Risk Factors Comparison 2023-10-12 to 2022-09-27 Form: 10-K

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RISKS RELATED TO OUR BUSINESS AND FINANCIAL POSITION We have incurred losses to date and can give no assurance of profitability. We have incurred losses in each year since our inception. As of the filing of this Annual Report on Form 10- K, there is a substantial doubt regarding our ability to continue as a going concern. Our net loss for the years ended June 30, **2023 and** 2022 ~~and 2021~~ was $ ~~110~~ **17** . ~~2~~ **1** million and $ ~~58~~ **108** . ~~3~~ **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 ~~and product candidates~~ ; ● difficulties in maintaining coverage and reimbursement for our products; ● lack of sufficient capital; ● U. S. and foreign regulatory approval of our products ~~and product candidates~~ ; ● unanticipated problems, delays, and expense relating to product development and implementation; ● lack of sufficient intellectual property; ● the ability to attract and retain qualified employees; ● competition; and ● technological changes. As a result of ~~our limited operating history and~~ the increasingly competitive nature of the markets in which we compete, our historical financial data is of limited value in anticipating future operating expenses. Our planned expense levels will be based in part on ~~our expectations~~ **ourexpectations** concerning future operations, which is difficult to forecast accurately based on ~~our limited operating history and~~ our historical strategy of product and / or business acquisition to develop our product and business portfolio. We may be unable to adjust spending in a timely manner to compensate for any unexpected budgetary shortfall. To obtain revenues from our products ~~and product candidates~~ , we must succeed, either alone or with others, in a range of challenging activities, including expanding markets for our existing products ~~and completing clinical trials of our product candidates~~ , **manufacturing** ~~obtaining positive results from those clinical trials~~ , ~~achieving~~ marketing ~~approval for those product candidates, manufacturing, marketing~~ and selling our existing products ~~and those products for which we, or our collaborators, may obtain marketing approval~~ , satisfying any post- marketing requirements **,** and obtaining reimbursement for our products from private insurance or government payors. We, and our collaborators, as applicable, may ~~never succeed~~ **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, we had accumulated deficit of $ 304. 1 million. Even though we plan to mitigate the conditions that raise 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 ~~yet~~ established an ongoing source of revenue sufficient to cover operating costs ~~and allow us to continue as a going concern~~ . Our ability to continue as a going concern is dependent on **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 ~~will~~ **may** need to raise additional funding, which may not be available on acceptable terms, or at all. Failure to obtain necessary capital when needed may force us to delay, limit or terminate our product expansion ~~and development~~ efforts or other operations. Further, future sales and issuances of our common stock or rights to purchase common stock will result in dilution of the percentage ownership of our existing stockholders and could cause our stock price to fall. We are expending resources to ~~continue the expansion of commercialization~~ **commercialize** ~~efforts for~~ our prescription ~~and consumer health products, and to obtain regulatory approval for, and to commercialize, our product~~ **products** ~~candidates~~ **and to service our debt obligations** . We ~~will~~ **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, ~~2022~~ **2023** , our cash ~~,~~ **and** cash equivalents ~~and restricted cash~~ totaled $ ~~19~~ **23** . ~~4~~ **0** million. During the year ended June 30, ~~2022~~ **2023** , we raised approximately $ ~~11~~ **15** . ~~7~~ **6** million, net of fees, from a combination of common stock offerings ~~and common stock warrant exercises~~ . Our operating ~~plan~~ **plans** may change as a result of many factors currently unknown to us, and we could need ~~significant~~ additional capital in the future to continue our operations and may need to seek additional funds sooner than planned. Raising funds in the current economic environment may present additional challenges. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. If we sell common stock, convertible securities or other equity securities in more than one transaction, ~~investors in a prior transaction may be materially diluted by subsequent sales. Additionally,~~ any such sales may result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to those of our existing common stockholders. Further, any future sales of our common stock by us or resales of our common stock by our existing stockholders could cause the market price of our common stock to decline. Any future grants of securities exercisable or convertible into our common stock, or the exercise or conversion of such shares, and any sales of such shares in the market, could also have an adverse effect on the market price of our common stock. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. The incurrence of **additional** indebtedness would result in increased fixed payment obligations and we may be required to agree to ~~certain~~ **additional** restrictive covenants, such as **further** limitations on our ability to incur additional debt, **additional**

limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek ~~funds~~ **23funds** through arrangements with collaborative partners or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or ~~product~~ **products** ~~candidates~~ or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be unable to expand the market for our products ~~, and / or be required to significantly curtail, delay or discontinue one or more of our research or development programs for our current or any future product candidates~~ or expand our operations generally or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. ~~26We~~ **We** may not have cash available to us in an amount sufficient to enable us to make interest or principal payments on our indebtedness when due. We have a $ 15. 0 million term loan with Avenue Capital and up to $ ~~12~~ **14** . 5 million of secured revolving loans with Eclipse. As of June 30, ~~2022~~ **2023** , $ ~~3~~ **1** . ~~8~~ **6** million was outstanding under the secured revolving loan. All obligations under our loans are secured by substantially all of our existing property and assets subject to certain exceptions. These debt financings and any future debt financings may create additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. ~~Since our inception, we have had significant operating losses. As of June 30, 2022, we had accumulated deficit of $ 288. 5 million. As we fund our product candidate pipeline, we expect to continue to incur net losses and have negative cash flow from operating activities for the foreseeable future.~~ As a result, we may not have sufficient funds, or may be unable to arrange for additional financing, to pay the amounts due on our outstanding indebtedness under our debt agreements. Further, funds from external sources may not be available on economically acceptable terms, if at all. For example, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our ~~product~~ **products** ~~candidates~~ or technologies, or to grant licenses on terms that are not favorable to us. If adequate funds are not available when and if needed, our ability to make interest or principal payments on our debt obligations, **and** finance our operations ~~, our research and development efforts~~ and other general corporate activities would be significantly limited and we may be required to delay, significantly curtail **,** or eliminate one or more of our programs. Failure to satisfy our current and future debt obligations under our loan agreements with Avenue Capital or Eclipse could result in an event of default and, as a result, our lenders could accelerate all of the amounts due. In the event of an acceleration of amounts due under one or both of our debt agreements as a result of an event of default, we may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness. In addition, our lenders could seek to enforce their security interests in any collateral securing such indebtedness. The terms of our loan agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility. The loan agreements with Avenue Capital and Eclipse subject us to financial covenants and restrictions on our ability to incur liens, incur additional indebtedness, make certain dividends and distributions with respect to equity securities, engage in mergers and acquisitions or make asset sales without the prior written consent of the lender. Failure to comply with such covenants could permit the lenders to declare our obligations under the loan agreements, together with accrued interest and fees, to be immediately due and payable, plus any applicable additional amounts relating to a prepayment or termination. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. Any declaration by the lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility. **24We recently announced that we have been engaged in discussions with various parties regarding potential strategic transactions 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 potential strategic transactions 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 over $ 20 million in projected future study costs over the next three fiscal years, 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** ability to use our net operating loss carryforwards and certain other tax attributes may be limited. As of June 30, ~~2022~~ **2023** , we had federal net operating loss carryforwards of approximately $ ~~503~~ **504** . ~~2~~ **0** million. The available net operating losses, if not utilized to offset taxable income in future periods, will begin to expire in 2024 and, except for certain indefinite- lived net operating loss carryforwards, will completely expire in 2037. Under the Internal Revenue Code of 1986, as amended (the " Code ") and the regulations promulgated thereunder, including, without limitation, the consolidated income tax return regulations, various corporate ownership changes could limit our ability to use our net operating loss carryforwards and other tax attributes to offset our income. ~~27An~~ **An** " ownership change " (generally a 50 % change in equity ownership over a three- year period) under Section 382 of the Code could limit our ability to offset, post- change, our U. S. federal taxable income. Section 382 of the Code imposes an annual limitation on the amount of post- ownership change taxable income a corporation may offset with pre- ownership change net operating loss carryforwards and certain recognized built- in losses. We believe that the June 2021 acquisition of Neos caused an ownership change of Neos, resulting in a limitation in our ability to use their pre- acquisition net operating loss carryovers. We also believe that the financing transactions in fiscal 2022 **and 2023** may have caused, together with equity ownership changes in the past ~~five~~ **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. If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management conducted an assessment of the effectiveness of our internal controls over financial reporting for the ~~year~~ **quarter** ended ~~June~~ **September** 30, ~~2021~~ **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 ~~our analysis for the accounting of goodwill and other intangible assets and~~ accounting for **complex warrant issuances and the classification of** ~~the~~ **these issued warrants** ~~impairment of long- lived assets. As a result, we sought and received technical guidance from a third- party provider~~ . In ~~response~~ **addition** , we **concluded** ~~have taken a number of steps, including incorporating the third- party provider review and expertise in our analysis, and we believe~~ that ~~the issue has been remediated. For~~ **we had a material weakness in internal control over financial reporting for** the year ended June 30, ~~2022~~ **2023 related to our analysis for the accounting for valuation of our inventory. Our Audit Committee conducted an internal investigation to identify and determine plans to remediate the material weaknesses and to enhance our overall control environment. We will not consider the material weaknesses remediated until our enhanced control is operational for a sufficient period of time and tested** , ~~we have~~ **enabling management to** ~~concluded~~ **conclude** that ~~our internal~~ **the enhanced controls are operating effectively. Our remediation plan includes the implementation of** controls over ~~financial reporting were effective~~ **the process of reviewing significant and complex contracts and agreements and we believe that the issues have been remediated** . **If** ~~However, if~~ in the future we were to conclude that our internal controls over financial reporting were not effective, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or their effect on our operations because there is presently no precedent available by which to measure compliance adequacy. As a consequence, we may not be able to complete any necessary remediation process in time to meet our deadline for compliance with Section 404 of the Sarbanes- Oxley Act. Also, there can be no assurance that we will not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 of the Sarbanes- Oxley Act. The presence of material weaknesses could result in financial statement errors which, in turn, could require us to restate our operating results. If we are unable to conclude that we have effective internal controls over financial reporting or if our independent auditors are unwilling or unable to provide us, when required, with an attestation report on the effectiveness of internal controls over financial reporting as required by Section 404 of the Sarbanes- Oxley Act, investors may lose confidence in our operating results, our stock price could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404 of the Sarbanes- Oxley Act, we may not be able to maintain listing on the NASDAQ Capital Market **. 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 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 at levels sufficient for us to attain profitability. We have not generated any revenues from product sales of any other product candidates and, to date, have incurred significant operating losses. ~~28We~~ **We** have incurred, and anticipate continuing to incur, significant costs associated with commercialization of our approved products and, if approved, any other product candidates that we may develop. It is possible that we will never attain sufficient product sales revenues to achieve profitability. ~~If~~ **27If** we are unable to differentiate our products ~~or product candidates~~ from branded drugs or existing generic therapies for similar treatments, or if the FDA or other applicable regulatory authorities approve **additional** generic products that compete with any of our products ~~or product candidates~~ , our ability to successfully commercialize such products ~~or product candidates~~ would be adversely affected. We expect to compete against branded drugs with distinct clinical attributes and to compete with their generic counterparts that will be sold for a lower price. Although we believe that our Rx Portfolio **is** ~~and product candidates are~~ or will be differentiated from branded drugs and their generic counterparts, if any, including through clinical efficacy or through improved patient compliance ~~and~~ **,** ease of administration **, 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 ~~product candidates~~ **accompanying support services** against other drugs, the opportunity for our products ~~and, if approved, product candidates~~ to achieve premium pricing and be commercialized successfully would be adversely affected. After ~~an~~ **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 ~~product~~ **products** ~~candidates would~~ **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 ~~product~~ **products** ~~candidates~~ . ~~[~~For example, on July 25, 2016, Neos received a paragraph IV certification from Actavis advising them that Actavis filed an ANDA with the FDA for a generic version of Adzenys XR- ODT. On October 17, 2017, ~~we~~ **Neos** entered into a Settlement Agreement and a Licensing Agreement with Actavis **(which is now owned by Teva)** , pursuant to which Neos 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 received a paragraph IV certification from Teva advising them that Teva filed an ANDA with the FDA for a generic version of Cotempla XR- ODT. On December 21, 2018, Neos entered into a Settlement Agreement and a Licensing Agreement with Teva, pursuant to which we have granted Teva the right to manufacture and market its **now approved** generic version of Cotempla XR- ODT under the ANDA beginning on July 1, 2026, or earlier under certain circumstances. ~~Our~~ **While we expect to wind down or monetize our** ~~consumer~~ **Consumer** ~~health~~ **Health** ~~division~~ **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~~ **Health** ~~division~~ **Segment** . Our ~~consumer~~ **Consumer** ~~health~~ **Health** ~~division actively~~ **Segment has** ~~pursues~~ **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 ~~physician prescribed~~ prescription to unsupervised over- the- counter use by the general public. The **continued** expansion of Rx- to- OTC switches is ~~critical~~ **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~~ **Consumer** ~~health~~ **Health** ~~division~~ **Segment** . ~~29Our~~ -- **Our** pharmaceutical ~~, device~~ and consumer health products may prove to be difficult to effectively commercialize as planned or on the timeframes we announce and expect. Various commercial, regulatory, and manufacturing factors may impact our ability to maintain or grow revenues from sales of our pharmaceutical ~~, device~~ and consumer health product offerings. Moreover, we have limited ~~experience~~ **28experience** 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 ~~product~~ **products** ~~candidates~~ may be delayed and our business, prospects and results of operations may be harmed. Specifically, we may encounter difficulty by virtue of the following, each of which could be negatively impacted if expected timeframe goals are not achieved: ● our available capital resources; ● our inability to ~~receive regulatory clearances required to market them as drugs; ● our inability to~~ have clear proprietary rights to the products; ● our inability to manufacture or cost- effectively manufacture the products; ● our inability to adequately market and increase sales of any of these products; ● existence of adverse side effects that make using the products less desirable; ● our inability to ~~adequately market and increase sales of any of these products; ● our inability to~~ attract and retain a skilled support team, marketing staff and sales force necessary to increase the market for our approved products and to maintain market acceptance for our ~~product~~ **products** ~~candidates~~ ; ● our inability to secure continuing prescribing of any of these products by current or previous users of the product; ● our inability to effectively transfer and scale manufacturing as needed to maintain an adequate commercial supply of these products; ● reimbursement and medical policy changes that may adversely affect the pricing, profitability or commercial appeal of pharmaceutical products; and ● our inability to effectively identify and align with commercial partners outside the U. S., or the inability of those selected partners to gain the required regulatory, reimbursement, and other approvals needed to enable commercial success of **our products** ~~the Healight Platform~~ . We rely on limited sources of supply for our products, and any disruption in the chain of supply may impact production and sales of our products, and cause delays in developing and commercializing our ~~product candidates and~~ currently manufactured and commercialized products. ~~Many~~ **Some** of our products are produced in single annual production lots by single- source suppliers. Due to the limited production quantities, production of these lots may not be prioritized by the third- party manufacturer, and may not be scheduled and produced at all. ~~Our ADHD products are currently manufactured in our own production facility in Grand Prairie, Texas.~~ We are reliant on a limited number of suppliers for resin, drug compounds, coating and other component substances of our final ~~product candidates and~~ products. If any of these single source suppliers were to ~~30breach~~ -- **breach** or terminate its supply agreement, if any, with us or otherwise not supply us, we would need to identify an alternative source for the supply of component substances for our ~~product candidates and~~ products. If we fail to procure supply of our products, we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected. Identifying an appropriately qualified source of alternative supply for any one or more of the component substances for our ~~product candidates or~~ products could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our approved products or ~~product candidates or~~ a decrease in sales of our approved products, which could harm our financial position and commercial potential for our ~~product candidates and~~ products. Any alternative vendor would also need to be qualified through an ~~NDA~~ **FDA Prior Approval** ~~supplement~~ **Supplement process** which could result in further delay ~~, including delays related to additional clinical trials~~ . The FDA, DEA, or other regulatory agencies outside of the United States may also require additional studies if we enter into ~~agreements~~ **29agreements** with new suppliers for the manufacture of our ADHD products that differ from the suppliers used for clinical development of such ~~product~~ **products** ~~candidates~~ . These factors could cause the delay of ~~clinical trials, regulatory submissions, required approvals or~~ commercialization of our products ~~and product candidates~~ , cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and APIs on a timely basis and at commercially reasonable prices, including if our suppliers did not receive adequate DEA quotas for the supply of certain scheduled components, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our ADHD products may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected. **We rely on** ~~Third~~ **third parties 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. **Our ADHD products are currently manufactured in our own production facility in Grand Prairie, Texas.** We ~~expect~~ **are in the process of outsourcing the manufacturing of our ADHD products** to ~~engage~~ **a** third ~~parties to~~ **- party** ~~manufacture~~ **manufacturer** to produce commercial quantities of our ADHD products **beginning in late calendar 2023** ~~. This may require us to fund the third party' s capital improvements to manufacture our~~ -- **or** ~~products~~ **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** all ~~of our products in the~~ **other products and** ~~near future. For~~ any future product, we expect to use third- party manufacturers because we ~~will~~ **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 ~~and product candidates~~. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured these components ourselves, including: ● reliance on third parties for regulatory compliance and quality assurance; ● possible breaches of manufacturing agreements by the third parties because of factors beyond our control; ● possible regulatory violations or manufacturing problems experienced by our suppliers; and ● possible termination or non-renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us. Further, if we are unable to secure the needed financing to fund our internal operations, we may not have adequate resources required to effectively and rapidly transition to a third- party CMO for our ADHD products. We may ~~not~~ **30not** be able to meet the demand for our products if one or more of any third- party manufacturers is unable to supply us with the necessary components that meet our specifications. It may be difficult to find alternate suppliers for any of our products ~~or product candidates~~ in a timely manner and on terms acceptable to us. ~~is compromised due to their failure to adhere to clinical protocols,regulatory requirements,or for other reasons.~~ The manufacturing processes and facilities of third- party manufacturers we have engaged for our current approved products are,and any future third- party manufacturer will be,required to comply with the federal Quality System Regulation,or QSR,which covers procedures and documentation of the design,testing,production,control,quality assurance,labeling,packaging,sterilization,storage and shipping of devices.The FDA enforces the QSR through periodic unannounced inspections of manufacturing facilities.Any inspection by the FDA could lead to additional compliance requests that could cause delays in our product commercialization.Failure to comply with applicable FDA requirements,or later discovery of previously unknown problems with the manufacturing processes and ~~46facilities~~ -- **facilities** of third- party manufacturers we engage,including the failure to take satisfactory corrective actions in response to an adverse QSR inspection,can result in,among other things:● administrative or judicially imposed sanctions;● injunctions or the imposition of civil penalties;● recall or seizure of the product in question;● total or partial suspension of production or distribution;● the FDA' s refusal to grant pending future clearance or pre- market approval;● withdrawal or suspension of marketing clearances or approvals;● clinical holds;● warning letters;● refusal to permit the export of the product in question;and ● criminal prosecution.Any of these actions,in combination or alone,could prevent us from marketing,distributing or selling our products,and would likely harm our business.In addition,a product defect or regulatory violation could lead to a government- mandated or voluntary recall by us.We believe the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception.Regulatory agencies in other countries have similar authority to recall drugs or devices because of material deficiencies or defects in design or manufacture that could endanger health.Any recall would divert our management attention and financial resources,expose us to product liability or other claims,and harm our reputation with customers. ~~We plan~~ **Third party performance failures may increase our development costs,delay our ability** to ~~outsource the manufacturing of~~ **obtain regulatory approval,and delay** ~~our~~ **or** ~~ADHD~~ **prevent the commercialization of our** products ~~to a third- party manufacturer to produce commercial quantities of our ADHD products~~. ~~This~~ **While we believe that there are numerous alternative sources to provide these services,in the event that we seek such alternative sources,we** may ~~require us to fund the third party' s capital improvements to manufacture our products.If the third party is~~ 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 our product candidates, if approved~~, or be unable to meet market demand, and may be unable to generate potential revenues. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. Pharmaceutical companies often encounter difficulties in manufacturing, particularly in scaling up production of their products. These problems include manufacturing difficulties relating to production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel, as well as compliance with federal, state, and foreign regulations. If we are unable to demonstrate stability in accordance with commercial requirements, or if our raw material manufacturers were to encounter difficulties or otherwise fail to comply with their obligations to us, our ability to obtain FDA approval and market our products ~~and product candidates~~ would be jeopardized ~~. In addition, any delay or interruption in the supply of clinical trial supplies could delay or prohibit the completion of our clinical trials, increase the costs associated with conducting our clinical trials and, depending upon the period of delay, require us to commence new trials at significant additional expense or to terminate a trial~~. We purchase raw materials and components from various suppliers in order to manufacture our ADHD products. If we are unable to source the required raw materials from our suppliers, or if we do not obtain DEA quotas or receive inadequate DEA quotas, we may experience delays in manufacturing our ADHD products, and may not be able to meet customer demand for our products. In addition, we **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 ~~or product candidates~~ is compromised due to failure to adhere to applicable laws or for other reasons, we may not be able to obtain, or to maintain once obtained, regulatory approval for such products or ~~product candidates or~~ successfully commercialize such products ~~or product candidates~~, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in ~~clinical development, regulatory submissions, approvals or~~ commercialization of our products ~~or product candidates~~, entail higher costs or adversely impact our commercialization of our products ~~or product candidates~~. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims. If our ~~sole~~ manufacturing facility becomes damaged or inoperable or we decide to or are required to vacate our facility, our ability to manufacture our ADHD products may be jeopardized. Our inability to continue manufacturing adequate supplies of our products could adversely affect our ability to generate revenues. ~~All~~ **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 ~~product candidates or~~ products for some period of time. While we seek to maintain finished goods inventory of our products outside of this facility, it is unlikely that the level of such inventory would be sufficient if we were to sustain anything other than a short- term disruption in our ability to manufacture our products ~~and product candidates~~ at our Grand Prairie, Texas facility. The inability to manufacture our products ~~and product candidates~~ if our facility or our equipment is inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facility and the equipment we use to manufacture our products ~~and product candidates~~ could become damaged and time consuming to repair or replace. It would be difficult, time consuming and expensive to rebuild our facility or repair or replace our equipment or to ~~32complete~~ -- **complete** the transfer of our proprietary technology to a third party, particularly in light of the requirements for a DEA registered manufacturing and storage facility like ours and FDA site change requirements. We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all. An ~~inability~~ **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 ~~product~~ **products** ~~candidates~~, we may not be able to successfully develop products and generate meaningful revenues. We may enter into collaborations with third parties to ~~conduct clinical testing, as well as to~~ commercialize and manufacture our products ~~and product candidates~~. If we are able to identify and reach an agreement with one or more collaborators, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Collaboration agreements typically call for milestone payments that depend on successful demonstration of efficacy and safety, obtaining regulatory approvals, and clinical trial results. Collaboration revenues are not guaranteed, even when efficacy and safety are demonstrated. Further, the economic environment at any given time may result in potential collaborators electing to reduce their external spending, which may prevent us from developing our ~~product~~ **products** ~~candidates~~. Collaboration agreements typically provide for the ownership of intellectual property. In some instances, there may not be adequate written provisions to address clearly the resolution of intellectual property rights that may arise from a collaboration and we may be limited in our ability to use, make or sell these inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Even if we succeed in securing collaborators, the collaborators may fail to develop or effectively commercialize our products ~~or product candidates~~. Collaborations involving our ~~product~~ **products** ~~candidates~~ pose a number of risks, including the following: ● collaborators may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus; ● collaborators may believe our intellectual property is not valid or is unenforceable or the product candidate infringes on the intellectual property rights of others; ● collaborators may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues; ● collaborators may decide to pursue a competitive product developed outside of the collaboration arrangement; ● collaborators may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals; ● collaborators may delay the development or commercialization of our ~~product~~ **products** ~~candidates~~ in favor of developing or commercializing their own or another party' s ~~product~~ **products** ~~candidate~~; or ● collaborators may decide to terminate or not to renew the collaboration for these or other reasons. ~~33As~~ **As** a result, collaboration agreements may not lead to development or commercialization of our ~~product~~ **products** ~~candidates~~ in the most

efficient manner or at all. ~~Collaboration~~ **33Collaboration** agreements are generally terminable without cause on short notice. Once a collaboration agreement is signed, it may not lead to commercialization of a product ~~candidate~~. We also face competition in seeking out collaborators. If we are unable to secure collaborations that achieve the collaborator' s objectives and meet our expectations, we may be unable to advance our products ~~or product candidates~~ and may not generate meaningful revenues. We face substantial competition from companies with considerably more resources and experience than we have, which may result in others discovering, developing, receiving approval for, or commercializing products before or more successfully than us. The biopharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We compete with companies that design, manufacture and market already- existing and new products. We anticipate that we will face increased competition in the future as new companies enter the market with new technologies and / or our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in product marketing and new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. Our competitors may be more successful in acquiring new products than we are. If we fail to acquire new products, implementation of our business plan would be delayed, which could have a negative adverse effect on our business and prospects. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable. Our ability to compete successfully will depend largely on our ability to: ● expand the market for our approved products, especially our pharmaceutical and devices regulated by the FDA; ● successfully commercialize our ~~product~~ **products** ~~candidates~~ alone or with commercial partners; ● discover and develop ~~product~~ **products** ~~candidates~~ that are superior to other products in the market; ● obtain required regulatory approvals; ● attract and retain qualified personnel; and ● obtain patent and / or other proprietary protection for our ~~product~~ **products** ~~candidates~~. Established pharmaceutical companies devote significant financial resources to discovering, developing or licensing novel compounds that could make our products ~~and product candidates~~ obsolete. Our competitors may obtain patent protection, receive FDA approval, and commercialize medicines before us. Other companies are or may become engaged in the discovery of compounds that may compete with the ~~product~~ **products** ~~candidates~~ we are developing. **We** ~~For our approved products, we~~ compete with companies that design, manufacture and market treatments that compete with our products. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and more experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an ~~34exclusive~~ -- **exclusive** basis drug products or drug delivery technologies that are more effective or less costly than that of our products or any product candidate that we are currently developing or that we may develop. ~~We~~ **34We** anticipate that we will face increased competition in the future as new companies enter the market with new technologies and our competitors improve their current products. One or more of our competitors may offer technology superior to ours and render our technology obsolete or uneconomical. Most of our current competitors, as well as many of our potential competitors, have greater name recognition, more substantial intellectual property portfolios, longer operating histories, significantly greater resources to invest in new technologies, more substantial experience in new product development, greater regulatory expertise, more extensive manufacturing capabilities and the distribution channels to deliver products to customers. If we are not able to compete successfully, we may not generate sufficient revenue to become profitable ~~. Any new product we develop or commercialize that competes with a currently- approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and / or safety in order to address price competition and be commercially successful~~. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer. Government restrictions on pricing and reimbursement, as well as other healthcare payor cost- containment initiatives, may negatively impact our ability to generate revenues. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following: ● our or our collaborators' ability to set a price we believe is fair for our approved products; ● our ability to generate revenue from our approved products and achieve profitability; and ● the availability of capital. The ~~2010 enactments of the~~ Patient Protection and Affordable Care Act, or PPACA, and the Health Care and Education Reconciliation Act, or the Health Care Reconciliation Act, significantly impacted the provision of, and payment for, health care in the U. S. Various provisions of these laws are designed to expand Medicaid eligibility, subsidize insurance premiums, provide incentives for businesses to provide health care benefits, prohibit denials of coverage due to pre- existing conditions, establish health insurance exchanges, and provide additional support for medical research. Amendments to the PPACA and / or the Health Care Reconciliation Act, as well as new legislative proposals to reform healthcare and government insurance programs, along with the trend toward managed healthcare in the U. S., could influence the purchase of medicines and medical devices and reduce demand and prices for our products ~~and product candidates~~, if approved. This could harm our or our collaborators' ability to market any approved products and generate revenues. As we expect to receive significant revenues from reimbursement of our Rx Portfolio products by commercial third-party payors and government payors, cost containment measures that health care payors and providers are instituting and the effect of further health care reform could significantly reduce potential revenues from the sale of any of our products ~~and product candidates~~ approved in the future, and could cause an increase in our compliance, manufacturing or other operating

expenses. In addition, in certain foreign markets, the pricing of prescription drugs and devices is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the federal and state level, as well as internationally, will continue and may increase, which may make it difficult for us to sell any approved product at a price acceptable to us or any of our future collaborators. In addition, in some foreign countries, the proposed pricing for a drug or medical device must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. A member state may require that physicians prescribe the generic version of a drug instead of our approved branded product. There can be no ~~35assurance~~ -- **assurance** that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products or product candidates. Historically, pharmaceutical products launched in the EU do not follow price structures of the U. S. and generally tend to have significantly lower prices. ~~Our~~ **35Our** financial results will depend on the acceptance among clinicians, ~~hospitals,~~ third- party payors and the medical community of our products ~~and product candidates~~ . Physicians may not choose to prescribe our products if we or any collaborator is unable to demonstrate that, based on experience, clinical data, side- effect profiles and other factors, our product is preferable to existing medicines or treatments. Our future success depends on the acceptance by our target customers, third- party payors, and the medical community that our products ~~and product candidates~~ are reliable, safe, and cost- effective. We cannot predict the degree of market acceptance of any of our approved products. Many factors may affect the market acceptance and commercial success of our products ~~and product candidates~~ , including: ● our ability to convince our potential customers of the advantages, safety and economic value our products and product candidates over existing technologies and products; ● the approved labeling for the product and any required warnings; ● the prevalence and severity of adverse events or publicity; ● potential product liability claims ● the relative convenience and ease of our products ~~and product candidates~~ over existing technologies and products; ● the introduction of new technologies and competing products that may make our products ~~and product candidates~~ less attractive for our target customers; ● our success in training medical personnel on the proper use of our products ~~and product candidates~~ ; ● the willingness of third- party payors to reimburse our target customers that adopt our products ~~and product candidates~~ ; ● increases in rebate payments with payors; ● the acceptance in the medical community of our products ~~and product candidates~~ ; ● the extent and success of our manufacturing, marketing, and sales efforts; and ● general economic conditions. If our future **products** ~~therapeutic candidates~~ fail to gain market access and acceptance, this will have a material adverse impact on our ability to generate revenue to provide a satisfactory, or any, return on our investments. Even if some therapies achieve market access and acceptance, the market may prove not to be large enough to allow us to generate significant revenue. If third- party payors do not reimburse our customers for the products we sell or if reimbursement levels are set too low for us to sell one or more of our products at a profit, our ability to sell those products and our results of operations will be harmed. While our pharmaceutical products are approved and generating revenues in the U. S., they may not receive, or continue to receive, ~~physician~~ **clinician** or ~~hospital~~ **patient** acceptance, or they may not maintain adequate reimbursement from third party ~~36payors. Additionally, even if one of our product candidates is approved and reaches the market, the product may not achieve physician or hospital acceptance, or it may not obtain adequate reimbursement from third party~~ payors. In the future, we might possibly sell other ~~product~~ **products** ~~candidates~~ to target customers substantially all of whom receive reimbursement for the health care services they provide to their patients from third- party payors, such as Medicare, Medicaid, other domestic and foreign government programs, private insurance plans and managed care programs. Reimbursement decisions by particular third- party payors depend upon a number of factors, including each third- party payor' s determination that use of a product is: ● a covered benefit under its health plan; **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 ~~our~~ **their** ~~calculation~~ **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 ~~37condition~~ -- **condition** and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in increased pressure on pricing and reimbursement of products and thus have an adverse impact on financial position or business operations. Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in a company having to carry a liability on its consolidated balance sheets for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, the company' s financial position and results of operations could be adversely affected. ~~In~~ **37In** addition to retroactive rebates and the potential for 340B Program refunds, if a pharmaceutical firm is found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to the Centers for Medicare & Medicaid Services (" CMS "), it may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate the Medicaid drug rebate agreement, pursuant to which companies participate in the Medicaid program. In the event that CMS terminates a rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for covered outpatient drugs. Additionally, if a pharmaceutical company overcharges the government in connection with the FSS program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, it is required to refund the difference to the government. Failure to make necessary disclosures and / or to identify contract overcharges can result in allegations against a company under the FCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time- consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Our collaborators are also subject to similar requirements outside of the U. S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues. Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our products ~~and product candidates~~ in foreign markets for which we intend to primarily rely on collaboration with third parties **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 ~~or product candidates~~ in foreign markets, we would be subject to additional risks and uncertainties, including: ● our inability to directly control commercial activities because we are relying on third parties; ● the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; ● different medical practices and customs in foreign countries affecting acceptance in the marketplace; ● import or export licensing requirements; ● longer accounts receivable collection times; ● longer lead times for shipping; ● language barriers for technical training; ● reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to our products; ~~38~~ ● foreign currency exchange rate fluctuations; ● our customers' ability to obtain reimbursement for our products in foreign markets; and ● the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. Foreign sales of our products ~~or product candidates~~ could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. ~~We~~ **38We** are subject to U. S. and foreign anti- corruption and anti- money laundering laws with respect to our operations and non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. In addition, we may engage third party intermediaries to ~~coordinate our clinical research activities abroad and / or to~~ obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities. We have adopted a Code of Business Conduct and Ethics that mandates compliance with the FCPA and other anti- corruption laws applicable to our business throughout the world. We cannot ensure, however, that our employees and third party intermediaries will comply with this code or such anti- corruption laws. Noncompliance with anti- corruption and anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage, and other collateral consequences. If any subpoenas, investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any such action will likely result in a materially significant diversion of management' s attention and resources and significant defense and compliance

costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. RISKS RELATED TO PRODUCT DEVELOPMENT AND REGULATORY APPROVALOur pre- commercial product candidates undergo clinical trials that are time- consuming and expensive, with uncertain timelines and the outcomes of which are unpredictable, and for which there is a high risk of failure. Delays, suspensions, and terminations in any clinical trial we undertake could result in increased costs to us and delay or prevent our ability to generate revenues. We may not be able to develop our current or future product candidates. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U. S. and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of future therapeutic candidates, we must demonstrate through lengthy, complex, and expensive nonclinical studies, preclinical studies and clinical trials that the applicable therapeutic candidate is both safe and effective for use in each target 39indication. A therapeutic candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. Pre- clinical testing and clinical trials are long, expensive and unpredictable processes that can be subject to extensive delays for reasons such as product safety and efficacy, agreeing on acceptable terms with prospective CROs and clinical trial sites, validating testing, obtaining or manufacturing sufficient quantities of the product being tested, obtaining approval of an IND from the FDA, obtaining appropriate board approvals, and determining dosing and design. Further, identifying, qualifying, and retaining patients to participate in our clinical trials will be critical to our success. Patient enrollment depends on many factors, including the available patient population size, identifying and enrolling willing and eligible patients, the safety profile of product candidate and its perceived risks, our ability to recruit qualified clinical trial investigators, the existence of competing clinical trials, the availability of approved products for the indication that is the subject of the clinical trial, and our ability to obtain and maintain patient informed consents. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. It may take several years to complete the pre- clinical testing and clinical development necessary to commercialize a drug, and delays or failure can occur at any stage. Delays, suspensions or terminations of trials can occur for various reasons, including product ineffectiveness; adverse events, safety issues or side effects; inability to fund the trial; trial design may be costly or lengthy; an inability to collaborate regarding development or commercialization; failing to follow regulatory requirements or to adjust to changes in regulations while the trial is in process; failure to obtain needed patient information due to patients ceasing contact after treatment; and interpretations of trial results that differ from ours. These factors may also lead to denial of an NDA for a product candidate. Sometimes our product candidates are developed for other indications by another sponsor. Undesirable adverse events that occur in relation to the activities by another sponsor related to our product candidate could cause us or regulatory authorities to interrupt, delay or halt development or could result in the delay or denial of regulatory approval by the FDA or other comparable regulatory authorities. Drug- related adverse events involving our product candidate by another sponsor could also harm our reputation, business, financial condition and business prospects. Interim results of clinical trials do not necessarily predict final results, and success in pre- clinical testing and early clinical trials does not ensure that later clinical trials will be successful. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials even after promising results in earlier trials and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. An unfavorable outcome in one or more trials would be a major set- back for that product candidate and for us. Due to our limited financial resources, an unfavorable outcome in one or more trials may require us to delay, reduce the scope of, or eliminate one or more product development programs, which could have a material adverse effect on our business, prospects, and financial condition and on the value of our common stock. In connection with clinical testing and trials, we face a number of risks, including: ● a product candidate is ineffective, inferior to existing approved medicines, unacceptably toxic, or has unacceptable side effects; ● patients may die or suffer other adverse effects for reasons that may or may not be related to the product candidate being tested; ● the results may not confirm the positive results of earlier testing or trials; and ● the results may not meet the level of statistical significance required by the FDA or other regulatory agencies to establish the safety and efficacy of the product candidate. 40If we do not successfully complete pre- clinical and clinical development, we will be unable to market and sell products derived from our product candidates and generate revenues. Even if we do successfully complete clinical trials, those results are not necessarily predictive of results of additional trials that may be needed before an NDA may be submitted to the FDA. Obtaining approval of an NDA is a complex, lengthy, expensive, and uncertain process, and the FDA may delay, limit or deny approval of any product candidate for many reasons, including, the issues identified in the list of risks above and others, including these: ● the FDA may require that we conduct additional clinical trials; ● the FDA may not approve the formulation, labeling or specifications of any product candidate; ● the CRO that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials; ● the FDA may find the data from pre- clinical studies and clinical trials insufficient to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks, such as the risk of drug abuse by patients or the public in general; ● the FDA may disagree with our interpretation of data from our pre- clinical studies and clinical trials; ● the FDA may not accept data generated at our clinical trial sites; ● if an NDA, if and when submitted, is reviewed by an advisory committee, the FDA may have difficulties scheduling an advisory committee meeting in a timely manner or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre- clinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions; ● the FDA may require development of a Risk Evaluation and Mitigation Strategy, or REMS,

as a condition of approval or post- approval; ● the FDA may not approve the manufacturing processes or facilities of third- party manufacturers with which we contract; or ● the FDA may change its approval policies or adopt new regulations. Although there are a large number of drugs in development in the U. S. and other countries, only a small percentage result in the submission of an NDA to the FDA, even fewer are approved for commercialization, and only a small number achieve widespread physician and consumer acceptance following regulatory approval. If our clinical trials are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business, prospects and financial condition will be materially harmed. In order to market and sell our products in the EU and many other jurisdictions, we, and our collaborators, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional testing. If we or our collaborators seek marketing approval for a product candidate outside the U. S., we will be subject to the regulatory requirements of health authorities in each country in which we seek approval. With respect to marketing authorizations in Europe, we will be required to submit a European Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMA, which conducts a validation and scientific approval process in evaluating a product for safety and efficacy. The approval procedure varies among regions and countries and may involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. 41Obtaining regulatory approvals from health authorities in countries outside the U. S. is likely to subject us to all of the risks associated with obtaining FDA approval described above. In addition, marketing approval by the FDA does not ensure approval by the health authorities of any other country, and approval by foreign health authorities does not ensure marketing approval by the FDA. The medical device regulatory clearance or approval process is expensive, time consuming and uncertain, and the failure to obtain and maintain required clearances or approvals could prevent us from broadly commercializing the Healight Platforms for clinical use. The development of Healight is based on scientific hypotheses and experimental approaches that may not lead to desired results. It is possible that the timeframe for obtaining proof of principle and other results may be considerably longer than originally anticipated, or may not be possible given time, resource, financial, strategic, and collaborator constraints. Success in one stage of testing is not necessarily an indication that the Healight program will succeed in later stages of testing and development. The discovery of unexpected side effects, inability to increase scale of manufacture, market attractiveness, regulatory hurdles, competition, as well as other factors may make the Healight technology unattractive of unsuitable for human use. We expect the Healight Platform will be subject to 510k (or, potentially 510k De Novo) clearance by the FDA prior to its marketing for commercial use in the U. S., and to regulatory approvals required by certain foreign governmental entities prior to its marketing outside of the U. S. In addition, any changes or modifications to a device that has received regulatory clearance or approval that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, may require the submission of a new application for 510k clearance, pre- market approval, or foreign regulatory approvals. The 510k clearance and pre- market approval processes, as well as the process of obtaining foreign approvals, can be expensive, time consuming and uncertain. It generally takes from four to twelve months from submission to obtain 510k De Novo clearance, and from one to three years from submission to obtain pre- market approval; however, it may take longer, and 510k, 510k De Novo clearance or pre- market approval may never be obtained. We have limited experience in filing FDA applications for 510k, 510k De Novo clearance and pre- market approval. In addition, we are required to continue to comply with applicable FDA and other regulatory requirements even after obtaining clearance or approval. There can be no assurance that we will obtain or maintain any required clearance or approval on a timely basis, or at all. Any failure to obtain or any material delay in obtaining FDA clearance or any failure to maintain compliance with FDA regulatory requirements could harm our business, financial condition and results of operations. Even if we, or our collaborators, obtain marketing approvals for our product candidates, we may be subject to additional marketing limitations, be subject to continual requirements and review by regulatory authorities or be subject to a withdraw of our product' s marketing for various reasons. Any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to post- approval marketing limitations that could limit the market for the product or put the product at a competitive disadvantage relative to alternative therapies. For instance, any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the therapy may be marketed or to the conditions of approval. For this type of limitation, the FDA or other regulatory authorities may (1) require a product to carry a warning in its labeling and on its packaging, where products with black box warnings are subject to more restrictive advertising regulations than products without such warnings, or (2) require the Company to carry out additional and costly post- marketing testing and monitoring, such as Phase IV clinical trials or a monitoring program to measure the safety and efficacy of such product candidates. These restrictions could make it more difficult to market any product candidate effectively. Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our product candidates, we, and our collaborators expect to continue to expend time, money, and effort in all areas of regulatory compliance. Furthermore, any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to continual requirements of and review by the FDA and other regulatory authorities. We would be required to extensively record, monitor, and report on our products, including their underlying 42therapeutic substances; the manufacturing and distributing processes for our products, any adverse events to our products, and any advertising and promotional efforts of our products. All of which is to ensure safety and continued compliance with cGMP and with good clinical practice (" GCP ") for any clinical trials that we conduct post- approval. These record and monitoring processes may result in significant expense and limit our ability to commercialize such therapies. Moreover, the FDA and other agencies, including the Department of Justice, closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off- label use and if we, or our collaborators, do not market any of our product candidates for which

~~we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off- label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion, and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state health care fraud and abuse laws and state consumer protection laws. Finally, any of our approved products and product candidates for which we, or our collaborators, obtain marketing approval may be subjected to a withdrawal of our product' s marketing approval for various reasons. Later discovery of previously unknown problems with any approved product candidate, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in (1) restrictions on the labeling, distribution, marketing or manufacturing of our future product candidates; (2) withdrawal of the product from the market or product recalls; (3) interruption, delay or halt of clinical trials or requirements to conduct post- marketing studies or clinical trials; (4) refusal by the FDA or other foreign regulatory body to approve pending applications or supplements to approved applications we filed or suspension or revocation of license approvals; (5) restrictions on coverage by third- party payors; (6) fines, restitution or disgorgement of profits or revenue; (7) suspension or withdrawal of marketing approvals; (8) product seizure or detention, or refusal to permit the import or export of the product; and (9) injunctions or the imposition of civil or criminal penalties.~~ We are subject to various health care fraud and abuse and reimbursement laws pertaining to the marketing of our approved products. We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of our products, including inducements to potential patients to request our products and services. Additionally, any product promotion educational activities, support of continuing medical education programs, and other interactions with health- care professionals must be conducted in a manner consistent with the FDA regulations **, 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 ~~product~~ **products** ~~candidates~~ , which may have a material adverse effect on our business, operating results and financial condition. ~~Certain of our products~~ **Adzenys XR- ODT and Cotempla XR- ODT** contain ~~, and future other product candidates may contain,~~ controlled substances, **and** ~~the~~ **their** manufacture, use, sale, importation, exportation, prescribing and distribution ~~of which~~ are subject to regulation by the DEA. ~~Certain of our products, such as,~~ Adzenys XR- ODT and Cotempla XR- ODT, (collectively, our " Controlled Substance Products ") **,** which are approved by the FDA, are regulated by the DEA as Schedule II controlled substances. ~~43Before~~ -- **Before** any commercialization of any product candidate that contains a controlled substance, the DEA ~~will need to determine~~ **determines** the controlled substance schedule **of a 39drug** , taking into account the recommendation of the FDA ~~. This may be a lengthy process that could delay our marketing of a product candidate and could potentially diminish any regulatory exclusivity periods for which we may be eligible~~ . Our Controlled Substance Products are, and our other **future** ~~product~~ **products** ~~candidates~~ may, if approved, be regulated as " controlled substances " as defined in the Controlled Substances Act of 1970, or CSA, and the implementing regulations of the DEA, which establish registration, security, recordkeeping, reporting, storage, distribution, importation, exportation, inventory, quota and other requirements administered by the DEA. These requirements are applicable to us, to our third- party manufacturers and to distributors, prescribers, and dispensers of our ~~product~~ **products** ~~candidates~~ . For example, Schedule II controlled substances are subject to various restrictions, including, but not limited to, mandatory written prescriptions and the prohibition of refills. The DEA regulates the handling of controlled substances through a closed chain of distribution. This control extends to the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce. A number of states and foreign countries also independently regulate these drugs as controlled substances. State- controlled substance laws and regulations may have more extensive requirements than those determined by the DEA and FDA. Though state- controlled substances laws often mirror federal law because the states are separate jurisdictions, they may schedule products separately. While some states automatically schedule a drug when the DEA does so, other states require additional state rulemaking or legislative action, which could delay commercialization. Some state and local governments also require manufacturers to operate a drug stewardship program that collects, secures, transports, and safely disposes of unwanted drugs. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use, and may not be marketed or sold in the U. S. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances are considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Amphetamine and methylphenidate, which are the active ingredients in our Adzenys XR- ODT and Cotempla XR- ODT products, **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 contract manufacturer 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 ~~product~~ **products** ~~candidates~~ containing controlled substances. Failure to comply with these laws and regulations could also result in withdrawal of our DEA registrations, disruption in manufacturing and distribution activities, consent decrees, criminal and civil penalties, and state actions, among other consequences. The design, development, manufacture, supply and distribution of our products ~~and product candidates~~ are highly regulated processes and technically complex. We are subject to extensive regulation of the preparation and manufacture of our products for commercial sale. Components of a finished therapeutic product approved for commercial sale or used in late stage clinical trials must be manufactured in accordance with cGMPs and equivalent foreign standards. These regulations govern manufacturing ~~44processes~~ -- **processes** and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes ~~can~~ **40can** lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our products ~~and product candidates~~ that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our approved products as well as any of our future potential ~~product~~ **products** ~~candidates~~ , are highly regulated processes and technically complex. We, along with our third **-** party suppliers, must comply with all applicable regulatory requirements of the FDA and foreign authorities. For instance, because each of our ADHD products is a regulated drug product and subject to the DEA and state- level regulations, we have had to, and will continue to, need to secure state licenses from each **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 ~~a clinical trial or~~ commercial sales or the temporary or permanent closure of our facility. Any such remedial measures imposed upon us could materially harm our business. If we fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new drug product or revocation of a pre- existing approval, or civil or criminal penalties. As a result, our business, financial condition and results of operations may be materially harmed. There is a risk we may be unable to sell and distribute certain of our products if we cannot **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. 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~~ **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 ~~of America~~ . Failure to comply with health and data protection laws and regulations could lead to U. S. federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect our operating results and business. We and any potential collaborators may be subject to U. S. federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health- related and other personal information. In addition, we may obtain health information from third parties, including research institutions ~~from which we obtain clinical trial data,~~ which are subject to privacy and security requirements under HIPAA, as amended by Health Information Technology for Economic and Clinical Health (" HITECH "). To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient- identifiable health information, mandates the adoption of standards relating to the privacy and security of patient- identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers, the federal government, and media outlets with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, we could be subject to significant civil, criminal, and administrative penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. ~~45Compliance~~ -- **Compliance** with U. S. and foreign privacy and data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in ~~government~~ **41government** enforcement actions (which could include civil, criminal, and administrative penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, ~~clinical trial subjects,~~ employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed

to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. We may use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time - consuming and costly. Our research and development processes may involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risk of accidental contamination or discharge and any resultant injury from these materials. We may be sued for any injury or contamination that results from our use or the use by third parties of these materials, and our liability may exceed any insurance coverage and our total assets. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters. Compliance with environmental laws and regulations may be expensive and may impair our research and development efforts. If we fail to comply with these requirements, we could incur substantial costs, including civil or criminal fines and penalties, clean- up costs or capital expenditures for control equipment or operational changes necessary to achieve and maintain compliance. In addition, we cannot predict the impact on our business of new or amended environmental laws or regulations or any changes in the way existing and future laws and regulations are interpreted and enforced. We rely on third parties to conduct..... from our clinical development program. 48RISKS -- **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 ~~or product candidates~~ and may not be able to prevent third parties from infringing on those rights. From time to time we may renegotiate the terms of our existing licensing agreements or other material contracts. There can be no guarantee that the terms of the renegotiated license agreement will be viewed favorably by the market although the renegotiated terms might be advantageous to our business or that the other party would agree to material changes to benefit the Company. For example, in May 2022, we negotiated to terminate the License, Development, Manufacturing and Supply agreement with Tris. The negotiations resulted in reducing the future minimum payments we owed to Tris by approximately $ 8 million. If we were unable to renegotiate the terms of the agreement, it would have had a material negative impact on our cash flows and financial position. **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 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 ~~product~~ **products** ~~candidates and proposed product candidates~~ and in obtaining and maintaining intellectual property rights in our products ~~, product candidates~~ , proprietary know- how and technology advances. We rely on patent protection, as well as a combination of trademark and trade secret laws to protect and prevent others from making, using and / or selling our compounds, processes, apparatuses and technology. While a presumption of validity exists with respect to patents issued to us in the U. S., there can be no assurance that any of our patents will not be challenged, invalidated, circumvented or rendered unenforceable. Such means may afford only limited protection of our intellectual property and may not (i) prevent our competitors from duplicating our inventions; (ii) prevent our competitors from gaining access to our proprietary information and technology; or (iii) permit us to gain or maintain a competitive advantage. In addition, our competitors or other third parties may obtain patents that restrict or preclude our ability to lawfully practice, produce or sell our products in a competitive manner ~~,~~ **.** Obtaining and maintaining a patent portfolio entails significant expense and resources. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent

protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. In addition, the patent scope can be limited in prosecution or by the courts after issuance. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business. ~~49Legal~~ -- **Legal** actions to enforce our patent rights and administrative challenges at the U. S. Patent and Trademark Office can be expensive and may involve the diversion of significant management time. In addition, these actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our business, prospects, financial condition and results of operations. ~~If~~ **43If** we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to patent protection, because we operate in the highly technical field of ~~discovery and~~ development of therapies and medical devices, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We expect to enter into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific and commercial collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party' s relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, courts outside the U. S. may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. We may not be able to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the U. S. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to pharmaceuticals and medical devices. This could make it difficult for us to stop the infringement of some of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. In addition, some countries allow patents to be challenged by third parties in administrative proceedings, which may result in a reduction in scope or cancelation of some or all of the claims. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the U. S. and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. ~~50A~~ **A** dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time consuming and costly, and an unfavorable outcome could harm our business. There is significant litigation in the pharmaceutical ~~and medical device industries~~ **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 ~~or product candidates~~ infringe ~~the~~ **44the** intellectual property rights of others. If our development and commercialization activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented drugs, compositions or devices that relate to our prescription and consumer health business. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third- party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies or universities involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation, wrongful disclosure of confidential information, or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a material adverse impact on our cash position and stock price. Any legal action

against us or our collaborators could lead to: ● payment of damages, potentially treble damages, if we are found to have willfully infringed a party' s intellectual property rights; ● injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or ● we or our collaborators having to enter into license arrangements that may not be available on commercially reasonable or acceptable terms, if at all, all of which could have a material adverse impact on our cash position and business, prospects and financial condition. As a result, we could be prevented from commercializing our products ~~and product candidates~~. RISKS RELATED TO OUR ORGANIZATION, STRUCTURE AND 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; ~~51~~ ● increased operating costs; ● limitations imposed by various governmental entities; and ● difficulties due to lack of or limited prior experience in any new markets we may enter. ~~Our~~ **45Our** inability to mitigate these risks or other problems encountered in connection with our strategies for growth and change could have a material adverse effect on our business, results of operations and financial condition. In addition, we may fail to fully achieve the savings or growth projected for current or future initiatives notwithstanding the expenditure of substantial resources in pursuit thereof. We may have difficulties integrating acquired products and businesses and as a result, our business, results of operations and / or financial condition may be materially adversely affected. We have completed a number of acquisitions, and we intend to continue to acquire additional products and businesses through mergers, asset purchases or in- licensing, businesses or products, or form strategic alliances as part of our business strategy. Such growth strategies involve risks, including: ● inability to efficiently operate new businesses or to integrate acquired products and businesses; ● inability to accurately predict delays in realizing the costs and benefits of acquisitions, partnerships, or joint ventures; ● unexpected losses of customers or suppliers of an acquired or existing business; ● difficulties in retaining key employees of acquired businesses; ● difficulties in realizing projected synergies; ● failure of the acquired business to produce the expected value; ● exposure to unanticipated liabilities, including unexpected environmental exposures, litigation challenging a merger, product liability or illegal activities conducted by an acquired company or a joint venture partner. Our inability to address these risks in a timely manner or at all could cause us to fail to realize the anticipated benefits of such acquisitions or joint ventures and could have a material adverse effect on our business, results of operations and financial condition. In fiscal ~~2022~~ **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, **2023 and** 2022 ~~and 2021~~. During the years ended June 30, **2023 and** 2022 ~~and 2021~~, three customers accounted for 78 % ~~and 54 %~~ of gross revenue, respectively. The loss of one or more of our significant **customers** ~~partners or collaborators~~ could have a material adverse effect on our business, operating results or financial condition. Any reduction, delay or cancellation of an order from these customers or the loss of any of these customers could cause our revenue to decline. If we are unable to diversify our customer base, we will continue to be susceptible to risks associated with customer concentration. Our accounts receivable subjects us to credit risk. We are also subject to credit risk from our accounts receivable related to our product sales. As of June 30, ~~2022~~ **2023**, three customers accounted for **83** ~~94 % of gross accounts receivable. As of June 30, 2021, three customers accounted for 86~~ % of gross accounts receivable. Our profitability and cash flow are dependent on receipt of timely payments from ~~52customers~~ -- **customers**. Any delay in payment by our customers may have an adverse effect on our profitability, working capital and cash flow. There is no assurance that we will be able to collect all or any of its trade receivables in a timely matter. If any of our customers face unexpected situations such as financial difficulties, we may not be able to receive full or any payment of the uncollected sums or enforce any judgment debts against such clients, and our business, results of operations and financial condition could be materially and adversely affected. ~~We~~ **46We** 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 Joshua Disbrow and Mark Oki have employment agreements, the existence of an employment agreement does not guarantee the retention of the executive officer for any period of time, and each agreement obligates us to pay the officer lump sum severance of two **and a half** years and one year, respectively, of salary if we terminate him without cause, as defined in the agreement, which could hurt our liquidity. The loss of the services of either of these individuals would likely have a material adverse effect on us. Our success also will depend upon our ability to attract and retain additional qualified management, marketing, technical, and sales executives and personnel. We do not maintain key person life insurance for any of our officers or key personnel. The loss of any of our directors or key executives, or the failure to attract, integrate, motivate, and retain additional key personnel could have a material adverse effect on our business. We compete for such personnel, including directors, against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. There can be no assurance that we will be successful in attracting or retaining such personnel, and the failure to do so could have a material adverse effect on our business, prospects, financial condition, and results of operations. Product liability and other lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our ~~product~~ **products**

~~candidates~~. We will be exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of therapeutic candidates. Any failure of future therapeutic candidates by us and our corporate collaborators ~~in clinical trials~~ may expose us to liability claims as may the potential sale of any therapies approved in the future. These claims might be made by patients who use our therapies, healthcare providers, pharmaceutical companies, our corporate collaborators or other third parties that research or sell our therapies. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our future therapeutic candidates or any prospects for commercialization of our future therapeutic candidates ~~. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our future therapeutic candidates causes adverse side effects during clinical trials or after regulatory approval, we may be exposed to substantial liabilities~~. The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical, medical device **, dietary supplement** and personal care products ~~and devices~~. Side effects of, or manufacturing defects in, products that we develop and commercialized could result in the deterioration of a patient' s condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits increases. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the affected products. We may be subject to legal or administrative proceedings and litigation other than product liability lawsuits which may be costly to defend and could materially harm our business, financial condition and operations. ~~53Although~~ -- **Although** we maintain general ~~liability, clinical trial~~ liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, insurance coverage is increasingly expensive and difficult to obtain. For example, we have experienced increasing difficulty in procuring insurance coverage for our products, in particular, our **ADHD** ~~opioid based~~ products, due to their status as controlled substances. Inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product or other legal or administrative liability claims could prevent or inhibit the commercial production and sale of any of our products ~~and product candidates~~ that receive regulatory approval, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our collaborators' ability to commercialize our products successfully. A successful product liability claim or series of ~~claims~~ **47claims** 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 ~~us~~ **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 ~~us~~ **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 ~~of these~~ 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 ~~product~~ **products** ~~or product candidates~~ ,

the withdrawal of currently approved products from the market, or result in other legal action. ~~In~~ **48In** addition, we are aware of other legislative, regulatory or industry measures to address the misuse of prescription opioid medications which could affect our business in ways that we may not be able to predict ~~. For example, the State of New York has undertaken efforts to create an annual surcharge on all manufacturers and distributors licensed to sell or distribute opioids in New York, as well as a tax on sales of opioids in the state. Other states have implemented and are also considering legislation that could require us to pay taxes, licensing fees, or assessments on the distribution of opioid medications in those states. These laws and proposed bills vary in the amounts and the means of calculation~~ . Liabilities for taxes or assessments under any such laws will likely have an adverse impact on our results of operations, unless we are able to mitigate them through operational changes or commercial arrangements where permitted and may result in us ceasing to continue to sell our products in these jurisdictions. **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, one stockholder holds approximately 20 % of our outstanding common stock and holds warrants which can be exercised to purchase additional shares of our common stock resulting in ownership of approximately 40 % of our currently outstanding common stock. Accordingly, this stockholder 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 stockholder has been granted the right to designate an individual to join our board of directors, who has since joined the board of directors, and to nominate an additional candidate who is acceptable to us to be elected to the Board, subject to Nasdaq regulations. 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 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 ~~54exchange~~ **exchange** ' s minimum bid price requirement, or prevent future non- compliance with such exchange' s listing requirements. ~~On May 24, 2022, we received a letter from the Nasdaq Stock Market, LLC (" Nasdaq ") indicating that, for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $ 1. 00 per share required for continued inclusion on the Nasdaq Capital Market under the Nasdaq Listing Rules (the " Notice "). The Notice has no effect at this time on the listing of our common stock, which will continue to trade on the Nasdaq Capital Market under the symbol " AYTU. " Under Nasdaq Listing Rule 5810 (c) (3) (A), if during the 180 calendar day period following the date of the Notice the closing bid price of our common stock is at or above $ 1. 00 for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and its common stock will continue to be eligible for listing on the Nasdaq Capital Market, absent noncompliance with any other requirement for continued listing. If, by November 21, 2022, we cannot demonstrate compliance with Nasdaq Listing Rules, we may be eligible for additional time. To qualify for additional time, we would be required to meet the continued listing requirements for the Nasdaq Capital Market, with the exception of the minimum bid price requirement, and would need to provide written notice of its intention to cure the deficiency during the second compliance period by effecting~~ **49Effecting** a reverse stock split, if ~~necessary. If we are not eligible for the second compliance period, then Nasdaq will provide notice that our securities will be subject to delisting. At such time, we may appeal the delisting determination to a Nasdaq Hearings Panel (" Panel "). We would remain listed pending the Panel' s decision. There can be no assurance that, if we appeal a subsequent delisting determination by the Panel, that such appeal would be successful. We intend to monitor the closing bid price of our common stock and consider our available options if the closing bid price of our common stock remains below $ 1. 00 per share. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement for the additional 180- day compliance period with respect to the minimum bid price requirement, or maintain compliance with the other listing requirements. Effecting a reverse stock split, if~~ determined by the Board in its discretion, may not achieve one or more of our objectives. We have ~~affected~~ **effected** ~~four~~ **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, there can be no assurance that a reverse stock split will result in a per- share market price that will attract institutional investors or investment funds or that such share price will satisfy investing guidelines of institutional investors or investment funds. As a result, the trading liquidity of our common stock may not necessarily improve. Further, if a reverse stock split is effected and the market price of our common stock declines, the percentage decline may be greater than would occur in the absence of a reverse stock split. ~~On May 24, 2022, we received notification from Nasdaq that we were not in compliance with the Nasdaq Listing Rules because we did not meet the minimum bid price of $ 1 per share requirement. We have 180 calendar days from May 24, 2022 to regain compliance and may be eligible for additional time to regain compliance. We have scheduled a special meeting of the Stockholders on October 5, 2022, for stockholders to approve a reverse stock split of our common stock of a ratio up to 1- for- 20. The approval of a reverse stock split will provide us with another means to regain compliance with the Nasdaq listing requirements. There are no certainties that we will 55receive stockholder approval for the reverse stock split. If approved by our stockholders, the Board may determine in its discretion to effect a reverse stock split.~~ Our share price is volatile and may be influenced by numerous factors, some of which are beyond our control. The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this prospectus, these factors include: ● the success of products ~~or product candidates~~ we acquire for development or commercialization relative to the success of our competitors ~~; ● clinical trial outcomes~~ ; ● product safety; ● conditions or trends in the healthcare, biotechnology and pharmaceutical industries, including healthcare payment systems; ● our ability to effectively manage operations, financial decisions, internal controls over financial reporting or disclosure controls, performance relative to projections, and attract and retain employees; ● our dependence on third parties, including CROs and scientific and medical advisors; ● adverse regulatory decisions or changes in laws or regulations; ● disputes or other developments relating to patents and other proprietary rights and our ability to obtain patent protection for our ~~product~~ **products** ~~candidates~~ ; ● general political and economic conditions and effects of natural or man- made catastrophic events; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, and the stocks of small- cap healthcare, biotechnology, and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in these " Risk Factors, " could have a dramatic and material adverse impact on the market price of our common stock. You might not be able to resell your shares at or above the price you paid for them. ~~If~~ **50If** securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and any trading volume could decline. Any trading market for our common stock that may develop will depend in part on the research and reports that securities or industry analysts publish about us or our business. We cannot control the number of securities and industry analysts who publish research on us, the extent of their coverage or the content of their reports. Downgrades of our stock or publishing inaccurate or unfavorable research about our business, would likely lead to a decline in our stock price. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we ~~would~~ **could** lose market visibility and demand for our stock could decrease, which might cause our stock price and any trading volume to decline. ~~56Some~~ -- **Some** provisions of our charter documents and applicable Delaware law may discourage an acquisition of us by others, even if the acquisition may be beneficial to some of our stockholders. Provisions in our Certificate of Incorporation and Amended and Restated Bylaws, as well as certain provisions of Delaware law, could make it more difficult for a third- party to acquire us, even if doing so may benefit some of our stockholders. These provisions include: ● the authorization of 50. 0 million shares of " blank check " preferred stock, the rights, preferences and privileges of which may be established and shares of which may be issued by our Board of Directors at its discretion from time to time and without stockholder approval; ● limiting the removal of directors by the stockholders; ● allowing for the creation of a staggered board of directors; ● eliminating the ability of stockholders to call a special meeting of stockholders; and ● establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by the board of directors. This provision could have the effect of discouraging, delaying or preventing someone from acquiring us or merging with us, whether or not it is desired by or beneficial to our stockholders. Any provision of our Certificate of Incorporation or Bylaws or of Delaware law that is applicable to us that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock in the event that a potentially beneficial acquisition is discouraged, and could also affect the price that some investors are willing to pay for our common stock. We do not intend to pay cash dividends on our capital stock in the foreseeable future. We have never declared or paid any dividends on our common stock and do not anticipate paying any dividends in the foreseeable future. Any payment of cash dividends in the future would depend on our financial condition, contractual restrictions, solvency tests imposed by applicable corporate laws, results of operations, anticipated cash requirements and other factors and will be at the discretion of our Board of Directors. Our

stockholders should not expect that we will ever pay cash or other dividends on our outstanding capital stock. **51We 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. 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** ~~may be adversely affected by the effects of the COVID- 19 pandemic. Our business could~~ **would suffer** ~~be adversely affected by health epidemics~~ in ~~regions where we have~~ **the event of system failures, cybersecurity attacks 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 ~~and could~~ **. As** ~~cause --~~ **use** ~~significant disruption to our operations or in the operations~~ of **digital technologies** ~~CMOs and CROs upon whom we rely. For example, beginning in late 2019, the outbreak of a novel strain of virus named SARS- CoV- 2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes coronavirus disease 2019, or COVID- 19,~~ has **increased** ~~evolved into a global pandemic. The coronavirus has spread to most regions of the world. 57As a result of the coronavirus pandemic~~ , **cyber incidents** ~~we may experience disruptions that could severely impact our business and clinical trials~~ , including **deliberate cybersecurity attacks** ~~: ● We believe that the COVID- 19 pandemic has had,~~ and **attempts** ~~may continue~~ to **gain unauthorized access to computer systems and networks,** have ~~,~~ **increased in frequency** ~~an~~ **and sophistication** ~~adverse impact on demand for our products due to government- imposed quarantines, stay- at- home orders, travel restrictions, mandated business closings and other public health safety measures which may result in patients not visiting their healthcare providers or their pharmacies to get their prescriptions filled . Initially, we suspended in- person interactions by our sales and marketing personnel in healthcare settings. We engaged with these~~ **These threats pose a risk** ~~customers remotely, via webinar programs and virtual meetings, as we sought~~ to ~~continue to support healthcare professionals and patient care. As parts of~~ the **security** ~~country reopened, our sales and marketing personnel reengaged with healthcare professionals, sometimes in limited number~~ of ~~in- person interactions. Remote interactions may be less effective than in- person interactions. ● We currently rely on third- party suppliers, CMOs, and third- party logistics providers. If any such third party in~~ our ~~supply chain for materials is adversely impacted by restrictions resulting from the COVID- 19 pandemic, including staffing shortages and retention, production shutdowns and disruptions in delivery~~ systems ~~, our supply chain may be disrupted, limiting our ability to manufacture commercial quantities of our products. ● In March 2020, we closed some of our offices~~ and **networks** ~~manufacturing facilities,~~ and **52** ~~requested that most of our personnel, including our administrative employees, work remotely, restricted on- site staff to only those personnel who must perform essential activities that must be completed on- site and limited the number of staff in any given location. We reopened our manufacturing in 2020 and our offices reopened on a voluntary basis for those personnel who prefer to work from the office. Our increased reliance on personnel working remotely may negatively~~

impact productivity, or disrupt, delay or otherwise adversely impact our business. ● We may in the future conduct clinical trials for product candidates in geographies which are affected by the coronavirus pandemic. Potential impacts of the coronavirus pandemic on our potential clinical trials may include disruptions or delays in site initiations, patient enrollment and recruitment, standard study monitoring practices, shipment of samples and availability of clinical trial materials, data analysis and reporting of results due to changes in policies at various clinical sites or in federal, state, local or foreign laws, rules and regulations. Other impacts could include quarantines or other travel restrictions. Interruption or delays in the operations of the FDA could also impair our ability to discuss clinical programs. It is unknown how long these pauses or disruptions could continue. ● Health regulatory agencies globally may experience disruptions in their operations as a result of the coronavirus pandemic. The FDA and comparable foreign regulatory agencies may have slower response times or be under- resourced to continue to monitor our clinical trials and, as a result, review, inspection, and other timelines may be materially delayed. It is unknown how long these disruptions could continue, were they to occur. ● The trading prices for our common shares and other biopharmaceutical companies have been highly volatile as a result of the coronavirus pandemic. As a result, we may face difficulties raising further capital through sales of our common shares or convertible debt or such sales may be on unfavorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of the coronavirus could materially and adversely affect our business and the value of our common shares. The coronavirus pandemic continues to rapidly evolve. The ultimate impact of the coronavirus pandemic on our business operations is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted, including the duration of the pandemic, the ultimate geographic spread of the disease, additional or modified government actions, new information that will emerge concerning the severity and impact of COVID- 19 and 58