hold composition- of- matter patents in the United States which we expect will provide Cotempla intellectual property protection until 2032, and a method- of- use patent was issued which extends protection to 2038. These patents are listed in the Orange Book. In addition, we entered into a settlement agreement with Teva Pharmaceuticals USA, Inc. (" Teva "), which resolved all ongoing litigation involving the Cotempla patents and Teva' s ANDA with the FDA for a generic version of Cotempla. Under the agreement with Teva, we granted Teva the right to manufacture and market its approved generic version of Cotempla under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. In conjunction with the approval of the Cotempla NDA, the FDA required us to perform additional clinical studies in preschool (age four to five years) children with ADHD as a post- marketing requirement. A pharmacokinetic study in this population was completed in 2019. In light of a new draft guidance for industry that was published in May 2019, " Attention Deficit Hyperactivity Disorder: Developing Stimulant Drugs for Treatment Guidance for Industry, " we remain in discussions with the FDA to gain concurrence on the design of the protocols required to meet the remaining post- marketing requirements. Prescription Products: Pediatric Portfolio Karbinal: Extended release carbinoxamine oral suspension for the treatment of seasonal and perennial allergies Karbinal ® ER (carbinoxamine maleate extended- release oral suspension) is an H1 receptor antagonist (antihistamine) indicated to treat seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant**

**allergens and food, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled, and amelioration of the severity of allergic reactions to blood or plasma for patients two years of age and above. More than 100 million people in the United States experience various types of allergies each year. Allergic conditions are one of the most common health issues affecting children in the United States. Numerous allergy treatments exist to address allergies and allergic symptoms depending upon the symptom (s). Oral antihistamines are considered a mainstay of allergy treatment, and the prescription antihistamine market is a large category with approximately 54 million antihistamine prescriptions written in 2023. The prescription antihistamine category is dominated by generic products and consists of first- generation and second- generation molecules. Generally, first-generation antihistamines block both histaminic and muscarinic receptors and pass the blood- brain barrier. Second-generation antihistamines mainly block histaminic receptors, but they do not pass the blood- brain barrier. First-generation antihistamines, which are generally characterized as more sedating, accounted for 6 % of 2023 total prescriptions, while non- sedating, second- generation antihistamines accounted for 94 % of total prescriptions. The most widely prescribed oral, second- generation antihistamines are cetirizine (brand name Zyrtec ®) and loratadine (brand name Claritin ®). Diphenhydramine (brand name Benadryl ®) is the most widely prescribed first- generation molecule. Karbinal is the only FDA- approved, 12- hour carbinoxamine oral suspension and is an effective antihistamine with a broad range of indications. Karbinal is positioned as a second- line allergy treatment for patients who continue to suffer from allergic symptoms following initial treatment with a second- generation, non- sedating antihistamine. Further, as Karbinal is an oral suspension formulation, children are the primary target patient given their preference for liquid treatments and, in many cases, their inability to swallow tablets or capsules. Karbinal is indicated for children as young as two years of age. Karbinal has a pleasant strawberry- banana taste and is available in 480 mL bottles. Through a supply and distribution agreement with Tris, we own exclusive rights to distribute Karbinal in the United States through August 2032, unless the agreement is terminated earlier pursuant to the termination provisions in the agreement. As part of the agreement, we pay sales- based royalties based on net revenue. Additionally, we are committed to making annual minimum payments to Tris through August 2025. Two core patents protect Karbinal in the United States, and both patents are listed in the FDA' s Orange Book. The first patent describes a coated drug- ion exchange resin complex comprising a core composed of a drug complexed with a pharmaceutically acceptable ion- exchange resin. The priority date for this family is March 29, 2009, so the standard 20- year exclusivity for this patent will expire in 2029. The second patent describes an aqueous liquid suspension containing a coated drug- ion exchange resin complex comprising a core molecule complexed with a pharmaceutically acceptable ion- exchange resin and an uncoated ion exchange resin complex. The priority date for this family is June 15, 2007, so the standard 20- year exclusivity for this patent will expire in 2027. Along with second- generation prescription oral antihistamines, Karbinal also faces competition from OTC products such as non- sedating antihistamines, sedating antihistamines as well as nasal steroids, nasal antihistamines, and anticholinergics. Poly- Vi- Flor and Tri- Vi- Flor: Our fluoride- based multivitamin prescription supplement product line for infants and children Poly- Vi- Flor and Tri- Vi- Flor are two complementary prescription fluoride- based supplement product lines containing combinations of vitamins and sodium fluoride in various oral formulations. These prescription supplements are prescribed for infants and children to treat or prevent fluoride deficiency due to poor diet or low levels of fluoride in drinking water and other sources while also providing multi- vitamin support and folic acid supplementation. Because these products contain at least. 25 mg of sodium fluoride, Poly- Vi- Flor and Tri- Vi- Flor are classified as products that should be administered under the supervision of a licensed prescriber. Fluoride supplementation has been proven to protect teeth from decay. Community water fluoridation prevents tooth decay by providing frequent and consistent contact with low levels of fluoride. By keeping the teeth strong and solid, fluoride stops cavities from forming and can rebuild the tooth' s surface. Community water fluoridation began in the United States in 1945 and as of 2016, more than 200 million people, or nearly 3 in 4 Americans who use public water supplies, drank water with enough fluoride to prevent tooth decay. However, Americans living in municipalities that do not fluoridate the water supply or in rural areas that rely on well water supplies frequently do not receive recommended levels of fluoride through fluoridation. Therefore, many children living in these areas often require daily fluoride supplementation as part of their mineral and vitamin intake. In many instances, physicians prescribe fluoride- based multi- vitamins (Vitamins A, B, C, D and folic acid) regularly to supplement their fluoride intake and enable convenient supplementation. Infants are prescribed easier- to- take multi- vitamin drops while older children are prescribed tablet formulations. In 2023, 7. 1 million multi- vitamin prescriptions were written in the United States. Of those prescriptions, multi- vitamins containing sodium fluoride accounted for 0. 9 million total prescriptions. Common multi- vitamin combinations contain vitamins A, B, C, D and E, but no other prescription pediatric multi-vitamin products contain Metafolin, which makes the Poly- Vi- Flor and Tri- Vi- Flor product lines distinct, single-source brands. Other brands include Tri- Vite (marketed by Method Pharmaceuticals), Floriva (marketed by BonGeo Pharmaceuticals) and Quflora (marketed by Carwin Pharmaceutical Associates). Poly- Vi- Flor is available in both chewable tablet and oral liquid suspension multivitamin formulations in six different product presentations: Poly- Vi-Flor Chewable Tablets. 25 mg,. 50 mg, and 1 mg tablets, Poly- Vi- Flor Chewable Tablets with Iron, Poly- Vi- Flor Oral Suspension and Poly- Vi- Flor Oral Suspension with Iron. Poly- Vi- Flor contains Vitamin A, Vitamins B1, B2, B3, and B6, Vitamin C, Sodium Fluoride in various doses and Metafolin, a proprietary, trademarked L- methylfolate form of folic acid developed by and licensed from Merck & Cie (" Merck "). Beginning in the second half of fiscal 2023, we introduced Poly- Vi- Flor and Tri- Vi- Flor containing Arcofolin, Arcofolin offers an improved profile over Metafolin as a body ready L- methylfolate. Arcofolin' s low water content and low molecular weight of the counterion yield higher**

**levels of assayed folate than other forms of L- methylfolate currently available on the market. It also has an improved purity profile, enhanced water solubility and an excellent overall stability profile. The addition of Arcofolin also broadens the brands' IP protection and extends the patent life and provides further differentiation with this novel ingredient. Tri- Vi- Flor is available as an oral liquid suspension (. 25 mg fluoride) containing Vitamin A, Vitamin C, Vitamin D3, Sodium Fluoride, Sodium Benzoate and L- methylfolate. By virtue of its L- methylfolate content, Tri- Vi- Flor offers a similar clinical profile: a fluoride- based multivitamin containing a proprietary, body- ready L- methylfolate. Arcofolin ®, which we also licensed exclusively in our field of use, is Merck' s manufactured calcium salt of L- 5- methyltetrahydrofolic or L- methylfolate. Arcofolin is a ' body ready' alternative to folic acid and offers good stability, solubility, and bioavailability. Folic acid supplementation is recommended in various patient groups, but a significant number of patients have difficulty metabolizing folate due to an enzymatic deficiency caused by a genetic mutation affecting the enzyme methylenetetrahydrofolate reductase, or MTHFR. MTHFR converts ingested folate (such as supplemented folic acid) into L- methylfolate, the body' s usable form. Clinical studies have demonstrated that 75 % of patients may have at least one MTHFR genetic mutation while 40 % may have two mutations. These mutations lead to impaired function of the enzyme and result in folate deficiency. Both Arcofolin and Metafolin are unaffected by the MTHFR mutation, thereby directly delivering bioavailable L- methylfolate, and offering a distinct clinical advantage over other folic acid supplements. The core family of patent covering Arcofolin has a priority date of March 31, 2017 and describes a crystalline sodium salt of 5- methyl- (6S)- tetrahydrofolic acid wherein the molar ratio of 5- methyl- (6S)- tetrahydrofolic acid to sodium is from 1: 0. 5 to 1: 1. 5 (in mol / mol) and / or hydrates and / or solvates thereof, as well as a process of obtaining the same. Upon issuance, the standard 20- year exclusivity for this patent would expire in 2037. The prescription multi- vitamin market is dominated by generic products, with brands accounting for 12. 3 % of the multivitamin plus fluoride market for the calendar year ending December 31, 2023. Poly- Vi- Flor and Tri- Vi- Flor primarily compete in the generic prescription multi- vitamin fluoride market and with the branded products FLORIVA and QFLORA. Manufacturing During fiscal 2024 we completed the process of transferring the manufacturing of our ADHD products to a United States- based contract manufacturing organization (" CMO "). The transfer of the manufacturing of pharmaceutical products required several steps including knowledge and method transfer, manufacturing of materials for feasibility studies and confirmation batch materials, bioequivalence studies, inspections from regulatory agencies, and regulatory filings. We completed the required steps, including the successful completion of bioequivalence studies, which were required in order to enable the transfer of both Adzenys and Cotempla. Our CMO started manufacturing both Adzenys and Cotempla during the third quarter of the 2024 fiscal year and will manufacture all of our ADHD products going forward. We are responsible for supplying the active pharmaceutical ingredients for the ADHD products to our CMO. Our CMO is responsible for manufacturing the products, conducting quality control, quality assurance, validation activities, stability testing, packaging and providing related services for the manufacture of the products. We are required to purchase all of our ADHD products from them, with certain exceptions. Our agreement with this CMO has an initial term beginning in November 2023, and ending in November 2028, and automatically renews after the initial term for successive terms of three years, with certain termination rights for both parties as outlined in the agreement Pediatric Product Portfolio We contract with CMOs for the manufacture and testing of our Pediatric Portfolio products. We have entered into the following key supply agreements for the commercial manufacture and supply of certain of these products: ● Karbinal is purchased through a supply agreement with Tris. This agreement terminates in August 2033, subject to earlier termination or extension in accordance with the terms of the agreement. ● Poly- Vi- Flor and Tri- Vi- Flor drops are purchased through supply agreements with CMOs based in the United States. Merck & Cie is responsible for providing Metafolin and Arcofolin to our designated CMO. We believe the third- party manufacturers have adequate capacity to manufacture sufficient quantities of our products to meet anticipated commercial demands. As we rely on CMOs, we continue to employ personnel with extensive technical, manufacturing, supply chain management, analytical and quality experience to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions. Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, and which govern record- keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among other activities. Our systems and our contractors are required to comply with these regulations, and we assess this compliance regularly through monitoring of performance and a formal audit program. Research and Development We have indefinitely suspended product candidate research and development activities in order to focus our resources on our commercialization efforts. Due to the suspension of product candidate research and development, the development of AR101, our lead product candidate, is on indefinite hold. We are pursuing strategic partnerships in order to advance this program but can make no assurance that a partnership will be consummated. Our Development Pipeline: AR101 (enzastaurin for the treatment of Vascular Ehlers- Danlos Syndrome (VEDS)) AR101 (enzastaurin) is an orally available investigational first- in- class small molecule, serine / threonine kinase inhibitor of the protein kinase C (" PKC ") beta, PI3K and AKT pathways. AR101 has been studied in more than 3, 300 patients across a range of solid and hematological tumor types. AR101 was originally developed by Eli Lilly and Company (" Lilly "), and worldwide rights were acquired by Denovo Biopharma in September 2014 following Lilly' s discontinuation of the enzastaurin development program. VEDS is a rare genetic disorder typically diagnosed in childhood and characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. VEDS is the severe subtype of Ehlers- Danlos Syndrome, affecting 1 in 50, 000 people worldwide. VEDS results from pathogenic variants in the COL3A1 gene, which encodes the chains of type III procollagen, a major protein in vessel walls and hollow organs. Twenty- five percent of VEDS patients have a first complication by the age of 20 years, and more than 80 percent have at least one complication by the age of 40.**

**VEDS patients have a median lifespan of 51 years. There are currently no FDA approved treatments for VEDS. The research underpinning the application of enzastaurin for the treatment of VEDS has been conducted by Dr. Harry (Hal) Dietz and his research colleagues. Dr. Dietz is the Victor A. McKusick Professor of Genetics in the departments of medicine, pediatrics, and molecular biology and genetics at The Johns Hopkins University School of Medicine and director of the William S. Smilow Center for Marfan Syndrome Research. He has also been an investigator at Howard Hughes Medical Institute since 1997. Dr. Dietz is a leading scientist in the field of genetic connective tissue disorders and developed the first preclinical model that mimics the human condition and recapitulates VEDS. His group' s research findings were published in the Journal of Clinical Investigation in February 2020. The VEDS knock- in murine preclinical model from Dr. Dietz has the same genetic mutation most prevalent in VEDS patients and is representative of the human condition in both the timing and location of vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high- throughput RNA sequencing of the aorta displayed a consistent molecular signature for excessive PKC / ERK cell signaling that is now known to be the driver of disease. Based on the scientific rationale for intervention along the PKC / ERK pathway, PKC inhibition and treatment with PKCβ inhibitors proved efficacious in multiple pre- clinical and murine studies and indeed prevented death due to vascular rupture. In fiscal 2022 we received Orphan Drug Designation for AR101 in Ehlers- Danlos Syndrome including VEDS and in Europe, allowing for seven years' marketing exclusivity in the United States and ten years in Europe. We also received Fast Track designation for AR101 in VEDS by the FDA, allowing for an accelerated review timeline upon submission of the New Drug Application (" NDA ") and more frequent interaction with the FDA during the development process. AR101 is protected by a suite of five pending patents being pursued in major markets globally which have been licensed from Johns Hopkins and have an earliest priority date of March 2017. The cornerstone of the intellectual property family surrounds enzastaurin initially targeting the treatment of VEDS focused on the United States and certain foreign jurisdictions which include Europe, Japan, China, Brazil, Mexico, Canada, Israel, Australia, New Zealand and South Korea. This pending patent provides compositions and methods for treating VEDS and associated connective tissue disorders and has a priority date of October 2018. The second pending patent provides methods and compositions for the diagnosis, treatment, and prevention of Marfan syndrome and related diseases, disorders and conditions and has a priority date of March 2017, in select geographies. The third pending patent, titled " Targeted Epigenetic Therapy for Inherited Aortic Aneurysm Conditions, " broadens the coverage of the potential therapeutic application of AR101 / Enzastaurin and has a priority date of September 2017. The fourth pending patent, titled " Pathway Targets for the Treatment of Vascular Ehlers- Danlos Syndrome ", and the fifth pending patent, titled " Endothelin- 1 Signaling Contributes to Vascular Rupture Risk ", deepens the scientific evidence of the pathophysiology of Vascular Ehlers- Danlos Syndrome and are highly confirmatory of the therapeutic approach for AR101 / Enzastaurin. These pending patents have priority dates of September 2020 and February 2022 respectively. Additional molecule specific intellectual property is afforded through the license with Denovo whose pending patent provides methods and compositions for the prediction of the activity of enzastaurin and has a priority date of September 1, 2016. We seek trademark protection in the United States when appropriate. We currently own or license registered trademarks for Aytu, Aytu BioPharma, Aytu RxConnect, Neos Therapeutics, Adzenys, Adzenys ER, Adzenys XR- ODT, Cotempla, Cotempla XR- ODT, Karbinal, Poly- Vi- Flor and Tri- Vi- Flor in the United States, as well as trademarks related to our DTRS technology. From time to time, we may find it necessary or prudent to obtain licenses from third party intellectual property holders. Government Regulation We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The FDCA and the FDA' s implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record- keeping, reporting, distribution, import, export, sale, advertising and promotion of our products and product candidates. We may seek approval for, and market, our products in other countries in the future. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Development and Approval Under the FDCA, FDA approval of an NDA is required before any new drug can be marketed in the United States. NDAs in the case of new drugs may require extensive studies and submission of a large amount of data by the applicant, including the following: Preclinical Testing Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the toxicity and dosing of the product. Clinical Trials Clinical trials involve the administration of a drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. ● Phase 1 clinical trials involve the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to evaluate the safety, metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. ● Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population and are designed to develop initial data regarding the product' s effectiveness, to determine dose response and the optimal dose range, and to gather additional information relating to safety and potential adverse effects (" AEs "). ● Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug' s overall risk- benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, multi- site, large- scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug at the proposed dosing regimen. Phase 3 data often form the primary basis on which**

**the FDA evaluates a drug' s safety and effectiveness when considering the product application. Post- Approval Regulation Once approved, drug products are subject to continuing regulation by the FDA. If ongoing regulatory requirements are not met or if safety or manufacturing problems occur after the product reaches the market, the FDA may at any time withdraw product approval or take actions that would limit or suspend marketing. Additionally, the FDA may require post- marketing studies or clinical trials, changes to a product' s approved labeling, including the addition of new warnings and contraindications, or the implementation of other risk management measures, including distribution- related restrictions, if there are new safety information developments. DEA Regulation Our ADHD products are considered a " controlled substance " as defined in the Controlled Substances Act of 1970, or CSA, because Adzenys contains amphetamine and Cotempla contains methylphenidate. Because amphetamine and methylphenidate are Schedule II controlled substances, the DEA has Adzenys and Cotempla listed and regulated as Schedule II controlled substances. None of our pediatric products (Karbinal, Poly- Vi- Flor and Tri- Vi- Flor) are considered " controlled substances. " Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in and / or imported into the United States- based on the DEA' s estimate of the quantity needed to meet legitimate scientific and medicinal needs. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our manufacturers' quotas of an active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay, limitation or refusal by the DEA in establishing our manufacturers' quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, financial position and results of operations. Individual states also independently regulate controlled substances. We and our manufacturers will be subject to state regulation on distribution of these products, including, for example, state requirements for licensures or registration. Additionally, we use third- party logistics firms to inventory and fill sales orders for our commercial portfolio. Human Capital As of September 16, 2024, we employed 102 employees, of which 99 were full- time employees. Of our 102 employees, 14 are involved in operations, 58 are involved in commercialization and 30 are involved in general and administrative activities. All of our colleagues are located in the United States. Of these colleagues, 50 % are female and 50 % are male. Our colleagues are not represented by a labor union. Our values – team- oriented, hard- working, relentlessly determined, integrity, visionary, entrepreneurial, and servant- minded – are built on the foundation that the colleagues we hire and the way we treat one another promote innovation, and high productivity, which spur our success. This culture depends in large part on our ability to attract, retain and develop a diverse population of talents and high- performing employees at all levels of our organization. Providing market competitive pay and benefit programs, opportunities to participate in the success they help create, while engaging colleagues in important dialogue regarding organization performance, we create a culture of inclusion in which all colleagues have the opportunity to thrive. Available Information Our principal executive offices are located at 7900 East Union Avenue, Suite 920, Denver, Colorado 80237, and our phone number is (720) 437- 6580. We maintain a website on the internet at https: / / aytubio. com. We make available, free of charge, through our website, by way of a hyperlink to a third- party site that includes filings we make with the United States Securities and Exchange Commission (" SEC ") website (www. sec. gov), our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K and amendments to those reports electronically filed or furnished pursuant to Section 15 (d) of the Exchange Act. The information on our website is not, and shall not be deemed to be, a part of this Annual Report or incorporated into any other filings we make with the SEC. In addition, the public may read and copy any materials we file with the SEC at the SEC' s Public Reference Room at 100 F Street, N. E., Washington D. C., 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1- 800- SEC- 0330. Code of Ethics We have adopted a written code of ethics that applies to our officers, directors, and employees, including our principal executive officer and principal accounting officer. We intend to disclose any amendments to, or waivers from, our code of ethics that are required to be publicly disclosed pursuant to rules of the SEC by filing such amendment or waiver with the SEC. This code of ethics and business conduct can be found in the corporate governance section of our website, https: / / investors. aytubio. com / corporate- governance # CorporateGovernance. ITEM 1A. RISK FACTORS Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in this Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our securities to decline and could cause you to lose all or part of your investment.** We have incurred losses in each year since our inception. ~~As of the filing of this Annual Report on Form 10- K, there is a substantial doubt regarding our ability to continue as a going concern.~~ Our net loss for the years ended June 30, **2024, and** 2023 **,** ~~and 2022~~ was $ **15. 8 million and $** 17. 1 ~~million and $ 108. 8~~ million, respectively. We have not demonstrated the ability to be a profit- generating enterprise to date. Even though we expect to have revenue growth in the next several fiscal years, it is uncertain that the revenue growth will be significant enough to offset our expenses and generate a profit in the future. Potential investors should evaluate us in light of the expenses, delays, uncertainties, and complications typically encountered by healthcare businesses, many of which will be beyond our control. These risks include the following: ● uncertain market acceptance of our products; ● difficulties in maintaining coverage and reimbursement for our products; ● lack of sufficient capital; ● **United States** ~~U. S.~~ 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** ~~ourexpectations~~ **expectations** concerning future operations, which is difficult to forecast accurately based on our historical strategy of product and / or business acquisition to develop our product and business portfolio. We may be unable to adjust spending in a timely manner to compensate for any unexpected budgetary shortfall. To obtain revenues from our products, we must succeed, either alone or with others, in a range of challenging activities, including expanding markets for our existing products, manufacturing, marketing and selling our existing products, satisfying any post- marketing requirements, and obtaining reimbursement for our products from private insurance or government payors. We, and our collaborators, as applicable, may not be successful in these activities and, even if we or our collaborators do, we may never generate revenues that are sufficient to achieve profitability. ~~We have not established sources of ongoing revenue sufficient to cover operating costs and allow us to continue as a going concern.~~ Since our inception, we have had significant operating losses. As of June 30, ~~2023~~ **2024**, we had accumulated deficit of $ ~~304~~ **320**. ~~1~~ **0** million. Even though **during fiscal 2024** we ~~plan to mitigate~~ **mitigated** the conditions that **gave** ~~raise~~ **rise to** substantial doubt about our ability to continue as a going concern, we may continue to incur net losses, and our ability to generate positive cash flows from operating activities is uncertain for the foreseeable future. We have not established an ongoing source of revenue sufficient to cover operating costs. Our ability to continue as a going concern is dependent on our continued operational improvements, refinancing, or obtaining adequate capital to fund operating losses until we become profitable. If we are unable to generate sufficient cash flows or obtain adequate capital, we may be unable to develop and commercialize our product offerings and we could be forced to cease operations. We may need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our **growth** ~~product expansion~~ 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, ~~2023~~ **2024**, our cash and cash equivalents totaled $ ~~23~~ **20**. 0 million. During the year ended June 30, ~~2023~~ **2024**, we ~~raised approximately~~ **received $ 13. 0 million of proceeds from the Eclipse Term Loan and $ 3. 6 million of proceeds from the exercise of warrants, a portion of which was used for the repayment of a** $ 15. ~~6~~ **0** million **term loan**, **which was replaced by the Eclipse Term Loan** ~~net of fees, from a combination of common stock offerings~~. 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 ~~23funds~~ **funds** through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or products or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be unable to expand the market for our products or expand our operations generally or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. We ~~may not~~ have ~~cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. We have~~ a $ ~~15~~ **13**. 0 million term loan ~~with Avenue Capital~~ and up to $ 14. 5 million of secured revolving loans with **the** Eclipse **Lender**. As of June 30, ~~2023~~ **2024**, $ ~~1~~ **2**. ~~6~~ **4** million was outstanding under the secured revolving loan. All obligations under our loans are secured by substantially all of our existing property and assets subject to certain exceptions. These debt financings and any future debt financings may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our debt agreements. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our products or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, and finance our operations and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail, or eliminate one or more of our programs. Failure to satisfy our current and future debt obligations under our loan agreements with **the** ~~Avenue Capital or~~ Eclipse **Lender** could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under one or both of our debt agreements

as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness. The ~~terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility. The~~ loan agreements with **the** ~~Avenue Capital and~~ Eclipse **Lender** subject us to financial covenants and restrictions on our ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of the lender. Failure to comply with such covenants could permit the lenders to declare our obligations under the loan agreements, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. **We are actively** ~~24We recently announced that we have been~~ engaged in discussions ~~with various parties~~ regarding **a** potential strategic ~~transactions~~ **transaction** ~~and potential financing options~~. There can be no assurance that this process will result in the pursuit or consummation of any potential transaction ~~, or that any such potential transaction, if implemented, will provide sufficient funding to continue our operations~~. We ~~recently announced that we~~ are engaged in discussions ~~with various parties~~ regarding **a** potential strategic ~~transactions~~ **transaction** ~~and potential financing,~~ which could include a ~~financing,~~ sale or licensing of assets, acquisition, merger, business combination, and / or other strategic transaction or series of related transactions. This process, including any uncertainty created by this process, involves a number of risks which could impact our business and our stockholders, including the following: ● significant fluctuations in our stock price could occur in response to developments relating to the process or market speculation regarding any such developments; ● we may encounter difficulties in hiring, retaining and motivating key personnel during this process or as a result of uncertainties generated by this process or any developments or actions relating to it; ● we may incur substantial increases in general and administrative expense associated with increased legal fees and the need to retain and compensate third- party advisors; and ● we may experience difficulties in preserving the commercially sensitive information that may need to be disclosed to third parties during this process or in connection with an assessment of our strategic options. The review process also requires significant time and attention from management, which could distract them from other tasks in operating our business or otherwise disrupt our business. Such disruptions could cause concern to our suppliers, strategic partners or other constituencies and may have a material impact on our business and operating results and volatility in our share price. There can be no assurance that this process will result in the pursuit or consummation of any potential transaction or strategy, or that any such potential transaction or strategy, if implemented, will provide sufficient funding to conduct our operations. Any outcome of this process would be dependent upon a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, regulatory approvals, and the availability of financing on reasonable terms. The occurrence of any one or more of the above risks could have a material adverse impact on our business, financial condition, results of operations and cash flows. We have indefinitely suspended ~~development of~~ our AR101 (enzastaurin) clinical development program and shifted our ~~strategic focus towards accelerating the growth of our commercial business. If we fail to execute successfully on this reprioritized strategic focus, our business, results of operations and financial condition could be materially and adversely affected. We have indefinitely suspended our AR101 (enzastaurin) clinical development program and shifted our~~ focus towards accelerating the growth of our commercial business and achieving operating cash flows. Though we expect that the suspension of this program will save **us costs related to a projected future study that if started would cost** over $ 20 million **and take** ~~in projected future study costs over the next~~ three ~~fiscal~~ years **to complete**, the process of reorienting our business strategy may be costly, time consuming and complex, and we have incurred, and may in the future incur, costs related to this strategic shift. Our strategic reprioritization may result in unexpected expenses or liabilities and / or write- offs. There is no assurance that we will be successful at executing on our revised strategy or that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. If we are unable to execute successfully on our reprioritized strategic focus, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected. ~~25Our~~ -- **Our** ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of June 30, ~~2023~~ **2024**, we had federal net operating loss carryforwards of ~~approximately~~ $ ~~504~~ **519**. ~~0~~ **6** million. The available net operating losses, if not utilized to offset taxable income in future periods, will ~~begin~~ **continue** to expire ~~in 2024~~ and, except for certain indefinite- lived net operating loss carryforwards, will completely expire in 2037. Under the Internal Revenue Code of 1986, as amended (the " ~~Code~~ **IRC** ") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes ~~could~~ limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income. ~~An " ownership~~ **Ownership changes have limited our ability to offset, post-** change ~~" (generally a 50 % change in equity ownership over a three- year period) under Section 382 of the Code could limit our ability to offset~~, **United States** ~~post- change, our U. S.~~ federal taxable income. Section 382 of the ~~Code~~ **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** ~~We believe that the June 2021 acquisition~~ **acquisitions** ~~of Neos~~ **, financing transactions, and equity ownership changes in the past five years have** caused ~~an ownership change of Neos, resulting in~~ a **significant** limitation ~~in~~ **on** our ability to use ~~their~~ **all $ 519. 6 million of** pre- acquisition net operating loss carryovers. **The** ~~We also believe that the financing transactions in fiscal 2022 and 2023 may have caused, together with equity~~

ownership changes ~~in the past three years, an ownership change resulting in a limitation of our ability to use our pre- acquisition net operating loss carryovers. The ownership change scenario could~~ result in ~~an~~ increased future tax liability ~~to us~~ **and are a driver of the change from a zero percent effective tax rate** . If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management conducted an assessment of the effectiveness of our internal controls over financial reporting for the quarter ended September 30, 2022, and concluded that a certain control was not effective. We concluded that we had a material weakness in internal control over financial reporting related to accounting for complex warrant issuances and the classification of these issued warrants. In addition, we concluded that we had a material weakness in internal control over financial reporting for the year ended June 30, 2023 **,** related to our analysis for the accounting for valuation of our inventory. ~~Our~~ **As previously reported in our public reports, our** Audit Committee conducted an internal investigation to identify and determine **a** ~~plans~~ **plan** to remediate the material weaknesses **described above** and to enhance our overall control environment. We ~~will not consider~~ **undertook steps to remediate these deficiencies and strengthen our internal control over financial reporting by enhancing existing controls and establishing additional review and procedure controls over the process of reviewing significant and complex contracts and agreements, and the valuation of inventory. Given the remediation efforts and that a sufficient period of time has passed with successful testing performed, management has concluded that** the material weaknesses **set forth above were** remediated **as** ~~until our enhanced control is operational for a sufficient period~~ of **March 31** ~~time and tested~~ , **2024** ~~enabling management to conclude that the enhanced controls are operating effectively. Our remediation plan includes the implementation of controls over the process of reviewing significant and complex contracts and agreements and we believe that the issues have been remediated~~ . If in the future we were to conclude that our internal controls over financial reporting were not effective, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effect on our operations because there is presently no precedent available by which to measure compliance adequacy. As a consequence, we may not be able to complete any necessary remediation process in time to meet our deadline for compliance with Section 404 of the Sarbanes- Oxley Act. Also, there can be no assurance that we will not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes- Oxley Act. The presence of material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent auditors are unwilling or unable to provide us, when required, with an attestation report on the effectiveness of internal controls over financial reporting as required by Section 404 of the Sarbanes- Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes- Oxley Act, we may not be able to maintain listing on the ~~NASDAQ~~ **Nasdaq** Capital Market. Due to our current filing status, we are not required to have our independent registered public accounting firm deliver an attestation report on the effectiveness of our internal control over financial reporting ~~. 26We have been and in the future may become a defendant in one or more stockholder derivative, class- action, and other litigation, and any such lawsuits may adversely affect our business, financial condition, results of operations and cash flows~~ . We and certain of our officers and directors have been and may in the future become defendants in one or more stockholder derivative actions or other class- action lawsuits. For example: ● Two putative class action lawsuits were filed on February 9, 2022 **,** and March 7, 2022 **,** derivatively and on behalf of all Aytu stockholders, challenging the grant in 2021 of certain stock option awards to directors and officers, and seeking rescission of the awards, unspecified damages to stockholders as a result of the awards, and attorneys' fees. ● A ~~shareholder~~ **stockholder** derivative suit was filed on September 12, 2022, derivatively and on behalf of all Aytu stockholders, against certain of our current and former directors and stockholders, alleging breaches of fiduciary duties in connection with certain acquisitions, and seeking unspecified damages, equitable relief, restitution, disgorgement of profits, enhanced governance and internal procedures, and attorneys' fees. See Part I, Item 3 ~~.~~ **,** Legal Proceedings for more information on these lawsuits. These lawsuits can divert our management' s attention and resources from our ordinary business operations, and we would likely incur significant expenses associated with their defense (including, without limitation, substantial attorneys' fees and other fees of professional advisors and potential obligations to indemnify current and former officers and directors who are or may become parties to such actions). In connection with these lawsuits, we may be required to pay material damages, consent to injunctions on future conduct and / or suffer other penalties, remedies or sanctions, or issue additional shares upon the exercise of certain warrants, which may cause additional dilution. In addition, any such future lawsuits could adversely impact our reputation and / or ability to launch and commercialize our products, thereby harming our ability to generate revenue. Accordingly, the ultimate resolution of these matters and any future matters could have a material adverse effect on our business, financial condition, results of operation and cash flow and, consequently, could negatively impact the trading price of our common stock. ~~RISKS RELATED TO COMMERCIALIZATIONWe are heavily dependent on the commercial success of our commercial products. To date, we have not generated sufficient revenues from the sales of these products to achieve profitability and we may never achieve or maintain profitability.~~ Our ability to become profitable depends upon our ability to generate increased revenues from sales of our prescription ~~and consumer health product~~ portfolios. While we have been selling pharmaceutical products for several years, we have limited commercial experience selling our current lineup of pharmaceutical products, having only generated revenues from the sale of our pediatric products since acquiring that portfolio in November 2019 and from our ADHD products since acquiring that portfolio in March 2021. None of our marketed prescription ~~or consumer health products~~ have thus far generated product ~~sales revenues~~ **revenue** at levels sufficient for us to attain profitability. We have not generated any ~~revenues~~ **revenue** from product sales of any other product candidates and, to date, have incurred significant operating losses **. Due to the completion of our wind down and divestiture of our Consumer Health Segment in the first quarter of fiscal 2025, we will not generate**

**significant revenue from the Consumer Health Segment in the future** . We have incurred, and anticipate continuing to incur, significant costs associated with commercialization of our approved products and, if approved, any other product candidates that we may develop. It is possible that we will never attain sufficient product sales revenues to achieve profitability. ~~27If~~ **If** we are unable to differentiate our products from branded drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve additional generic products that compete with any of our products, our ability to successfully commercialize such products would be adversely affected. We expect to compete against branded drugs with distinct clinical attributes and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our Rx Portfolio is or will be differentiated from branded drugs and their generic counterparts, if any, including through clinical efficacy or through improved patient compliance, ease of administration, and our patient support programs, it is possible that such differentiation will not impact our market position. If we are unable to achieve significant differentiation for our products and accompanying support services against other drugs, the opportunity for our products to achieve premium pricing and be commercialized successfully would be adversely affected. After a New Drug Application (“ NDA ”), including a 505 (b) (2) application, is approved, the covered product becomes a “ listed drug ” that, in turn, can be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. The FDCA, implementing regulations and other applicable laws provide incentives to manufacturers to create modified, non- infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient (s), dosage form, strength, route of administration, and conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as our product candidate. These generic equivalents, which must meet the same quality standards as the listed drugs, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product, such as our Rx Portfolio products, can be lost to the generic version. Accordingly, competition from generic equivalents to our products could materially adversely impact our revenues, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in our products. For example, on July 25, 2016, ~~Neos~~ **we** received a paragraph IV certification from Actavis advising them that Actavis filed an ANDA with the FDA for a generic version of Adzenys XR- ODT. On October 17, 2017, ~~Neos~~ **we** entered into a Settlement Agreement and a Licensing Agreement with Actavis (which is now owned by Teva), pursuant to which ~~Neos~~ **we** granted Actavis the right to manufacture and market its now approved generic version of Adzenys XR- ODT under the ANDA beginning on September 1, 2025, or earlier under certain circumstances. On October 31, 2017, ~~Neos~~ **we** received a paragraph IV certification from Teva advising them that Teva filed an ANDA with the FDA for a generic version of Cotempla XR- ODT. On December 21, 2018, ~~Neos~~ **we** entered into a Settlement Agreement and a Licensing Agreement with Teva, pursuant to which we have granted Teva the right to manufacture and market its now approved generic version of Cotempla XR- ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. ~~While we expect to wind down or monetize our Consumer Health Segment, the Consumer Health Segment relies heavily on obtaining products that change from a prescription to over the counter through an FDA approval process. Any delays in this process might impact the financial performance of our consumer Health Segment. Our Consumer Health Segment has pursued opportunities where existing prescription drugs have recently, or are expected to, change from a prescription to over- the- counter. Historically the FDA has highly scrutinized any product application submitted to switch a product from prescription to unsupervised over- the- counter use by the general public. The continued expansion of Rx- to- OTC switches is important to our Consumer Health Segment' s future growth. Reluctance of FDA to approve Rx- to- OTC switches in new product categories could impact that growth and could impact the financial performance of our Consumer Health Segment.~~ Our pharmaceutical ~~and consumer health~~ products may prove to be difficult to effectively commercialize as planned or on the timeframes we announce and expect. Various commercial, regulatory, and manufacturing factors may impact our ability to maintain or grow revenues from sales of our pharmaceutical ~~and consumer health~~ product offerings. Moreover, we have limited ~~28experience~~ -- **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; ● ~~existence~~ of adverse side effects that make using the products less desirable; ● our inability to attract and retain a skilled support team, marketing staff and sales force necessary to increase the market for our approved products and to maintain market acceptance for our products; ● our inability to secure continuing prescribing of any of these products by current or previous users of the product; ● our inability to effectively transfer and scale manufacturing as needed to maintain an adequate commercial supply of these products; ● reimbursement and medical policy changes that may adversely affect the pricing, profitability or commercial appeal of pharmaceutical products; and ● our inability to effectively identify and align with commercial partners outside the **United States** ~~U. S.~~, 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** ~~in single annual production lots~~ by single-

source suppliers **, including but not limited to Halo Pharmaceutical, Inc** . Due to the limited production quantities, production of these ~~lots~~ **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 ~~, if any~~ , with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our products. If we fail to procure supply of our products, we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected. Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our products could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our approved products or a decrease in sales of our approved products, which could harm our financial position and commercial potential for our products. Any alternative vendor would also need to be qualified through an FDA Prior Approval Supplement process which could result in further delay. The FDA, DEA, or other regulatory agencies outside of the United States may also require additional studies if we enter into ~~29agreements~~ -- **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 ~~the~~ **a** delay of commercialization of our products, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our ADHD products may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected. We **completed the process of outsourcing the** ~~rely on third parties manufacture certain products, and third- party~~ manufacturing **of** ~~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. Our~~ ADHD products ~~are currently manufactured in our own production facility in Grand Prairie, Texas. We are in the process of outsourcing the manufacturing of our ADHD products~~ to a third- party manufacturer **based in the United States,** to produce commercial quantities of our ADHD products **during fiscal** ~~beginning in late calendar 2023 or early calendar~~ 2024. If the third **-** party is not successful or does not meet our expectations (for example, timeliness of production, quantity of production, maintenance of needed documentation or regulatory compliance), we may have to find a different manufacturer and incur expenses and delays in the process. Manufacturers of our ADHD products must comply with good manufacturing practice ( ~~"~~ **“** GMP ~~"~~ **”** ) requirements enforced by the FDA, NMPA, EMA and other comparable foreign health authorities through facilities inspection programs. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our FDA regulated products may be unable to comply with these GMP requirements and with other FDA, NMPA, EMA, DEA, state, and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to a manufacturer’ s failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our drugs, which would seriously harm our business. ~~For~~ **We do not expect to have our own manufacturing capabilities, thus for** all other products and any future ~~product~~ **products** , we expect to use third- party manufacturers ~~because we do not expect to have our own manufacturing capabilities~~ . In determining the required quantities of any product and the manufacturing schedule, we must make significant judgments and estimates based on inventory levels, current market trends **,** and other related factors. Because of the inherent nature of estimates and our limited experience in marketing our current products, there could be significant differences between our estimates and the actual amounts of product we require. If we do not effectively maintain our supply agreements, we will face difficulty finding replacement suppliers, which could harm sales of those products. If we fail in similar endeavors for future products, we may not be successful in establishing or continuing the commercialization of our products. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured these components ourselves, including: ● reliance on third parties for regulatory compliance and quality assurance; ● possible breaches of manufacturing agreements by the third parties because of factors beyond our control; ● possible regulatory violations or manufacturing problems experienced by our suppliers; and ● possible termination or non- renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us. Further, if we are unable to secure the needed financing to fund our internal operations, we may not have adequate resources required to effectively and rapidly transition to a third- party CMO for our ADHD products. We may ~~30not~~ -- **not** be able to meet the demand for our products if one or more of any third- party manufacturers is unable to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers for any of our products in a timely manner and on terms acceptable to us. The manufacturing processes and facilities of third- party manufacturers we have engaged for our current approved products are, and any future third- party manufacturer will be, required to comply with the federal Quality System Regulation, or QSR, which covers procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of devices. The FDA enforces the QSR through periodic unannounced inspections of manufacturing facilities. Any inspection by the FDA could lead to additional compliance requests that could cause delays in our product commercialization. Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with the manufacturing processes and facilities of third- party manufacturers we engage, including the failure to take satisfactory corrective actions in response to an adverse QSR inspection, can result in, among other things: ● administrative or judicially imposed sanctions; ● injunctions or the imposition of civil penalties; ● recall or seizure of the product in question; ● total or partial suspension of production or distribution; ● the FDA’ s refusal to grant pending future clearance or pre- market approval; ● withdrawal or suspension of marketing clearances or approvals; ● clinical holds; ● warning letters; ● refusal to

permit the export of the product in question; and ● criminal prosecution. Any of these actions, in combination or alone, could prevent us from marketing, distributing or selling our products, and would likely harm our business. In addition, a product defect or regulatory violation could lead to a government- mandated or voluntary recall by us. We believe the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall drugs or devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert our management **’ s** attention and financial resources, expose us to product liability or other claims, and harm our reputation with customers. Third party performance failures may increase our development costs, delay our ability to obtain regulatory approval, and delay or prevent the commercialization of our products. While we believe that there are numerous alternative sources to provide these services, in the event that we seek such alternative sources, we may not be able to enter into replacement arrangements without incurring delays or additional costs. ~~31If we or our contract manufacturer fail to manufacture our ADHD products in sufficient quantities and at acceptable quality and pricing levels, or fail to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of these products, or be unable to meet market demand, and may be unable to generate potential revenues.~~ The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state, and foreign regulations. If ~~we are~~ **our third- party is** unable to demonstrate stability in accordance with commercial requirements, or if our raw material manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products would be jeopardized. We purchase raw materials and components from various suppliers in order to manufacture our ADHD products. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing our ADHD products, and may not be able to meet customer demand for our products. In addition, ~~we and~~ our contract manufacturer must comply with federal, state, and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. We may be unable to comply with these cGMP requirements and with other FDA and foreign regulatory requirements. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or voluntary recall, or withdrawal of product approval. If the safety of any of our products is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such products or successfully commercialize such products, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in commercialization of our products, entail higher costs or adversely impact our commercialization of our products. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re- stocking costs, damage to our reputation and potential for product liability claims ~~. If our manufacturing facility becomes damaged or inoperable or we decide to or are required to vacate our facility, our ability to manufacture our ADHD products may be jeopardized. Our inability to continue manufacturing adequate supplies of our products could adversely affect our ability to generate revenues. While we are in the process of transferring manufacturing at our Grand Prairie, Texas facility to a third- party manufacturer, all of our ADHD products manufacturing capabilities are currently housed in our sole manufacturing facility located in Grand Prairie, Texas. Our facility and equipment could be harmed or rendered inoperable by natural or manmade disasters, including war, fire, tornado, power loss, communications failure or terrorism, any of which may render it difficult or impossible for us to operate our drug delivery technology platform and manufacture our products for some period of time. While we seek to maintain finished goods inventory of our products outside of this facility, it is unlikely that the level of such inventory would be sufficient if we were to sustain anything other than a short- term disruption in our ability to manufacture our products at our Grand Prairie, Texas facility. The inability to manufacture our products if our facility or our equipment is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to manufacture our products could become damaged and time consuming to repair or replace. It would be difficult, time consuming and expensive to rebuild our facility or repair or replace our equipment or to complete the transfer of our proprietary technology to a third party, particularly in light of the requirements for a DEA registered manufacturing and storage facility like ours and FDA site change requirements. We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. An 32inability to continue manufacturing adequate supplies of our ADHD products at our Grand Prairie, Texas facility could result in a disruption in the supply of our products to physicians and pharmacies, which would adversely affect our ability to generate revenues. In conjunction with transferring the manufacturing of our ADHD products to a CMO, we entered into an agreement with AMT Manufacturing Solutions, LLC to sublease approximately 30 % of our Grand Prairie, Texas manufacturing facility. Commencing as early as April 1, 2024, but no later than December 31, 2024, the sublease will be expanded to include the remaining portion of the manufacturing facility~~ . If we do not secure collaborations with strategic partners to test, commercialize and manufacture products, we may not be able to successfully develop products and generate meaningful revenues. We may enter into collaborations with third parties to commercialize and manufacture our products. If we are able to identify and reach an agreement with one or more collaborators, our ability to generate revenues from these arrangements will depend on our collaborators’ abilities to successfully perform the functions assigned to them in these

arrangements. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. Further, the economic environment at any given time may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our products. Collaboration agreements typically provide for the ownership of intellectual property. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration and we may be limited in our ability to use, make or sell these inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize our products. Collaborations involving our products pose a number of risks, including the following: ● collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus; ● collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others; ● collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues; ● collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement; ● collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; ● collaborators may delay the development or commercialization of our products in favor of developing or commercializing their own or another party' s products; or ● collaborators may decide to terminate or not to renew the collaboration for these or other reasons. As a result, collaboration agreements may not lead to development or commercialization of our products in the most efficient manner or at all. ~~33Collaboration~~ -- **Collaboration** agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product. We also face competition in seeking out collaborators. If we are unable to secure collaborations that achieve the collaborator' s objectives and meet our expectations, we may be unable to advance our products and may not generate meaningful revenues. We face substantial competition **, including the introduction of generics,** from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us. The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete with companies that design, manufacture and market already- existing and new products. We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and / or our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in product marketing and new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. Our competitors may be more successful in acquiring new products than we are. If we fail to acquire new products, implementation of our business plan would be delayed, which could have a negative adverse effect on our business and prospects. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable. Our ability to compete successfully will depend largely on our ability to: ● expand the market for our approved products, especially our pharmaceutical and devices regulated by the FDA; ● successfully commercialize our products alone or with commercial partners; ● discover and develop products that are superior to other products in the market; ● obtain required regulatory approvals; ● attract and retain qualified personnel; and ● obtain patent and / or other proprietary protection for our products. Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our products obsolete. Our competitors may obtain patent protection, receive FDA approval, and commercialize medicines before us. Other companies are or may become engaged in the discovery of compounds that may compete with the products we are developing. We compete with companies that design, manufacture and market treatments that compete with our products. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than that of our products or any product candidate that we are currently developing or that we may develop. ~~34We~~ **We** anticipate that we will face increased competition in the future as new companies enter the market with new technologies ~~and~~ our competitors improve their current products **, and companies introduce generic equivalents** . One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer. ~~Government restrictions on pricing and reimbursement, as well as~~

~~other healthcare payor cost- containment initiatives, may negatively impact our ability to generate revenues.~~ The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following: ● our or our collaborators' ability to set a price we believe is fair for our approved products; ● our ability to generate revenue from our approved products and achieve profitability; and ● the availability of capital. The Patient Protection and Affordable Care Act ~~, or~~ **(the "** PPACA ~~,~~**")** and the Health Care and Education Reconciliation Act **(**~~, or~~ the **"** Health Care Reconciliation Act ~~,~~**")** significantly impacted the provision of, and payment for, health care in the **United States** ~~U. S~~. Various provisions of these laws are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre- existing conditions, establish health insurance exchanges, and provide additional support for medical research. Amendments to the PPACA and / or the Health Care Reconciliation Act, as well as new legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the **United States** ~~U. S.~~, could influence the purchase of medicines and medical devices and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market any approved products and generate revenues. As we expect to receive significant revenues from reimbursement of our Rx Portfolio products by commercial third- party payors and government payors, cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of any of our products approved in the future, and could cause an increase in our compliance, manufacturing or other operating expenses. In addition, in certain foreign markets, the pricing of prescription drugs and devices is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell any approved product at a price acceptable to us or any of our future collaborators. In addition, in some foreign countries, the proposed pricing for a drug or medical device must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. A member state may require that physicians prescribe the generic version of a drug instead of our approved branded product. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products or product candidates. Historically, pharmaceutical products launched in the EU do not follow price structures of the **United States** ~~U. S.~~ and generally tend to have significantly lower prices ~~. 35Our financial results will depend on the acceptance among clinicians, third- party payors and the medical community of our products~~ . Physicians may not choose to prescribe our products if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side- effect profiles and other factors, our product is preferable to existing medicines or treatments. Our future success depends on the acceptance by our target customers, third- party payors, and the medical community that our products are reliable, safe, and cost- effective. We cannot predict the degree of market acceptance of any of our approved products. Many factors may affect the market acceptance and commercial success of our products, including: ● our ability to convince our potential customers of the advantages, safety and economic value our products and product candidates over existing technologies and products; ● the approved labeling for the product and any required warnings; ● the prevalence and severity of adverse events or publicity; ● potential product liability claims **;** ● the relative convenience and ease of our products over existing technologies and products; ● the introduction of new technologies and competing products that may make our products less attractive for our target customers; ● our success in training medical personnel on the proper use of our products; ● the willingness of third- party payors to reimburse our target customers that adopt our products; ● increases in rebate payments with payors; ● the acceptance in the medical community of our products; ● the extent and success of our manufacturing, marketing, and sales efforts; and ● general economic conditions. If our future products fail to gain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some therapies achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue. If third- party payors do not reimburse our customers for the products we sell or if reimbursement levels are set too low for us to sell one or more of our products at a profit, our ability to sell those products and our results of operations will be harmed. While our pharmaceutical products are approved and generating revenues in the **United States** ~~U. S.~~, 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; ~~36~~ ● appropriate and medically necessary for the specific indication; ● cost effective; and ● neither experimental nor investigational. Third- party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with cost- effective diagnosis methods, as determined by the third- party payor, or was used for an unapproved indication. Third- party payors also may refuse to reimburse for procedures and devices deemed to be experimental. Obtaining coverage and reimbursement approval for a product from each government or third- party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost- effectiveness data for the use of our potential product to each government or third- party payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to

make a profit or even cover their costs. Third- party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third- party payors may adversely affect the demand for and reimbursement available for any product or product candidate, which in turn, could negatively impact pricing. If our customers are not adequately reimbursed for our products, they may reduce or discontinue purchases of our products, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition. Reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to comply with those obligations could subject us to penalties and sanctions. As a condition of reimbursement by various federal and state health insurance programs, pharmaceutical companies are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is a lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. Pharmaceutical companies are required to report any revisions to their calculations, price reporting and payment obligations previously reported or paid. Such revisions could affect liability to federal and state payers and also adversely impact reported financial results of operations in the period of such restatement. Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If a company becomes subject to investigations, restatements, or other inquiries concerning compliance with price reporting laws and regulations, it could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on the business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations. Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company' s financial position and results of operations could be adversely affected. ~~37In~~ **In** addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to the Centers for Medicare & Medicaid Services (" CMS "), it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs. Additionally, if a pharmaceutical company overcharges the government in connection with the FSS program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against a company under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Our collaborators are also subject to similar requirements outside of the **United States** ~~U. S.~~ and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues. Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our products in foreign markets for which we intend to primarily rely on collaboration with third parties such as the agreement we entered into with Medomie ~~Pharma Ltd.~~ in July 2023 to sell Adzenys and Cotempla in Israel and the Palestinian Authority. If we commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including: ● our inability to directly control commercial activities because we are relying on third parties; ● the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; ● different medical practices and customs in foreign countries affecting acceptance in the marketplace; ● import or export licensing requirements; ● longer accounts receivable collection times; ● longer lead times for shipping; ● language barriers for technical training; ● reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to our products; ● foreign currency exchange rate fluctuations; ● our customers' ability to obtain reimbursement for our products in foreign markets; and ● the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. Foreign sales of our products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. ~~38We~~ **We** are subject to **United States** ~~U. S.~~ and foreign anti-corruption and anti- money laundering laws with respect to our operations and non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to the **United States** ~~U. S.~~ Foreign Corrupt Practices Act of 1977, as amended **("** ~~, or the~~ FCPA **")** , the **United States** ~~U. S.~~ domestic bribery statute contained in 18 U. S. C. § 201, the **United States** ~~U. S.~~ Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to obtain necessary permits, licenses, and other

regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities. We have adopted a Code of Business Conduct and Ethics that mandates compliance with the FCPA and other anti- corruption laws applicable to our business throughout the world. We cannot ensure, however, that our employees and third - party intermediaries will comply with this code or such anti- corruption laws. Noncompliance with anti- corruption and anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any such action will likely result in a materially significant diversion of management ' ' s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. We are subject to various health care fraud and abuse and reimbursement laws pertaining to the marketing of our approved products. We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products, including inducements to potential patients to request our products and services. Additionally, any product promotion educational activities, support of continuing medical education programs, and other interactions with health- care professionals must be conducted in a manner consistent with the FDA regulations, Physician Payments Sunshine Act, and the Anti- Kickback Statute. The Anti- Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Violations of the Anti- Kickback Statute can also carry potential federal False Claims Act liability. Additionally, many states have adopted laws similar to the Anti- Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third- party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors. These and any new regulations or requirements may be difficult and expensive for us to comply with, may adversely impact the marketing of our existing products or delay introduction of our products, which may have a material adverse effect on our business, operating results and financial condition. Adzenys ~~XR- ODT~~ and Cotempla ~~XR- ODT~~ contain controlled substances, and their manufacture, use, sale, importation, exportation, prescribing and distribution are subject to regulation by the DEA. Adzenys ~~XR- ODT~~ and Cotempla ~~XR- ODT~~, (collectively, our " Controlled Substance Products "), which are approved by the FDA, are regulated by the DEA as Schedule II controlled substances. Before any commercialization of any product candidate that contains a controlled substance, the DEA determines the controlled substance schedule of a ~~39drug~~ -- **drug**, taking into account the recommendation of the FDA. Our Controlled Substance Products are, and our other future products may, if approved, be regulated as " controlled substances " as defined in the Controlled Substances Act of 1970, or CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our third- party manufacturers and to distributors, prescribers, and dispensers of our products. For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances. State- controlled substance laws and regulations may have more extensive requirements than those determined by the DEA and FDA. Though state- controlled substances laws often mirror federal law because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, other states require additional state rulemaking or legislative action, which could delay commercialization. Some state and local governments also require manufacturers to operate a drug stewardship program that collects, secures, transports, and safely disposes of unwanted drugs. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the **United States** ~~U. S~~. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances are considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Amphetamine and methylphenidate, which are the active ingredients in our Adzenys ~~XR- ODT~~ and Cotempla ~~XR- ODT~~ products, 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. ~~We currently manufacture these products in our own facilities, which are registered with and inspected by the DEA.~~ Our ~~planned~~ **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 ~~highly regulated processes and~~ technically complex **and require** ~~. We are subject to extensive regulation~~ **regulatory compliance** ~~of the preparation and manufacture of our products for commercial sale~~. **Our** ~~Components of a finished therapeutic product approved for commercial sale or used in late stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes 40can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our approved products as well as any of our future potential products, are highly regulated processes and technically complex. We, along with our~~ third- party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of our ADHD products is a regulated drug product and subject to the DEA and state-level regulations, we have had to, and will continue to, need to secure state licenses from each required state in which we intend to sell such product allowing us to distribute a regulated drug product in such state. ~~Regulatory authorities also may audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we may be required to take remedial measures that may be costly and / or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales or the temporary or permanent closure of our facility. Any such remedial measures imposed upon us could materially harm our business.~~ If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or revocation of a pre- existing approval, or civil or criminal penalties. As a result, our business, financial condition and results of operations may be materially harmed. There is a risk we may be unable to sell and distribute certain of our products if we cannot 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** ~~By the end of 2023 we will be~~ 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** ~~U. S.~~ federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business. We and any potential collaborators may be subject to **United States** ~~U. S.~~ federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health- related and other personal information. In addition, we may obtain health information from third parties, including research institutions which are subject to privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health (“ HITECH ”). To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient- identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers, the federal government, and media outlets with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. Compliance with **United States** ~~U. S.~~ and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in ~~41government~~ **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 PROPERTYWe are dependent on our relationships and license agreements, and we rely on the intellectual property rights granted to us pursuant to the license agreements.~~ A number of our patent and trademark rights are derived from our license agreements with third parties. Pursuant to these license agreements, we have licensed rights to various patents, patent applications, trademarks and trademark applications within and outside of the United States. We may lose our rights to this intellectual property if we breach our obligations under such license agreements, including, without limitation, our financial obligations to the licensors. If we violate or fail to perform any term or covenant of the license agreements, the licensors may terminate the license agreements upon satisfaction of applicable notice requirements and expiration of any applicable cure periods. Additionally, any termination of license agreements, whether by us or the licensors may not relieve us of our obligation to pay any license fees owing at the time of such termination. If we fail to retain our rights under these license agreements, we will not be able to commercialize certain products subject to patent or patent application or trademark or trademark application, and our business, results of operations, financial condition and prospects would be materially adversely affected. In addition, the licensor may not be able to obtain valid and enforceable patents that protect the licensed products and may not be able to prevent third parties from infringing on those rights. From time to time **,** we may renegotiate the terms of our existing licensing agreements or other material contracts. There can be no guarantee that the terms of the renegotiated license agreement will be viewed favorably by the market although the renegotiated terms might be advantageous to our business or that the other party would agree to material changes to benefit the Company. For example, in May 2022, we negotiated to terminate the License, Development, Manufacturing and Supply agreement with Tris. The negotiations resulted in reducing the future minimum payments we owed to Tris by approximately $ 8 **. 0** million. If we were unable to renegotiate the terms of the agreement, it would have had a material negative impact on our cash flows and financial position. ~~42The expiration or loss of patent protection may adversely affect our future revenues and operating results.~~ The suite of composition- of- matter patents for Adzenys ~~XR- ODT~~ are scheduled to expire in 2026 and 2032. The composition- of- matter patents in the **United States** ~~U. S.~~ for Cotempla ~~XR- ODT~~ 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** ~~U. S.~~, there can be no assurance that any of our patents will not be challenged, invalidated, circumvented or rendered unenforceable. Such means may afford only limited protection of our intellectual property and may not (i) prevent our competitors from duplicating our inventions; (ii) prevent our competitors from gaining access to our proprietary information and technology; or (iii) permit us to gain or maintain a competitive advantage. In addition, our competitors or other third parties may obtain patents that restrict or preclude our ability to lawfully practice, produce or sell our products in a competitive manner. Obtaining and maintaining a patent portfolio entails significant expense and resources. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. In addition, the patent scope can be limited in prosecution or by the courts after issuance. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business. Legal

actions to enforce our patent rights and administrative challenges at the **United States** ~~U. S.~~ Patent and Trademark Office can be expensive and may involve the diversion of significant management time. In addition, these actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our business, prospects, financial condition and results of operations. ~~43If~~ **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** ~~U. S.~~ may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. We may not be able to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the **United States** ~~U. S~~. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and medical devices. This could make it difficult for us to stop the infringement of some of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In addition, some countries allow patents to be challenged by third parties in administrative proceedings, which may result in a reduction in scope or cancelation of some or all of the claims. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the **United States** ~~U. S.~~ and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. A dispute concerning the infringement or misappropriation of our proprietary rights **,** or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business. There is significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our products infringe ~~44the~~ **the** intellectual property rights of others. If our development and commercialization activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs, compositions or devices that relate to our prescription and consumer health business. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third- party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies or universities involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation, wrongful disclosure of confidential information, or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Any legal action against us or our collaborators could lead to: ● payment of damages, potentially treble damages, if we are found to have willfully infringed a party' s intellectual property rights; ● injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or ● we or our collaborators having to enter into license arrangements that may not be available on commercially reasonable or acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, prospects and financial condition. As a result, we could be prevented from commercializing our products ~~. RISKS RELATED TO OUR ORGANIZATION, STRUCTURE AND OPERATIONOur efforts to expand and transform our businesses may require significant investments; if our strategies are unsuccessful, our~~

~~business, results of operations and / or financial condition may be materially adversely affected~~ . We continuously evaluate opportunities for expansion and change. These initiatives may involve making acquisitions, entering into partnerships and joint ventures, divesting assets, restructuring our existing operations and assets, creating new financial structures and building new facilities — any of which could require a significant investment and subject us to new kinds of risks. We may incur additional indebtedness to finance these opportunities. If our strategies for growth and change are not successful, we could face increased financial pressure, such as increased cash flow demands, reduced liquidity and diminished access to financial markets, and the equity value of our businesses could be diluted. The implementation of strategies for growth and change may create additional risks, including: ● diversion of management time and attention away from existing operations; ● requiring capital investment that could otherwise be used for the operation and growth of our existing businesses; ● disruptions to important business relationships; ● increased operating costs; ● limitations imposed by various governmental entities; and ● difficulties due to lack of or limited prior experience in any new markets we may enter. ~~45Our~~ -- **Our** inability to mitigate these risks or other problems encountered in connection with our strategies for growth and change could have a material adverse effect on our business, results of operations and financial condition. In addition, we may fail to fully achieve the savings or growth projected for current or future initiatives notwithstanding the expenditure of substantial resources in pursuit thereof. We may have difficulties integrating acquired products and businesses and as a result, our business, results of operations and / or financial condition may be materially adversely affected. We have completed a number of acquisitions, and we intend to continue to acquire additional products and businesses through mergers, asset purchases or in- licensing, businesses or products, or form strategic alliances as part of our business strategy. Such growth strategies involve risks, including: ● inability to efficiently operate new businesses or to integrate acquired products and businesses; ● inability to accurately predict delays in realizing the costs and benefits of acquisitions, partnerships, or joint ventures; ● unexpected losses of customers or suppliers of an acquired or existing business; ● difficulties in retaining key employees of acquired businesses; ● difficulties in realizing projected synergies; ● failure of the acquired business to produce the expected value; **and** ● exposure to unanticipated liabilities, including unexpected environmental exposures, litigation challenging a merger, product liability or illegal activities conducted by an acquired company or a joint venture partner. Our inability to address these risks in a timely manner or at all could cause us to fail to realize the anticipated benefits of such acquisitions or joint ventures and could have a material adverse effect on our business, results of operations and financial condition. ~~In fiscal 2023, the great majority of our gross revenue and gross accounts receivable were due to three significant customers, the loss of which could materially and adversely affect our results of operations.~~ Three customers contributed greater than 10 % of our gross revenue during the years ended June 30, **2024, and** 2023 ~~and 2022~~ . During the years ended June 30, **2024, and** 2023 ~~and 2022~~ , three customers accounted for ~~78~~ **70** % of gross revenue, respectively. ~~The~~ **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, ~~2023~~ **2024** , three customers accounted for ~~83~~ **80** % of gross accounts receivable. Our profitability and cash flow are dependent on receipt of timely payments from customers. Any delay in payment by our customers may have an adverse effect on our profitability, working capital and cash flow. There is no assurance that we will be able to collect all or any of its trade receivables in a timely matter. If any of our customers face unexpected situations such as financial difficulties, we may not be able to receive full or any payment of the uncollected sums or enforce any judgment debts against such clients, and our business, results of operations and financial condition could be materially and adversely affected. ~~46We~~ **We** depend on key personnel and attracting qualified management personnel and our business could be harmed if we lose personnel and cannot attract new personnel. Our success depends to a significant degree upon the technical and management skills of our directors, officers, and key personnel. Any of our directors could resign from our board at any time and for any reason. Although our named executive officers **(individually " NEO " and collectively " NEOs "),** Joshua **R.** Disbrow ~~and ,~~ Mark **K.** Oki **, Jarrett T. Disbrow and Greg Pyszczymuka** have employment agreements, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time, and ~~each~~ **the** ~~agreement~~ **agreements** ~~obligates~~ **obligate** us to pay ~~the officer~~ **Joshua R. Disbrow a** lump sum severance of two and a half years **his base salary, for Mr. Jarrett T. Disbrow a lump sum severance of two years his base salary,** and **for Mr. Oki, and Mr. Pyszczymuka** one year ~~, respectively,~~ of **their base** salary ~~if~~ **paid in installments over 12 months in accordance with the company' s payroll schedule. If** we terminate ~~him~~ **them** without cause, as defined in ~~the~~ **their respective** ~~agreement~~ **agreements** , ~~which~~ **or if a NEO leaves for " Good Reason " as defined in their respective employment agreements, such severance payments** could ~~hurt~~ **negatively affect** our liquidity. The loss of the services of ~~either~~ **any** of these individuals would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, marketing, technical, and sales executives and personnel. We do not maintain key person life insurance for any of our officers or key personnel. The loss of any of our directors or key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business. We compete for such personnel, including directors, against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so could have a material adverse effect on our business, prospects, financial condition, and results of operations. Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our products. We will be exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of therapeutic candidates. Any failure of future therapeutic candidates by us and our corporate collaborators may expose us to liability claims as may the

potential sale of any therapies approved in the future. These claims might be made by patients who use our therapies, healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that research or sell our therapies. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our future therapeutic candidates or any prospects for commercialization of our future therapeutic candidates. The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical, medical device, dietary supplement and personal care products. Side effects of, or manufacturing defects in, products that we develop and commercialized could result in the deterioration of a patient' s condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products. We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial condition and operations. Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, insurance coverage is increasingly expensive and difficult to obtain. For example, we have experienced increasing difficulty in procuring insurance coverage for our products, in particular, our ADHD products, due to their status as controlled substances. Inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit the commercial production and sale of any of our products that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully. A successful product liability claim or series of ~~47claims~~ -- **claims** brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business ~~. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to the Company~~ . Our certificate of incorporation provides that we will indemnify our directors to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our bylaws provide that: ● we may, in our discretion, indemnify other officers, employees and agents in those circumstances where indemnification is permitted by applicable law; ● we are required to advance expenses, as incurred, to our directors and executive officers in connection with defending a proceeding, except that such directors or executive officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; ● we will not be obligated pursuant to our bylaws to indemnify any director or executive officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by our Board of Directors, (iii) such indemnification is provided by us, in our sole discretion, pursuant to the powers vested in the corporation under applicable law or (iv) such indemnification is required to be made pursuant to our amended and restated bylaws; ● the rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and ● we may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. As a result, if we are required to indemnify one or more of our directors or executive officers, it may reduce our available funds to satisfy successful third- party claims against us, may reduce the amount of money available to us and may have a material adverse effect on our business and financial condition. ~~Public concern over the abuse of medications that are controlled substances, including increased legislative, legal and regulatory action, could negatively affect our business.~~ Products containing controlled substances may generate public controversy. Certain governmental and regulatory agencies, as well as state and local jurisdictions, are focused on the abuse of controlled substances such as opioids in the United States. State and local governmental agencies have commenced investigations into pharmaceutical companies and others in the supply chain in connection with the distribution of opioid medications. For example, on March 7, 2018 **,** and April 18, 2019, Neos ~~Therapeutics~~ , which we now own, received citations advising Neos that the County of Harris Texas and the County of Walker Texas filed lawsuits on December 13, 2017 **,** and January 11, 2019, respectively, against Neos and various other alleged manufacturers, promoters, sellers and distributors of opioid pharmaceutical products. Through these lawsuits, each of Harris County and Walker County seek to recoup as damages some of the expenses they allegedly have incurred to combat opioid use and addiction. Each of Harris County and Walker County also seeks punitive damages, disgorgement of profits and attorneys' fees. In addition, multiple lawsuits have been filed against pharmaceutical companies alleging, among other claims, failures to provide effective controls and procedures to guard against the diversion of controlled substances, negligence by distributing controlled substances to pharmacies that serve individuals who abuse controlled substances, and failures to report suspicious orders of controlled substances in accordance with regulations. Certain cases noted above have recently been settled, some for hundreds of millions of dollars. In the future, political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict, the introduction and marketing of our products, the withdrawal of currently approved products from the market, or result in other legal action. ~~48In~~ **In** addition, we are aware of other legislative, regulatory or industry measures to address the misuse of prescription opioid medications which could affect our business in ways that we may not be able to predict. Liabilities for taxes or assessments under any such laws will likely have an adverse impact on our results of operations, unless we are able to mitigate them through operational changes or commercial arrangements where permitted and may result in us ceasing to continue to sell our products in these jurisdictions. Certain of our stockholders own a significant percentage of our stock and may and their interests may conflict with yours. As of June 30, ~~2023~~ **2024** , ~~one~~ **two** ~~stockholder~~ **stockholders** ~~holds~~ **hold** approximately ~~20~~ **18. 2** % **and 9. 5 %, respectively,** of our outstanding common stock and ~~holds~~ **hold warrants and pre-**

**funded** warrants which can be exercised to purchase additional shares of our common stock resulting in **an** ownership of ~~approximately 40~~ **19. 99** % of our currently outstanding common stock **, and in excess of 19. 99 % subject to stockholder approval** . Accordingly, ~~this~~ **these** ~~stockholder~~ **stockholders** will be able to exert a significant degree of influence over our management and affairs and over matters requiring security holder approval. In addition, in connection with our recent public offering of securities in June 2023, ~~this~~ **the 18. 2 %** stockholder has been granted the right to designate an individual to join our ~~board~~ **Board** of ~~directors~~ **Directors** , who has since joined the board of directors, and to nominate an additional candidate who is acceptable to us to be elected to the Board, subject to Nasdaq regulations **. To date this shareholder only occupies one board seat** . The interests of this stockholder could conflict with the interests of our other stockholders. Our business could be negatively affected as a result of the actions of activist stockholders. Proxy contests have been waged against many companies in the pharmaceutical industry over the last several years. It is possible that one or more of our stockholders may publicly voice opposition to certain aspects of our corporate governance and strategy ~~,~~ or undertake a proxy contest to reconstitute our board. If faced with a proxy contest or other type of stockholder activism, we may not be able to respond successfully to the contest or other type of activism which would be disruptive to our business. Even if we are successful, our reputation and / or business could be adversely affected by a proxy contest or other form of stockholder activism because: ● responding to proxy contests and other actions by activist stockholders can be costly and time- consuming, disrupting operations and diverting the attention of management and employees; ● perceived uncertainties as to our company and future strategic direction may result in the loss of potential financing, acquisitions, collaboration, in- licensing or other business opportunities, and may make it more difficult to attract and retain qualified personnel and business partners; and ● if individuals are elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively and timely implement our strategic plan and create additional value for our stockholders. Any or all of these activities could cause our stock price to decline or experience periods of volatility ~~,~~ and could be particularly problematic as our company seeks to transition to a commercial enterprise in a challenging environment. ~~RISK RELATED TO SECURITIES MARKETS AND INVESTMENT IN OUR SECURITIESOur~~ **Risk Related to Securities Markets and Investment in Our Securities Our** failure to meet the continued listing requirements of the Nasdaq Capital Market could result in a delisting of our common stock. If we fail to satisfy the continued listing requirements of the Nasdaq Capital Market, such as the corporate governance requirements or the minimum closing bid price requirement, the exchange may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting notification, we anticipate that we would take actions to restore our compliance with applicable exchange requirements, such as stabilize our market price, improve the liquidity of our common stock, prevent our common stock from dropping below such exchange' s minimum bid price requirement, or prevent future non- compliance with such exchange' s listing requirements. ~~49Effecting~~ -- **Effecting** a reverse stock split, if determined by the Board in its discretion, may not achieve one or more of our objectives. We have effected five reverse stock splits since June 8, 2015, each of which has impacted the trading liquidity of the shares of our common stock. There can be no assurance that the market price per share of our common stock after a reverse stock split will remain unchanged or increase in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. The market price of our shares may fluctuate and potentially decline after a reverse stock split. Accordingly, the total market capitalization of our common stock after a reverse stock split may be lower than the total market capitalization before the reverse stock split. Moreover, the market price of our common stock following a reverse stock split may not exceed or remain higher than the market price prior to the reverse stock split. Additionally, **on June 21, 2024, Nasdaq filed a proposed rule change with the SEC that would change how it views reverse stock splits. Nasdaq' s proposal suggests it would initiate the delisting process for any company whose common stock bid price had closed below $ 1. 00 per share for 30 consecutive business days (the " Minimum Bid Requirement ") if, within the prior year, the company conducted a reverse stock split, regardless of the ratio. Given our history of effectuating reverse stock splits in order to comply with the Minimum Bid Requirement,** there **can be no assurance that our securities will continue to be listed on Nasdaq if we do not comply with the Minimum Bid Requirement. There** can be no assurance that a reverse stock split will result in a per- share market price that will attract institutional investors or investment funds or that such share price will satisfy investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve. Further, if a reverse stock split is effected and the market price of our common stock declines, the percentage decline may be greater than would occur in the absence of a reverse stock split. Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this ~~prospectus~~ **Annual Report** , these factors include: ● the success of products we acquire for development or commercialization relative to the success of our competitors; ● product safety; ● conditions or trends in the healthcare, biotechnology and pharmaceutical industries, including healthcare payment systems; ● our ability to effectively manage operations, financial decisions, internal controls over financial reporting or disclosure controls, performance relative to projections, and attract and retain employees; ● our dependence on third parties, including CROs and scientific and medical advisors; ● adverse regulatory decisions or changes in laws or regulations; ● disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our products; ● general political and economic conditions and effects of natural or man- made catastrophic events; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, and the stocks of small- cap healthcare, biotechnology, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other

risks, including those described in ~~these~~ **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. ~~50If~~ **If** securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and any trading volume could decline. Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. We cannot control the number of securities and industry analysts who publish research on us, the extent of their coverage or the content of their reports. Downgrades of our stock or publishing inaccurate or unfavorable research about our business, would likely lead to a decline in our stock price. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose market visibility and demand for our stock could decrease, which might cause our stock price and any trading volume to decline. Some provisions of our charter documents and applicable Delaware law may discourage an acquisition of us by others, even if the acquisition may be beneficial to some of our stockholders. Provisions in our Certificate of Incorporation and Amended and Restated Bylaws, as well as certain provisions of Delaware law, could make it more difficult for a third- party to acquire us, even if doing so may benefit some of our stockholders. These provisions include: ● the authorization of 50. 0 million shares of " blank check " preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval; ● limiting the removal of directors by the stockholders; ● allowing for the creation of a staggered ~~board~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **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~~ **Board** of ~~directors~~ **Directors** . This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by or beneficial to our stockholders. Any provision of our Certificate of Incorporation or Bylaws or of Delaware law that is applicable to us that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock in the event that a potentially beneficial acquisition is discouraged, and could also affect the price that some investors are willing to pay for our common stock. We do not intend to pay cash dividends on our capital stock in the foreseeable future. We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Our stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock. ~~51We~~ **We** are and may continue to be subject to short selling strategies. Short sellers of our stock may be manipulative and may attempt to drive down the market price of shares of our Common Stock. Short selling is the practice of selling securities that the seller does not own but rather has borrowed from a third party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is therefore in the short seller' s best interests for the price of the stock to decline, many short sellers (sometime known as " disclosed shorts ") publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects to create negative market momentum and generate profits for themselves after selling a stock short. Although traditionally these disclosed shorts were limited in their ability to access mainstream business media or to otherwise create negative market rumors, the rise of the Internet and technological advancements regarding document creation, videotaping and publication by blogging have allowed many disclosed shorts to publicly attack a company' s credibility, strategy and veracity by means of so- called " research reports " that mimic the type of investment analysis performed by large Wall Street firms and independent research analysts. These short attacks have, in the past, led to selling of shares in the market, on occasion in large scale and broad base. Issuers who have limited trading volumes and are susceptible to higher volatility levels than large- cap stocks, can be particularly vulnerable to such short seller attacks. These short seller publications are not regulated by any governmental, self- regulatory organization or other official authority in the United States, are not subject to certification requirements imposed by the SEC and, accordingly, the opinions they express may be based on distortions or omissions of actual facts or, in some cases, fabrications of facts. In light of the limited risks involved in publishing such information, and the enormous profit that can be made from running a successful short attack, unless the short sellers become subject to significant penalties, it is more likely than not that disclosed short sellers will continue to issue such reports. Significant short selling of a company' s stock creates an incentive for market participants to reduce the value of that company' s common stock. Short selling may lead to the placement of sell orders by short sellers without commensurate buy orders because the shares borrowed by short sellers do not have to be returned by any fixed period of time. If a significant market for short selling our common stock develops, the market price of our common stock could be significantly depressed. **General Risk Factors Our** ~~The Sabby litigation may result in the issuance of additional shares on the exercise of certain of our warrants and cause dilution to existing shareholders. A complaint was filed on February 22, 2023 by holders of certain warrants to purchase common stock, against the Company. The complaint alleges that the Company improperly adjusted the exercise price of the warrants and miscalculated the number of shares the warrantholders may receive, and that the Company failed to provide prompt notice to the warrantholders of such adjustment. The complaint seeks, among other things, a declaratory judgment of the~~

~~warrant share calculation such that 2, 325, 581 warrant shares be due to the warrantholders on the exercise of the warrants rather than 1, 265, 547 shares. While we believe that this lawsuit is without merit and we intend to vigorously defend against it, we are not able to predict at this time whether this proceeding will have a material impact on our financial condition or results of operations. If this lawsuit is successful and the warrantholders exercise their warrants, it will result in significant dilution of the percentage ownership of our existing stockholders and could cause our stock price to fall. See Part I, Item 3. Legal Proceedings for more information on this lawsuit. GENERAL RISK FACTORSOur~~ business and operations would suffer in the event of system failures, cybersecurity attacks **, data leakages** or other security breaches. We utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including deliberate cybersecurity attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our systems and networks and ~~52~~ **the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in preventing cyber- attacks or successfully mitigating their effects. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from such cybersecurity attacks, including computer viruses, unauthorized access, ransomware attacks, phishing expeditions, natural disasters, terrorism, war and telecommunication and electrical failures. Such an event could cause interruption of our operations. To the extent that any disruption or security breach were to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could suffer reputational harm or face litigation, or adverse regulatory action and the development of our products could be delayed. Our sales force and other employees, third party logistics partners, CMOs, CROs, principal investigators, collaborators, independent contractors, consultants and other vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. Major bank failure or sustained financial market illiquidity, could adversely affect our business, financial condition and results of operations. We face certain risks in the event of a sustained deterioration of domestic or international financial market liquidity. In particular: ● We may be unable to access funds in our deposit accounts on a timely basis. Any resulting need to access other sources of liquidity or short- term borrowing would increase our costs. ● In the event of a major bank failure, we could face major risks to the recovery of our bank deposits. A substantial portion of our cash and cash equivalents are either held at banks that are not subject to insurance protection against loss or exceed the deposit insurance limit. While we are not currently aware of any liquidity issues directly impacting the financial institutions where we hold cash deposits or securities, if financial liquidity deteriorates, there can be no assurance we will not experience an adverse effect, which may be material, on our ability to access capital and on our business, financial condition and results of operations. Deterioration in general economic conditions in the United States and globally, including the effect of prolonged periods of inflation on our customers and suppliers, could harm our business and results of operations. Our business and results of operations could be adversely affected by changes in national or global economic conditions. These conditions include but are not limited to inflation, rising interest rates, availability of capital markets, energy availability and costs (including fuel surcharges), the negative impacts caused by pandemics and public health crises (such as the COVID- 19 pandemic), negative impacts resulting from the military conflicts between Russia and Ukraine and between Israel and Palestine, and the effects of governmental initiatives to manage economic conditions. Impacts of such conditions could be passed on to our business in the form of a reduced customer base and / or potential for new bookings due to possible reductions in pharmaceutical and biotech industry- wide spend on research and development and / or economic pressure on our suppliers to pass on increased costs.**