Risk Factors Comparison 2024-03-11 to 2023-03-08 Form: 10-K

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In addition to other information in this report, please consider the following discussion of factors that make an investment in our securities risky. The risks or uncertainties described in this Form 10 - K can materially and adversely affect our business, **reputation, stock price,** results of operations **, cash flows** or financial condition. The risks and uncertainties described below have been grouped under general risk categories, one or more of which categories may be applicable to the risk factors described. The risks and uncertainties described in this Form 10 - K are not the only ones facing us. Additional risks and uncertainties of which we are unaware or that we currently deem immaterial may also become important factors that can harm our business, **reputation, stock price,** results of operations ~~and~~ **, cash flows, or** financial condition. Summary of Risk Factors The following is a summary of the risks more fully described below and should not be relied upon as an exhaustive summary of the material risks facing our business. Risks Related to Commercial, Regulatory and Other Business Matters • We may not be successful in **driving the growth in sales and profitability of ROLVEDON and / or** commercializing our products using our ~~transformative~~ **sales force and** non- personal ~~and digital~~ promotion ~~strategies~~ **model capabilities** . • **We may be unable to maintain attractive reimbursement of ROLVEDON through government programs such as Medicare and Medicaid. • The INDOCIN products,** Cambia and Zipsor recently began facing competition from generics **,** ~~and INDOCIN suppositories recently began facing competition from a 503B outsourcing facility (commonly referred to as a 503B compounder)~~ which adversely affects our business. Approval of **additional** generic versions of our other products ~~, including the INDOCIN products which are not patent protected and may face generic competition at any time,~~ would have ~~an~~ **a further** adverse effect on our business. • We may not succeed in executing business development **strategies** , strategic partnerships **, acquisitions of businesses, products or technologies,** and investment opportunities ~~. • Failure to successfully identify and acquire complementary businesses~~ , **which** ~~products or technologies~~ will limit our business growth and prospects. • Strategic transactions ~~may~~ **that** fail **to achieve the anticipated levels of revenue, synergies and profit growth will cause our business to suffer** . • We may not be able to integrate any business, product or technology we acquire. • Our success is dependent in large part upon continued services of our executive management team with whom we do not have employment agreements. • ~~The COVID- 19 pandemic has been affecting the Company' s business and operations and may continue to do so. •~~ We depend on one qualified supplier for the active pharmaceutical ingredient in each of our products and single source suppliers to manufacture our products. • Failure to comply with ongoing regulatory requirements for approved products could adversely impact our ability to commercialize our products and result in increased costs. • Commercial disputes may adversely affect the commercial success of our products. • We may be unable to compete successfully in the pharmaceutical **and biological product** industry. • We may be unable to negotiate acceptable pricing or obtain adequate reimbursement for our products. • Business interruptions can adversely impact our ability to operate our business. • Data breaches and cyber- attacks can cause damage to our business. • Our corporate structure may not prevent veil piercing. • We ~~are impacted by~~ **incur significant costs and devote significant management focus on** governmental investigations, regulatory actions and lawsuits regarding Assertio Therapeutics' historical commercialization of opioids. • We may not be able to adequately protect ourselves from product liability losses and other litigation liability. Risks Related to Our Industry • We are impacted by changes in laws and regulations applicable to, and increased scrutiny and investigations of, the pharmaceutical **and biological product** industry. • We may fail to comply with applicable statutes or regulations. • We may incur significant liability if it is determined that we have promoted " off- label " use of drugs. • Healthcare reform may increase our expenses and impact our products. • We are not always able to protect our intellectual property and are subject to risks from liability for infringing the intellectual property of others. • Settlements to ANDA litigation can be challenged and have the potential to lead to significant damage awards. Risks Related to Our Financial Position • We may not ~~have sufficient capital resources or~~ be able to obtain future debt or equity financing necessary to fund our future operations or **execute attractive** product acquisitions and strategic transactions. • We may be unable to generate sufficient cash flow from our business to make **interest** payments on and repay our ~~2027 Convertible Notes. • Conversions of the 2027 Convertible Notes or future sales of our common stock or equity- linked securities in the public market could lower the market price of our common stock and adversely impact the trading price of the~~ 2027 Convertible Notes. • We have incurred operating losses in the past and may incur operating losses in the future. • We have significant amounts of long-lived assets which depend upon future positive cash flows to support the values recorded in our balance sheet. • We may be impacted by our customer concentration. • ~~Our product revenues have typically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. •~~ The fair value of contingent consideration obligation ~~assumed~~ **incurred** as part of **our merger with Zyla Life Sciences (" Zyla ") in May 2020 (** the **"** Zyla Merger **")** may change. • We may be unable to satisfy regulatory requirements relating to internal controls. • Our financial results are impacted by management' s assumptions and use of estimates. Risks Related to Future Product Development • Future product candidates may not be approved for marketing or, if approved, may not achieve market acceptance. • We customarily depend on third- party contract research organizations, clinical investigators and clinical sites to conduct clinical trials with regard to product candidates. • We may not obtain necessary regulatory approvals. • We are subject to risks associated with NDAs submitted under Section 505 (b) (2) of the **Food, Drug and Cosmetic Act (the "** FDCA **")** . Risks Related to Share Ownership and Other Stockholder Matters ~~• The price of our common stock historically has been volatile.~~ • Our common stock may be delisted from the Nasdaq Capital Market if we are unable to **regain and** maintain compliance with Nasdaq' s continued listing standards. • ~~We~~ **The price of our common stock historically has been volatile. • As of December 31, 2023, we** are **no longer** a " smaller reporting company **,** "

~~and~~ **but in accordance with the SEC' s transition rules,** we **continue to** take advantage of reduced disclosure and governance requirements applicable to such companies ~~, which could result in our common stock being less attractive to investors~~ . • We are subject to risks from future proxy fights or the actions of activist shareholders. • We are subject to risks related to unsolicited takeover attempts in the future. **• Conversions of the 2027 Convertible Notes or future sales of our common stock or equity-linked securities in the public market could lower the market price of our common stock and adversely impact the trading price of the 2027 Convertible Notes.** If we **are not successful in driving the growth in sales and profitability of ROLVEDON and / or** do not successfully commercialize our products, our business, financial condition and results of operations will be materially and adversely affected **. In light of substantial reductions in sales, profits and cash flows arising from launch of generic alternatives to the INDOCIN products, our operating results and cash flows are expected to be materially lower thus placing greater risk and higher concentration on ROLVEDON results. Any failure to successfully commercialize ROLVEDON may result in us not realizing the full anticipated advantages of the Spectrum Merger, which could have a material and adverse impact on our business. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant growth in revenues from sales of ROLVEDON. The commercial success of ROLVEDON will depend on a number of factors, including the following: • our partners' ability to consistently manufacture ROLVEDON on a timely basis and supply product to us on commercially acceptable terms; • the prevalence, duration and severity of potential side effects or other safety issues that patients may experience with ROLVEDON; • achieving and maintaining, and, where applicable, ensuring that our third- party contractors achieve and maintain, compliance with our contractual obligations and with all regulatory requirements applicable to ROLVEDON; • the differentiation of ROLVEDON from other available approved or investigational drugs and treatments for patients with chemotherapy- induced neutropenia, and the willingness of physicians, operators of hospitals and clinics and patients to adopt and utilize ROLVEDON; • our ability to successfully develop and execute a commercial strategy focusing on clinics and hospitals; • the availability of coverage and adequate and timely reimbursement from managed care plans, private insurers, government payors (such as Medicare and Medicaid and similar foreign authorities) and other third- party payors for ROLVEDON; • patients' ability and willingness to pay out- of- pocket for ROLVEDON in the absence of coverage and / or adequate reimbursement from third- party payors; • patient demand for ROLVEDON; • the extent to which data from the ROLVEDON same- day dosing trial, if and when completed, may support our ongoing commercialization efforts; • our ability to establish and enforce intellectual property rights in and to ROLVEDON; and • our ability to avoid third- party patent interference, intellectual property challenges or intellectual property infringement claims** . In addition to the risks discussed elsewhere in this section, our ability to successfully commercialize and generate revenues from our products depends on a number of factors, including, but not limited to, our ability to: • develop and execute our ~~digital~~ **sales, marketing** and **promotion strategies for our products using our capability to market products through both a sales force and a** non- personal **promotion model** ~~sales and marketing strategies for our products~~ ; • achieve, maintain and grow market acceptance of, and demand for, our products; • obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third-party payors; • **adapt our commercial strategies while minimizing disruption of relationships with prescribers and other decision- makers; •** maintain, manage or scale the necessary sales, marketing, manufacturing, managed markets and other capabilities and infrastructure that are required to successfully integrate and commercialize our products; • obtain adequate supply of our products; • maintain and extend intellectual property protection for our products; and • comply with applicable legal and regulatory requirements. In December 2020, we eliminated our in- person sales force and have since moved to a digital sales and product promotion model. **In connection** ~~Accordingly, our experience~~ with ~~a digital~~ **the consummation of the Spectrum Merger in July 2023, we acquired Spectrum' s oncology sales force which is currently focused on ROLVEDON. Our reliance on our non** - ~~only sales~~ **personal promotion** model ~~is limited and this model~~ **to promote certain other products** may be less successful than in- person promotion ~~, particularly as pandemic restrictions ease and in- person promotion resumes, including for competing products~~ . If we are unable to successfully achieve or perform these functions **, including our capabilities to market products through both a sales force and a non- personal promotion model** , we will not be able to maintain or increase our revenues and our business, financial condition and results of operations will be materially and adversely affected **. Sales of ROLVEDON depend on coverage and reimbursement from third- party payors and a failure to obtain or a reduction in the coverage and / or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations. Sales of ROLVEDON are dependent on the availability and extent of coverage and reimbursement, or level of reimbursement, from third- party payors, including government programs and private insurance plans. Governments and private payors may regulate prices, reimbursement levels and / or access to our products to contain costs or to affect levels of use. We rely in large part on the reimbursement of ROLVEDON through government programs such as Medicare and Medicaid in the U. S., and a failure to obtain or a reduction in the coverage and / or reimbursement for our products could have a material adverse effect on our product sales, business and results of operations. A substantial portion of our ROLVEDON business relies on reimbursement from the U. S. federal government under Medicare Part B coverage. Most of our products furnished to Medicare beneficiaries in both a physician office setting and hospital outpatient setting will be reimbursed under the Medicare Part B Average Sales Price (" ASP ") payment methodology. ASP- based reimbursement of ROLVEDON under Medicare may be below or could fall below the cost that some medical providers pay for such products, which could materially and adversely affect sales of ROLVEDON. We also face risks relating to the reporting of pricing data that affect the U. S. reimbursement of and discounts for our products. ASP data are calculated by the manufacturer based on a formula defined by statute and regulation and are then submitted to the CMS, the agency responsible for administering the Medicare program, on a quarterly basis. CMS uses those ASP data to determine the applicable**

reimbursement rates for ROLVEDON under Medicare Part B. However, the statute, regulations and CMS guidance do not define specific methodologies for all aspects of the reporting of ASP data. As a result, we are required to apply our reasonable judgment to certain aspects of calculating ASP data. If our submitted ASP data are incorrect, we may become subject to substantial fines and penalties or other government enforcement actions, which could have a material adverse impact on our business and results of operations. The Indocin products, Cambia, and Zipsor recently began facing competition from generics, which adversely affects our business. Approval of additional generic versions of our products would have a further adverse effect on our business . Under the FDCA, the FDA can approve an ANDA for a generic version of a branded drug without the ANDA applicant undertaking the clinical testing necessary to obtain approval to market a new drug. In place of such clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient (s) and is bioequivalent to the branded product, in addition to any data necessary to establish that any difference in strength, dosage, form, inactive ingredients or delivery mechanism does not result in different safety or efficacy profiles, as compared to the reference drug. There are no patents covering the INDOCIN products (which accounted for ~~64~~ **57** % of our revenue in ~~2022~~ **2023**), which means that a generic drug company could introduce a generic for these drugs at any time. **For example, in August 2023, a generic pharmaceutical company received approval from the FDA for, and began to market, 50mg indomethacin suppositories, the generic version of INDOCIN Suppositories. The launch of that generic version had and is expected to continue to have a material and adverse impact on our sales of INDOCIN Suppositories. In January 2024, a pharmaceutical company received FDA approval for a generic version of INDOCIN oral suspension. As a result, the INDOCIN products now face generic competition.** In addition, we are aware of other drug companies that have had interactions with regulatory agencies including **the** FDA relating to indomethacin, which could indicate the development of one or more **additional** INDOCIN product generics or other formulations of indomethacin. ~~Furthermore~~ **Accordingly** , **we could face competition from other generic versions of the INDOCIN Suppositories at any time now that the 180- day CGT exclusivity expired in January 2024 and we could face competition from other generic versions of INDOCIN oral suspension any time after the CGT exclusivity expires in July 2024. As a result of the generic competition, we have lost significant market share and have had to provide pricing concessions to certain customers of INDOCIN Suppositories. In addition, we also face competition for INDOCIN Suppositories from hospitals and other institutions, including** a 503B outsourcing facility (commonly referred to as a 503B compounder) ~~recently~~ **, which** began compounding 100 mg indomethacin suppositories in **2022 in** what we believe to be violation of **state and federal** ~~certain provisions of the FDCA, including, among others, Section 505 approval~~ requirements for new drugs and labeling requirements related to adequate directions for use. For a 503B compounder to qualify for exemptions from these **state and federal** requirements, the 503B compounder must meet certain conditions set forth in Section 503B of the FDCA, including (1) using only bulk drug substances (i. e., indomethacin) that appear on a list identifying the bulk substances for which the FDA has determined that there is clinical need to use in compounding or that the drug product compounded from a bulk drug substance appears on **the** FDA' s drug shortage list; and (2) compounding a drug product that is not " essentially a copy " of an FDA-approved product. We believe that the 503B compounder compounding 100 mg indomethacin suppositories does not meet these conditions as indomethacin **, while it is included on the FDA' s Category 1 list of bulk substances it is evaluating,** is not on **the** FDA' s list of bulk substances for which there is a clinical need and INDOCIN ~~suppositories~~ **Suppositories** are not on the FDA' s drug shortage list; and we believe that the 100 mg indomethacin suppositories being compounded are " essentially a copy " of **our** ~~Zyla' s~~ FDA- approved INDOCIN ~~suppositories~~ **Suppositories** . **We** ~~As a result, Zyla currently faces competition for INDOCIN suppositories from what we believe is an unlawful compounder and could face generic competition at any time for the INDOCIN products. Although Zyla is vigorously pursuing remedies against this compounder, we~~ cannot guarantee that ~~Zyla~~ **we** will be successful in causing it to discontinue sales of its unapproved indomethacin suppository product. **We filed an unfair competition lawsuit in the U. S. District Court (S. D. Tex.) against this 503B compounder, which was dismissed on September 27, 2023; we have filed a notice of appeal and the appeal is pending.** With respect to Cambia and Zipsor (which accounted for ~~16~~ **5** % and 2 % of our revenue in ~~2022~~ **2023** , respectively), we ~~have~~ entered into settlement agreements with generic drug companies, under which generic versions of these products **were launched** ~~can be marketed~~ beginning in January 2023 and March 2022, respectively. As a result, we face generic competition for Cambia and Zipsor. **On February 22, 2024, our partner Miravo, which commercializes a specific formulation of Cambia in Canada, commenced a patent infringement action in Canadian federal court against a generic company seeking approval of a generic version of Cambia in Canada. Under our license agreement with Miravo, we are obligated to reimburse Miravo for a portion of its litigation expenses, which we expect will reduce our quarterly royalties during the pendency of the litigation. Our royalties from Miravo' s net sales of Cambia in Canada will be further adversely impacted if Miravo' s patent infringement litigation fails to keep the generic from launching before the relevant patents expire.** The introduction of ~~one or more~~ **known and potential additional** generic versions of our products, as well as sales of indomethacin suppositories by compounders, or disclosure of ANDA filings and / or similar applications in respect to any of our products, have and in the future could adversely impact our business, financial condition, results of operations and stock price. Moreover, if the ~~orange book~~ patents covering **ROLVEDON (which expire in 2042), Sympazan (which expire in 2040) and / or** Otrexup (which expire in 2031 ~~) and / or Sympazan (which expire in 2040~~) are not upheld in litigation or if a generic competitor is found not to infringe these patents, the resulting generic competition for **ROLVEDON, Sympazan and / or** Otrexup ~~and / or Sympazan~~ would have a further adverse effect on our business, financial condition and results of operations. Our success is dependent on our ~~executive management team' s~~ ability to successfully execute business development **strategies** , strategic partnerships **, acquisitions of businesses, products or technologies,** and investment opportunities to build and grow for the future. ~~Since 2017~~ **Failure to do so will limit our business growth and prospects. Over the past several years** , we have been in the process of transforming into a leading diversified, specialty pharmaceutical company ~~with a goal of rapidly deleveraging~~ **and**

have actively pursued and executed several opportunistic business development and strategic transactions designed to grow our revenues and profits and improve our balance sheet, ~~growing our core business~~ **with varying levels of success. Successfully identifying** and **executing on such** ~~opportunistically building for the future via~~ business development ~~. Since~~ **and strategic transactions is not easily achievable and depends on several factors, including, but not limited to,** ~~then~~ **the** ~~,~~ **availability and willingness of other parties to transact on terms** we ~~have completed a number of~~ **find attractive and our ability to fund such** transactions ~~to advance toward achieving our stated goals. As a result of the transformation~~ from **our existing cash flows** ~~these transactions, we have positioned ourselves to actively pursue business development, strategic partnerships, and investment opportunities to build and grow for~~ **or** ~~the future~~ **raise funds from third parties** . **If** ~~Given the near- term potential for generic competition with a number of our marketed products,~~ we are ~~focused on pursuing~~ **unable to find attractive opportunities, finance them and successfully execute and integrate such acquisitions, our** business **growth** ~~development opportunities. If our executive management team is not able, in a timely manner, to develop, implement~~ and **prospects** ~~execute successful business strategies and plans to maintain and increase our product revenues, our business, financial condition and results of operations~~ will be ~~materially and~~ adversely **impacted** affected, and the existing business may..... will limit our business growth and prospects . An important element of our business strategy is to actively seek to acquire products **, technologies** or companies and to in- license or seek co- promotion rights to additional products. In the past **,** we have acquired **ROLVEDON,** Otrexup, Sympazan, NUCYNTA, NUCYNTA ER (both of which were subsequently divested to Collegium in February 2020), CAMBIA, Zipsor, as well as ~~,~~ **the** INDOCIN products and SPRIX. We cannot be certain that we will be able to successfully identify, pursue **, finance** and complete any ~~further~~ **future** acquisitions or whether we would be able to successfully integrate or develop any acquired business, product or technology **, successfully commercialize and realize the anticipated benefits from acquired products** or retain any key employees. **For example, the anticipated growth and cost savings from the Spectrum Merger, if achieved, may be lower than expected and may take longer to achieve than anticipated.** If we are unable to enhance and broaden our product offerings, our business and prospects will be limited. ~~Strategic transactions that fail~~ **In addition, if our executive management team is not able, in a timely manner,** to **develop,** implement and execute ~~our~~ **successful** business strategies and plans ~~.Any delay in the execution of~~ **to maintain and increase our product revenues,** our business ~~plans by~~ **,financial condition and results of operations will be materially and adversely affected,and the existing business may be required to take further steps to reduce its costs at some point in time.It may take time for** our executive management team, **despite their significant industry- related experience** ~~or any future changes to such management team~~ , ~~could affect our ability~~ to develop,implement and execute our business strategies and plans ~~,which could have an adverse effect on our business,financial condition and results of operations~~ .Further,our future business strategies and plans may differ materially,or may continue to evolve,from those we previously pursued.If our business strategies and plans,or our efforts to realize future operational efficiencies,cause disruption in our business or operations or do not ~~achieve the level of success or results we anticipate,our business,financial condition and results of operations~~ achieve the ~~anticipated~~ **level of success or** results **we anticipate, our business, financial condition** and ~~synergies~~ **results of operations** will ~~cause our business to suffer~~ **be materially and adversely affected** . We seek to engage in strategic transactions with third parties, such as product or company acquisitions, strategic partnerships, joint ventures, divestitures or business combinations. We ~~may~~ face significant competition in seeking potential strategic partners and transactions, and the negotiation process for acquiring any product or engaging in strategic transactions can be time- consuming and complex. Engaging in strategic transactions, such as acquisitions of companies and product rights, divestitures and commercialization arrangements, **have in the past and** may **in the future** require us to incur non- recurring and other charges, increase our near- and long- term expenditures, pose integration challenges and fail to achieve the anticipated results or synergies or distract our management and business, which may harm our business. As part of an effort to acquire a product or company or to enter into other strategic transactions, we conduct business, legal and financial due diligence with the goal of identifying, evaluating and assessing material risks involved in the transaction. Despite our efforts, ~~we ultimately~~ **it is not possible to ascertain, evaluate and accurately assess all possible risks, which** may **impact our ability to** ~~be unsuccessful in ascertaining, evaluating and accurately assessing all such risks and, as a result, might not~~ realize the intended advantages of the transaction. We ~~may~~ also assume liabilities and legal risks in connection with a transaction, including those relating to activities of the seller prior to the consummation of the transaction and contracts that we assume. Failure to realize the expected benefits from acquisitions or strategic transactions that we may consummate, or that we have completed, such as those described above, whether as a result of identified or unidentified risks, integration difficulties, regulatory setbacks, governmental investigations, independent actions of or financial position of our collaborative partners, litigation or other events, could adversely affect our business, results of operations and financial condition **. These factors, many of which are beyond our control, could delay or prevent the achievement of our business objectives and cause our business, financial condition and results of operations to be materially and adversely affected** . Failure to integrate any business, product or technology we acquire, will cause our business, financial condition and operating results to suffer. Integrating any business, product or technology we acquire is expensive and time- consuming and can disrupt and adversely affect our ongoing business, including product sales, and distract our management. Our ability to successfully integrate any business, product or technology we acquire depends on a number of factors, including, but not limited to, our ability to: • **combine our and the acquired business' operations and corporate functions, if any; • meet the capital requirements of the acquired business in a manner that permits us to achieve any cost savings or other synergies anticipated to result from the acquisition; •** minimize the disruption and distraction of our management and other employees in connection with the integration of any acquired business, product or technology; • maintain and increase sales of our existing products; • establish or manage the transition of the manufacture and supply of any acquired product, including the necessary active pharmaceutical ingredients, excipients and components **; • integrate personnel from the acquired business; • integrate the technologies and technologies licensed from third parties; • integrate and unify the offerings and services available to customers; • identify**

and eliminate redundant and underperforming functions and assets; • harmonize our and the acquired business' operating practices, compensation programs, internal controls and other policies, procedures and processes; • maintain existing agreements with customers, suppliers, distributors and vendors, avoid delays in entering into new agreements with prospective customers, suppliers, distributors and vendors, and leverage relationships with such third parties; • address possible differences in business backgrounds, corporate cultures and management philosophies, if any ; • identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology; • manage the transition and migration of all commercial, financial, legal, clinical, regulatory and other pertinent information relating to any acquired business, product or technology; • comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology; • obtain and maintain adequate coverage, reimbursement and pricing from managed care, government and other third- party payors with respect to any acquired product; and • maintain and extend intellectual property protection for any acquired product or technology. If we are unable to perform the above functions or otherwise effectively integrate any acquired businesses, products or technologies, our business, financial condition and operating results will suffer. Our success is dependent in large part upon the continued services of our executive management team with whom we do not have employment agreements. Our success is dependent in large part upon the continued services of members of our executive management team, and on our ability to attract and retain key management and operating personnel. We do not have agreements with any of our executive officers that provide for their continued employment with us. Management, scientific and operating personnel are in high demand in our industry and are often subject to competing offers. **Changes in our management team may disrupt our business, strategic and employee relationships, which may delay or prevent the achievement of our business objectives, strategies and plans. During such transition periods, there may be uncertainty among investors, employees and others concerning our future direction and performance. For example, Dan A. Peisert separated from his service as our CEO effective as of January 2, 2024. Heather L. Mason, an existing member of our Board of Directors, was appointed to serve as our Interim CEO while the Board conducts a search for a permanent CEO. In addition, effective as of November 8, 2023, Ajay Patel was appointed as our CFO to replace Paul Schwichtenberg, who now serves as our Chief Commercial Officer. As with any significant leadership change, these transitions involve inherent risks and any failure to timely identify and appoint a suitable permanent CEO and execute a smooth transition could hinder employee retention and recruitment and our strategic planning, business execution, and future performance, which could have an adverse effect on our business, financial condition and results of operations. We cannot provide assurances that any current or future changes of management personnel, including the appointment of a permanent CEO, will not cause disruption to operations or customer relationships, a decline in our operating results or a delay in the execution of our business strategies and plans.** The loss of the services of one or more members of management or key employees or the inability to hire additional personnel as needed could result in delays in the research, development and commercialization of our products and potential product candidates, or otherwise adversely impact our business ~~. The COVID- 19 pandemic has affected our business and operations and may continue to affect these operations for a sustained period. Because COVID- 19 impacted our ability to see in- person providers who prescribe our products, we adapted our approach during 2020 and increased virtual visits, ultimately eliminating our in- person sales force in favor a fully digital sales strategy. Additionally, due to the limitations on elective surgeries and changes in patient behavior since the outbreak of COVID- 19, we experienced a decline and subsequent volatility in prescriptions associated with those elective procedures. The extent to which our operations may continue to be impacted by the COVID- 19 pandemic depends largely on future developments, which are highly uncertain and cannot be accurately predicted, including actions by government authorities to contain the outbreak, the emergence of new COVID- 19 variants and the related potential for new surges in infections, the impact on third parties on which we rely, including suppliers and distributors, and the impacts of increases in virtual physician visits on prescriber behavior. For example, although many public health restrictions have eased, future surges could result in additional restrictions or other factors that may contribute to decreases in elective procedures~~ . We depend on one qualified supplier for the active pharmaceutical ingredient in each of our products, and we depend on third parties that are single source suppliers to manufacture our products. Insufficient availability of our products or the active pharmaceutical ingredients and other raw materials necessary to manufacture our products, or the inability of our suppliers to manufacture and supply our products **on commercially reasonable terms** , will adversely impact our sales **and / or margins** upon depletion of the active ingredient and product inventories. We have one qualified supplier for the active pharmaceutical ingredient **(" API ")** in each of our products. We do not have, and we do not intend to establish in the foreseeable future, internal commercial- scale manufacturing capabilities. Rather, we intend to use the facilities of third parties to manufacture products for commercialization and clinical trials. Our dependence on third parties for the manufacture of our products and any future product candidates may adversely affect our ability to obtain such products on a timely or competitive basis, if at all. Any stock out, quality concern or failure to obtain sufficient supplies of our products, or the necessary **APIs** ~~active pharmaceutical ingredients~~ , excipients or components, from our suppliers, including as a result ~~to~~ **of** disruptions to supplier operations resulting from factors such as supply chain delays, public health emergencies, climate events or political unrest, or failures by us to satisfy minimum order requirements due to declines in product demand or otherwise, would adversely affect our business, results of operations and financial condition. In particular, our suppliers may be impacted by **epidemics,** ~~ongoing supply chain disruptions and inflationary pressures related to the COVID- 19 pandemic~~ **pandemics or other disease outbreaks or public health emergencies** and general macroeconomic conditions **, including inflationary pressures, economic slowdown or recession, relatively high interest rates, changes in monetary policy, potential U. S. federal government shutdowns, geopolitical conflicts and financial institution instability** , which may result in supply delays and cost increases. The manufacturing process for pharmaceutical products is highly regulated, and regulators may from time to time shut down manufacturing facilities that they believe do not comply with regulations. We, our third- party manufacturers and our

suppliers are subject to numerous regulations, including current FDA regulations governing manufacturing processes, stability testing, record keeping, product serialization and quality standards. Similar regulations are in effect in other countries. Our third-party manufacturers and suppliers are independent entities who are subject to their own operational and financial risks which are out of our control. If we or any third- party manufacturer or supplier fails to perform as required or fails to comply with the regulations of the FDA and other applicable governmental authorities, our ability to deliver adequate supplies of our products to our customers on a timely basis **and on commercially reasonable terms** , or to conduct clinical trials, could be adversely affected **. For example, in October 2023, Spectrum' s drug product manufacturer for ROLVEDON demanded a significant price increase despite fixed pricing provisions in Spectrum' s supply agreement through the latter half of 2025. We have renegotiated supply to meet our demands through 2024 and into 2025 and had to accept higher prices than were previously contracted for, but have no assurance our supplier will not make further demands that may impact future supply or have a material adverse impact on our business. Additionally, although we have fixed pricing with our contract manufacturer for INDOCIN Suppositories through July 2028, we understand the API provider to our INDOCIN contract manufacturer has demanded a significant price increase to continue supplying API to our contract manufacturer on a purchase order basis. We are assessing the legal and business implications of these circumstances and cannot predict how they may ultimately be resolved** . The manufacturing processes of our third- party manufacturers and suppliers may also be found to violate the proprietary rights of others. To the extent these risks materialize and adversely affect such third- party manufacturers' and / or suppliers' performance obligations to us, and we are unable to contract for a sufficient supply of required products on acceptable terms, or if we encounter delays and difficulties in our relationships with manufacturers or suppliers, our business, results of ~~operation~~ **operations** and financial condition could be adversely affected. We are subject to numerous ongoing regulatory requirements and continual review with respect to products that have obtained regulatory approval. In addition, the discovery of previously unknown problems with a product or manufacturer may result in restrictions on the product, manufacturer or manufacturing facility, including withdrawal of the product from the market. Manufacturers of approved products are also subject to ongoing regulation and inspection, including compliance with FDA regulations governing cGMP ~~or Quality System Regulation (" QSR ")~~ . The FDCA, the ~~CSA~~ **PHSA, the Controlled Substance Act of 1970** and other federal and foreign statutes and regulations govern and influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of our products. In addition, we and our partners are also subject to ongoing DEA regulatory obligations, including annual registration renewal, security, record keeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. The failure to comply with these regulations could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, non- renewal of marketing applications or authorizations or criminal prosecution, which could adversely affect our business, results of operations and financial condition. We are also required to report adverse events associated with our products to the FDA and other regulatory authorities. Unexpected or serious health or safety concerns could result in labeling changes, recalls, market withdrawals or other regulatory actions. Recalls may be issued at our discretion or at the discretion of the FDA or other empowered regulatory agencies. Our commercialization, collaborative and other arrangements may give rise to disputes over commercial terms, contract interpretation and ownership or protection of our intellectual property and may adversely affect the commercial success of our products. We currently have or have had in the past collaboration or license arrangements with a number of companies, including commercialization or collaborative arrangements, some of which have been based on less definitive agreements, such as memoranda of understanding, material transfer agreements, options or feasibility agreements. Commercialization and collaborative relationships are generally complex and can give rise to disputes regarding the relative rights, obligations and revenues of the parties, including the ownership of intellectual property and associated rights and obligations, especially when the applicable collaborative provisions have not been fully negotiated and documented. Such disputes have arisen in the past from time to time and, if they arise again could delay collaborative research, development or commercialization of potential products, and can lead to lengthy, expensive litigation or arbitration. The terms of such arrangements may also limit or preclude us from commercializing products or technologies developed pursuant to such collaborations. Additionally, the commercialization or collaborative partners under these arrangements might breach the terms of their respective agreements or fail to maintain, protect or prevent infringement of the licensed patents or our other intellectual property rights by third parties. Moreover, negotiating commercialization and collaborative arrangements often takes considerably longer to conclude than the parties initially anticipate, which could cause us to enter into less favorable agreement terms that delay or defer recovery of our development costs and reduce the funding available to support key programs. Any failure by our commercialization or collaborative partners to abide by the terms of their respective agreements with us (including their failure to accurately calculate, report or pay any royalties payable to either us or a third party or their failure to repay, in full or in part, either any outstanding receivables or any other amounts for which we are entitled to reimbursement) may adversely affect our results of operations. We are not always able to enter into commercialization or collaborative arrangements on acceptable terms, which can harm our ability to develop and commercialize our current and potential future products and technologies. Other factors relating to collaborations that may adversely affect the commercial success of our products include: • any parallel development by a commercialization or collaborative partner of competitive technologies or products; • arrangements with commercialization or collaborative partners that limit or preclude us from developing products or technologies; • premature termination of a commercialization or collaboration agreement or the inability to renegotiate existing agreements on favorable terms; or • failure by a commercialization or collaborative partner to devote sufficient resources to the development and commercial sales of products using our current and potential future products and technologies. Our commercialization or collaborative arrangements do not necessarily restrict our commercialization or collaborative partners from competing with us or restrict their ability to market or sell competitive products. Our current and any future commercialization or

collaborative partners may pursue existing or other development- stage products or alternative technologies in preference to those being commercialized or developed in collaboration with us. In addition, contract disputes with customers or other third parties may arise from time to time. Our commercialization or collaborative partners, or customers or other third parties, may also terminate their relationships with us or otherwise decide not to proceed with the development, commercialization or purchase of our products. We and our commercial partners may be unable to compete successfully in the pharmaceutical **and biological product** industry. Competition in the pharmaceutical **and biological product** industry is intense and we expect competition to increase. Competing products currently under development or developed in the future may prove superior to our products and may achieve greater commercial acceptance. Most of our principal competitors have substantially greater financial, sales, marketing, personnel and research and development resources than we and our commercial partners do **On October 27,** ~~® (pegfilgrastim- pbbk).In November 2023~~ **2022** , **we completed** the **Sympazan Acquisition from Aquestive.Sympazan competes** ~~FDA approved the 3rd novel LA- GCSF,RYZNEUTA ® (efbemalenograstim alfa- vuxw),~~ with ~~a market launch anticipated in mid- 2024.In addition,there~~ **other** ~~are~~ **generic and branded products in the treatment of LGS,including clobazam tablets and oral solution options.Competition in the LGS marketplace includes branded and generic anti-seizure medications,surgery,neuromodulations,and diet.Pursuant** ~~two~~ **to** ~~new molecular entities:one currently on~~ the ~~market and one in development which may compete with ROLVEDON.In connection with our merger with Zyla Life Sciences (" Zyla ") in May 2020 (the "~~ Zyla Merger ~~")~~ ,we acquired SPRIX and two forms of INDOCIN.SPRIX is an NSAID indicated in adult patients for the short- term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level.INDOCIN products are approved for moderate to severe rheumatoid arthritis including acute flares of chronic disease,moderate to severe ankylosing spondylitis,moderate to severe osteoarthritis,acute painful shoulder (bursitis and / or tendinitis) and acute gouty arthritis **.We face and will continue to face competition from other companies in the pharmaceutical,medical devices and drug delivery industries with respect to SPRIX and INDOCIN products** .These products compete with currently marketed oral opioids,transdermal opioids,local anesthetic patches,stimulants and implantable and external infusion pumps that can be used for infusion of opioids and local anesthetics,non- narcotic analgesics,local and topical analgesics and anti- arthritics. ~~There are~~ . On December 15, 2021, we acquired Otrexup. Otrexup competes with other branded methotrexate products, including other injection and auto- injector products. Competition in the methotrexate market also includes tablets and parenteral dosage forms. In addition, other commonly used pharmaceutical treatments for rheumatoid arthritis include analgesics, NSAIDs, corticosteroids and biologic response modifiers. On October 27, 2022, we..... topical analgesics and anti- arthritics. An alternate formulation of diclofenac is the active ingredient in CAMBIA that is approved in the U. S. for the acute treatment of migraines in adults. CAMBIA competes with a number of triptans that are used to treat migraines and certain other headaches. Currently, eight triptans are available generically and sold in the U. S. (almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan, sumatriptan- naproxen and zolmitriptan). There are other products prescribed for or under development for the treatment or prevention of migraines that are now or may become competitive with CAMBIA, including CGRP inhibitor products. **Certain parties who have entered into settlement agreements with us began to market generic versions of CAMBIA in January 2023.** Diclofenac, the **API** ~~active pharmaceutical ingredient~~ in Zipsor, is an NSAID that is approved in the U. S. for the treatment of mild to moderate pain in adults, including the symptoms of arthritis. Both branded and generic versions of diclofenac are marketed in the U. S. Zipsor competes against other drugs that are widely used to treat mild to moderate pain in the acute setting. In addition, a number of other companies are developing NSAIDs in a variety of dosage forms for the treatment of mild to moderate pain and related indications. Other drugs are in clinical development to treat acute pain. If we are unable to negotiate acceptable pricing or obtain adequate reimbursement for our products from third- party payors, our business will suffer. Sales of our products depend significantly on the availability of acceptable pricing and adequate reimbursement from third- party payors such as: • government health administration authorities; • private health insurers; • health maintenance organizations; • managed care organizations; • pharmacy benefit management companies; and • other healthcare- related organizations. If reimbursement is not available for our products or any future product candidates, demand for our products may be limited. Further, any delay in receiving approval for reimbursement from third - party payors could have an adverse effect on our future revenues. Third- party payors frequently require pharmaceutical companies to negotiate agreements that provide discounts or rebates from list prices and that protect the payors from price increases above a specified annual limit. We have agreed to provide such discounts and rebates to certain third- party payors. We expect increasing pressure to offer larger discounts and rebates or discounts and rebates to a greater number of third- party payors to maintain acceptable reimbursement levels for and access to our products for patients at co- pay levels that are reasonable and customary. Consolidation among large third- party payors may increase their leverage in negotiations with pharmaceutical companies. If we are forced to provide additional discounts and rebates to third- party payors to maintain acceptable access to our products for patients, our results of operations and financial condition could be adversely affected. If third- party payors or wholesalers do not accurately and timely report the eligibility and utilization of our products under discounted programs, our reserves for rebates or other amounts payable to third- party payors may be lower than the amount we are invoiced and we may be required to dispute the amount payable, which would adversely affect our business, financial condition and results of operations. For example, we have had, and continue to have, disputes with managed care providers over rebates related to our products. Even when rebate claims made by such managed care providers are without merit, we may be forced to pay such disputed amounts to the extent our failure to do so could otherwise adversely impact our business, such as our ability to maintain a favorable position on such provider' s formulary. In addition, if competitors reduce the prices of their products, or otherwise demonstrate that they are better or more cost effective than our products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce sales of our products and harm our results of operations. The process for determining whether a third- party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that such third- party payor will pay for the product once coverage is

approved. Third- party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, including one or more of our products. Any third- party payor decision not to approve pricing for, or provide adequate coverage and reimbursement of, our products, including by reducing, limiting or denying reimbursement for new products or excluding products that were previously eligible for reimbursement, would limit the market acceptance and commercial prospects of our products and harm our business, financial condition and results of operations. For example, sales of SPRIX have been negatively impacted by a formulary action by a large ~~PBM~~ **pharmacy benefit manager** in 2020. In addition, any third- party payor decision to impose restrictions, limitations or conditions on prescribing or reimbursement of our products, including on the dosing or duration of prescriptions for our products, would harm our business, financial condition and results of operations. Business interruptions can limit our ability to operate our business and adversely impact the success of our commercialization partners. Our operations and infrastructure, and those of our partners, third- party suppliers, manufacturers and vendors are vulnerable to damage or interruption from cyber- attacks and security breaches, human error, natural disasters, fire, flood, the effects of climate change, actual or threatened public health crises, power loss, telecommunications failures, equipment failures, intentional acts of theft, vandalism, terrorism, **epidemics, pandemics and other disease outbreaks, other** public health crises **, adverse economic conditions, including inflationary pressures, economic slowdown or recession, relatively high interest rates, changes in monetary policy, potential U. S. federal government shutdowns, geopolitical conflicts, financial institution instability** and similar events. We have not established a formal disaster recovery plan, and our back- up operations and our business interruption insurance may not be adequate to compensate us for losses that occur. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations. Data breaches and cyber- attacks can compromise our intellectual property or other sensitive information and cause significant damage to our business. In the ordinary course of our business, we collect, maintain and transmit sensitive data on our computer networks and information technology systems, including our intellectual property and proprietary or confidential business information. The secure maintenance of ~~this~~ **such** information is critical to our business **. Furthermore, we have outsourced elements of our operations to third- party vendors, who each have access to our confidential information, which increases our disclosure risk** . We believe that companies have been increasingly subject to a wide variety of security incidents, cyber- attacks and other attempts to gain unauthorized access, including ransomware attacks. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to a state- sponsored attack and motives (including corporate espionage). Cyber threats may be generic, or they may be custom- crafted to target our information systems **or those of our third- party vendors** . Cyber- attacks are becoming increasingly more prevalent and much harder to detect and defend against. **Sophisticated cyber attackers are skilled at adapting to existing security technology and developing new methods of gaining access to organizations' sensitive business data, which could result in the loss of proprietary information, including trade secrets. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently and may not be recognized until or after they are launched.** Our network and storage applications and those of our third- party vendors may be subject to unauthorized access by hackers or breached due to operator error, malfeasance or other system disruptions. **We** ~~Although our Board of Directors, through our Audit Committee, regularly discusses with management our policies~~ and **certain of the third** ~~practices~~ --- **parties** ~~regarding~~ **for which we depend on to operate our business may, and certain of such third parties have, experienced cybersecurity incidents, including third- party unauthorized access to and misappropriation of personal information, and may experience similar incidents in the future. Our and our third- party vendors'** information technology **and other internal infrastructure** systems **face the risk of breakdown or other damage or interruption from service interruptions** , **system malfunctions, natural disasters, terrorism, war, and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyber- attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of** information ~~management~~ **), each of which could compromise our** ~~systems~~ **system** ~~and related~~ infrastructure ~~, including our~~ **or** ~~information technology and information management~~ **lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets. There can be no assurance that our** ~~security~~ **cybersecurity** , risk management ~~and back~~ **protocols will be sufficient to prevent or mitigate cyber** - **attacks. In addition** ~~up policies, practices and infrastructure~~ , it is often difficult to anticipate or immediately detect such incidents and the damage that may be caused by such incidents. These data breaches and any unauthorized access or disclosure of our information or intellectual property could compromise our intellectual property and expose sensitive business information, including our financial information or the information of our business partners. Cyber- attacks could cause us to incur significant remediation costs, result in product development delays, disrupt key business operations **, harm our reputation** and divert attention of management and key information technology resources **. We expect to incur significant costs in an effort to detect and prevent security incidents and otherwise implement our internal security and business continuity measures, and actual, potential, or anticipated attacks may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, and engage third- party experts and consultants. We may face increased costs and find it necessary or appropriate to expend substantial resources in the event of an actual or perceived security breach** . Our network security and data recovery measures and those of our third- party vendors may not be adequate to protect against such security breaches and disruptions. These incidents could also subject us to ~~liability~~ **litigation and regulatory investigations** , expose us to significant expense and cause significant harm to our business. Our insurance coverage may not be sufficient to prevent or recover from ~~cyberattacks~~ **cyber- attacks** , including coverage of applicable resulting losses arising from any such incident **. In addition, such insurance may not be available to us**

in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Furthermore, if the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring . Despite our corporate structure, creditors of our operating subsidiaries could be successful in piercing the corporate veil and reaching the assets of one another, which could have an adverse effect on us and our operating results, results from continued operations, and financial condition. Our operating subsidiaries are separate legal entities within our holding company corporate structure. There can be no assurance that our efforts to preclude corporate veil- piercing, alter ego, control person, or other similar claims by creditors of any one particular entity within our corporate structure from reaching the assets of the other entities within our corporate structure to satisfy claims will be successful. If a court were to allow a creditor to pierce the corporate veil and reach the assets of such other entities within our corporate structure, despite such entities not being directly liable for the underlying claims, it could have a material adverse effect on us and our operating results, results from continued operations, and financial condition. Governmental investigations and inquiries, regulatory actions and lawsuits brought against us by government agencies and private parties with respect to Assertio Therapeutics' historical commercialization of opioids can adversely affect our business, financial condition and results of operations. As a result of the greater public awareness of the public health issue of opioid abuse, there has been increased scrutiny of, and investigation into, the commercial practices of opioid manufacturers generally by federal, state and local regulatory and governmental agencies, as well as increased legal action brought by state and local governmental entities and private parties. For example, Assertio Therapeutics is currently named as a defendant, along with numerous other manufacturers and distributors of opioid drugs, in multiple lawsuits alleging common- law and statutory causes of action for alleged misleading or otherwise improper marketing and promotion of opioid drugs. Such litigation and related matters are described in " Item 8. Financial Statements and Supplementary Data- Note ~~13~~ **15** . Commitments and Contingencies. " In March 2017, Assertio Therapeutics received a letter from Sen. Claire McCaskill (D- MO), the then- Ranking Member on the U. S. Senate Committee on Homeland Security and Governmental Affairs, requesting certain information regarding Assertio Therapeutics' historical commercialization of opioid products. Assertio Therapeutics voluntarily furnished information responsive to Sen. McCaskill' s request. Assertio Therapeutics has also received subpoenas or civil investigative demands focused on historical promotion and sales of Lazanda, NUCYNTA, and NUCYNTA ER from various state attorneys general seeking documents and information regarding our historical sales and marketing of opioid products. In addition, the **State of California Department of Insurance (" "** CDI **")** has issued a subpoena to Assertio Therapeutics seeking information relating to its historical sales and marketing of Lazanda. The CDI subpoena also ~~seeks~~ **sought** information on Gralise, a non- opioid product which Assertio Therapeutics divested to Alvogen in 2020. Assertio Therapeutics has also received subpoenas from the DOJ and the New York Department of Financial Services seeking documents and information regarding its historical sales and marketing of opioid products. **We have also received a subpoena from the New York Attorney General in May 2023, pursuant to which the New York Attorney General is seeking information concerning the historical sales and marketing of former opioid products (Lazanda, NUCYNTA, NUCYNTA ER, and OXAYDO) by** Assertio Therapeutics **and Zyla. The Company** also from time to time receives and complies with subpoenas from governmental authorities related to investigations primarily focused on third parties, including healthcare practitioners. ~~Assertio Therapeutics~~ **The Company** is cooperating with the foregoing governmental investigations and inquiries. These matters are described in " Item 8. Financial Statements and Supplementary Data- Note ~~13~~ **15** . Commitments and Contingencies. " These and other governmental investigations or inquiries, as well as lawsuits, in which we are and may become involved may result in additional claims and lawsuits being brought against us by governmental agencies or private parties. It is not possible at this time to predict either the outcome or the potential financial impact of the opioid- related lawsuits mentioned above or any governmental investigations or inquiries of us or any lawsuits or regulatory responses that may result from such investigations or inquiries or otherwise. It is also not possible at this time to predict the additional expenses related to such ongoing opioid- related litigation and investigations, which may be significant. The initiation of any additional investigation, inquiry or lawsuit relating to us, the costs and expenses associated therewith, or any assertion, claim or finding of wrongdoing by us, could: • adversely affect our business, financial condition and results of operations; • result in reputational harm and reduced market acceptance and demand for our products; • harm our ability and our commercial partners' ability to market our products; • cause us to incur significant liabilities, costs and expenses; and • cause our senior management to be distracted from execution of our business strategy. Furthermore, these pending investigations, inquiries and lawsuits could negatively affect our ability to raise capital and impair our ability to engage in strategic transactions. We face risks relating to product liability losses and other litigation liability for which we may be unable to maintain or obtain adequate protection. We are or may be involved in various legal proceedings, lawsuits and certain government inquiries and investigations, including with respect to, but not limited to, patent infringement, product liability, personal injury, antitrust matters, securities class action lawsuits, breach of contract, Medicare and Medicaid reimbursement claims, opioid- related matters, promotional practices and compliance with laws relating to the manufacture and sale of controlled substances. For example, we, along with other opioid manufacturers and, often, distributors, have been named in lawsuits related to the manufacturing, distribution, marketing and promotion of opioids. In addition, we have also received various subpoenas and requests for information related to the distribution, marketing and sale of our former opioid products. Moreover, we ~~recently~~ **have** settled coverage litigation with our primary product liability insurer **and first excess carrier** regarding whether opioid litigation claims noticed by us are covered by our policies with such ~~insurer~~ **insurers . Further, Spectrum is named in several securities class action and shareholder derivative lawsuits filed by former Spectrum stockholders** . Such litigation and related matters are described in " Item 8. Financial Statements and Supplementary Data ~~- -~~

Note ~~13~~ **15** . Commitments and Contingencies. ” If any of these legal proceedings, inquiries or investigations were to result in an adverse outcome, the impact could have an adverse effect on our competitive position, business, financial condition, results of operations and cash flows. We have obtained product liability insurance for sales of our products and any future clinical trials currently underway, but: • we may be unable to maintain product liability insurance on acceptable terms; • we may be unable to obtain product liability insurance for future trials; • we may be unable to obtain product liability insurance for future products; or • our insurance may not provide adequate protection against potential liabilities (including pending and future claims relating to opioid litigation), or may provide no protection at all. Our inability to obtain or maintain adequate insurance coverage at an acceptable cost could prevent or inhibit the commercialization of our products. Defending a lawsuit could be costly and significantly divert management’ s attention from conducting our business. If third parties were to bring a successful product liability or other claims, or series of claims, against us for uninsured liabilities, or in excess of our insured liability limits, our business, results of operations and financial condition could be adversely affected. We are subject to risks from changes in laws and regulations applicable to, and increased scrutiny and investigations of, the pharmaceutical industry, including the opioid market, which can adversely affect our business, financial condition and results of operations. The manufacture, marketing, sale, promotion, and distribution of our products are subject to comprehensive government regulation. Changes in laws and regulations applicable to, and increased scrutiny and investigations of, the pharmaceutical industry, including the opioid market, could adversely affect our business and our ability to commercialize our products, thereby adversely affecting our financial condition and results of operations. For example, various federal and state governmental entities, including the ~~U. S. Department of Justice (“~~ DOJ ~~”)~~ and a number of state attorneys general, have launched investigations into the marketing and sales practices of pharmaceutical companies that market or have marketed opioid and non- opioid pain medications, including us. For instance, we have received subpoenas or civil investigative demands from the DOJ, several state attorneys general, the New York Department of Financial Services and other state regulators seeking documentation and information in connection with Assertio Therapeutics’ historical sales and marketing of opioid products. Any negative regulatory request or action taken by a regulatory agency, including the FDA, with respect to our products could adversely affect our ability to commercialize such products or otherwise adversely affect our business, results of operations, and financial condition and may result in increased administrative costs in responding to government inquiries. The regulatory actions described above, as well as the related litigation and investigations, not only create financial and operational pressure on us, but could also put pressure on other companies in our industry and with which we have contractual arrangements. Such pressures could negatively impact our contractual counterparties and may give rise to contract cancellations, breaches or rejections in bankruptcy. Furthermore, in the event that a contract counterparty seeks to reject a contract, we may have an unsecured claim for damages, which may not be paid in full (if at all), and we may be forced to return payments made within 90 days of the date of filing for bankruptcy protection. If any of these events should occur, it may have a material adverse effect on our business, financial condition and results of operations. Pharmaceutical **and biological product** marketing is subject to substantial regulation in the U. S. and any failure by us or our commercial and collaborative partners to comply with applicable statutes or regulations can adversely affect our business. Our current marketing activities associated with our products, as well as marketing activities related to any other products that we may acquire, or for which we or our collaborative partners obtain regulatory approval, are and will be subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical **and biological** products. The FDA regulates post- approval promotional labeling and advertising to ensure that they conform to statutory and regulatory requirements. In addition to FDA restrictions, the marketing of prescription drugs is subject to laws and regulations prohibiting fraud and abuse under government healthcare programs. For example, the federal healthcare program anti- kickback statute prohibits giving things of value to induce the prescribing or purchase of products that are reimbursed by federal healthcare programs, such as Medicare and Medicaid. In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government. Under these laws, in recent years, the federal government has brought claims against drug manufacturers alleging that certain marketing activities caused false claims for prescription drugs to be submitted to federal programs. Many states have similar statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, and, in some states, such statutes or regulations apply regardless of the payor. Governmental authorities may also seek to hold us responsible for any failure of our commercialization or collaborative partners to comply with applicable statutes or regulations. If we, or our commercial or collaborative partners, fail to comply with applicable FDA regulations or other laws or regulations relating to the marketing of our products, we could be subject to criminal prosecution, civil penalties, seizure of products, injunctions and exclusion of our products from reimbursement under government programs, as well as other regulatory or investigatory actions against our future product candidates, our commercial or collaborative partners or us. We may incur significant liability if it is determined that we are promoting or have in the past promoted the “ off- label ” use of drugs. Companies may not promote drugs for “ off- label ” use — that is, uses that are not described in the product’ s labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off- label uses, and such off- label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician’ s choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off- label uses of drug products by pharmaceutical companies. The Office of Inspector General of the U. S. Department of Health and Human Services (“ OIG ”), the FDA, and the DOJ all actively enforce laws and regulations prohibiting promotion of off- label use and the promotion of products for which marketing clearance has not been obtained. If any of the investigations of the DOJ, the attorneys general identified above, and the CDI, as well as the actions filed by states and municipalities against us, result in a finding that we engaged in wrongdoing, including sales and marketing practices for our former, current and / or future products that violate applicable laws and regulations, we would be subject to significant liabilities. Such liabilities would harm our business, financial condition and results of operations as well as divert management’ s attention from our business operations and damage our reputation. For additional information regarding potential liability, see also “ ~~–~~ –

Governmental investigations and inquiries, regulatory actions and lawsuits brought against us by government agencies and private parties with respect to Assertio Therapeutics' historical commercialization of opioids can adversely affect our business, financial condition and results of operations. " Healthcare reform can increase our expenses and adversely affect the commercial success of our products. There have been, and there will continue to be, legislative, regulatory and third- party payor proposals to change the healthcare system in ways that could impact our ability to commercialize our products profitably. We anticipate that the federal and state legislatures and the private sector will continue to consider and may adopt and implement healthcare policies, such as the IRA and ACA, intended to curb rising healthcare costs. These cost- containment measures may include, among other measures: requirements for pharmaceutical companies to negotiate prescription drug prices with government healthcare programs; controls on government- funded reimbursement for drugs; new or increased requirements to pay prescription drug rebates to government healthcare programs, including if drug prices increase at a higher rate than inflation; controls on healthcare providers; challenges to or limits on the pricing of drugs, including pricing controls or limits or prohibitions on reimbursement for specific products through other means; requirements to try less expensive products or generics before a more expensive branded product; and public funding for cost effectiveness research, which may be used by government and private third- party payors to make coverage and payment decisions. For example, the ACA includes numerous provisions that affect pharmaceutical companies. For example, the ACA seeks to expand healthcare coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The ACA also imposes substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit and an annual fee imposed on all manufacturers of brand prescription drugs in the U. S. The ACA also requires increased disclosure obligations and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics and contains cost- containment measures that could reduce reimbursement levels for pharmaceutical products. The ACA also includes provisions known as the Physician Payments Sunshine Act, which require manufacturers of drugs, biologics, devices and medical supplies covered under Medicare and Medicaid to record any transfers of value to physicians and teaching hospitals and to report this data to the **CMS** ~~Centers for Medicare and Medicaid Services~~ for subsequent public disclosure. Similar reporting requirements have also been enacted on the state level domestically, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with healthcare professionals. Failure to report appropriate data may result in civil or criminal fines and / or penalties. In addition, the IRA contains provisions intended to lower beneficiary drug spending. **The** ~~Beginning in 2023, the~~ IRA enables Medicare to negotiate prescription drug prices with manufacturers of certain high- cost drugs for the first time. A separate provision requires drug manufacturers to pay rebates to Medicare if their drug prices increase at a higher rate than the rate of inflation (the so- called inflation rebate provision). Additionally, ~~effective~~ **beginning** in 2024, the IRA ~~will eliminate~~ **eliminates** the 5 % coinsurance for catastrophic coverage under Medicare Part D; in 2025, the IRA will cap the beneficiary annual out- of- pocket expenditure. These efforts to reduce aggregate beneficiary spending are expected to shift some costs to drug manufacturers. Any new laws or regulations that have the effect of imposing additional costs or regulatory burden on pharmaceutical manufacturers, or otherwise negatively affect the industry, could adversely affect our ability to successfully commercialize our products and any future product candidates. The implementation of any price controls, caps on prescription drugs or price transparency requirements, whether at the federal level or state level, could adversely affect our business, operating results and financial condition. Our success depends in part on our ability to obtain and maintain patent protection for our products and technologies, and to preserve our trade secrets. Our policy is to seek to protect our proprietary rights by, among other methods, filing patent applications in the U. S. and foreign jurisdictions to cover certain aspects of our technology. We hold patents in the U. S. and in foreign countries. In addition, we may pursue patent applications relating to our technologies in the U. S. and abroad. Any such patent applications may lack priority over other applications or may not result in the issuance of patents. Even if issued, our patents may not be sufficiently broad to provide protection against competitors with similar technologies and may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or may not provide us with competitive advantages against competing products. We also rely on trade secrets and proprietary know- how, which are difficult to protect. We seek to protect such information, in part, by entering into confidentiality agreements with employees, consultants, collaborative partners and others before such persons or entities have access to our proprietary trade secrets and know- how. These confidentiality agreements may not be effective in certain cases, due to, among other things, the lack of an adequate remedy for breach of an agreement or a finding that an agreement is unenforceable. In addition, our trade secrets may otherwise become known or be independently developed by competitors. Our ability to develop our technologies and to make commercial sales of products using our technologies also depends on not infringing other patents or intellectual property rights. We are not aware of any such intellectual property claims directly against us. The pharmaceutical industry has experienced extensive litigation regarding patents and other intellectual property rights. Patents issued to third parties could in the future be asserted against us, although we believe that we do not infringe any valid claim of any patents. If claims concerning any of our products were to arise and it was determined that these products infringe a third party' s proprietary rights, we or our commercial partners could be subject to substantial damages for past infringement or could be forced to stop or delay activities with respect to any infringing product, unless we or our commercial partner, as applicable, can obtain a license, or our product may need to be redesigned so that it does not infringe upon such third party' s patent rights, which may not be possible or could require substantial funds or time. Such a license may not be available on acceptable terms, or at all. Even if we, our collaborators or our licensors were able to obtain a license, the rights may be nonexclusive, which could give our competitors access to the same intellectual property. In addition, any public announcements related to litigation or interference proceedings initiated or threatened against us, even if such claims are without merit, could cause our stock price to decline. In circumstances where we settle patent litigation claims asserted against generic drug companies, the terms of these settlements have the potential to generate new litigation, such as our ~~recent~~ litigation over a term

of our Glumetza (metformin) ANDA settlement. Entry into other patent litigation settlement agreements subjects us to additional potential claims challenging these settlements under antitrust laws or other novel theories. Our existing capital resources are not necessarily sufficient to fund our future operations or product acquisitions and strategic transactions that we may pursue. We fund our operations primarily through revenues from product sales and do not have any committed sources of capital. To the extent that our existing capital resources and revenues from ongoing operations are insufficient to fund our future operations, product acquisitions and strategic transactions that we may pursue, or our litigation- related costs, we will have to raise additional funds through the sale of our equity securities, through additional debt financing, from development and licensing arrangements or from the sale of assets. We may be unable to raise such additional capital on a timely basis and on favorable terms, or at all. If we raise additional capital by selling our equity or convertible debt securities, the issuance of such securities could result in dilution of our shareholders' equity positions. Our failure to generate sufficient cash flow from our business to make payments on our debt would adversely affect our business, financial condition and results of operations. Our indebtedness could limit our ability to incur additional debt to fund our operations. We have significant indebtedness under the 2027 Convertible Notes. Holders of the 2027 Convertible Notes will have the right to require us to repurchase their 2027 Convertible Notes for cash upon the occurrence of a " fundamental change, " as defined in the indenture for the 2027 Convertible Notes, and we may elect to settle all or a portion of the conversion obligation of the 2027 Convertible Notes in cash. Our ability to make scheduled payments of the principal of, to pay interest on, to offer to repurchase the 2027 Convertible Notes upon a fundamental change as defined in the indenture for the 2027 Convertible Notes, or to refinance the 2027 Convertible Notes and any additional debt obligations we may incur depends on our future performance, which is subject to economic, financial, competitive and other factors that may be beyond our control. If we are unable to generate the necessary cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Any failure to generate sufficient cash flow to satisfy our obligations under the 2027 Convertible Notes or any future indebtedness could lead to a default under the 2027 Convertible Notes or such indebtedness. The indenture for the 2027 Convertible Notes contains covenants limiting our ability in the future to secure our or our subsidiaries' assets or have our subsidiaries issue guarantees without equally and ratably securing or guaranteeing the 2027 Convertible Notes. These covenants may make it more difficult for us to incur indebtedness to fund our operations on attractive terms or at all. We may seek to refinance all or a portion of our outstanding indebtedness in the future. Any such refinancing would depend on the capital markets and business and financial conditions at the time, which could affect our ability to obtain attractive terms if or when desired or at all. In addition, our significant indebtedness, combined with our other financial obligations and contractual commitments, could have other important consequences to our business. For example, it could: • make it more difficult for us to meet our payment and other obligations under our indebtedness; • result in other events of default under our indebtedness, which events of default could result in all of our debt becoming immediately due and payable; • make us more vulnerable to adverse changes in general economic, industry and competitive conditions and adverse changes in government regulation; • limit our ability to borrow additional amounts for working capital and other general corporate purposes, including funding possible acquisitions of, or investments in, new and complementary businesses, products and technologies, which is a key element of our corporate strategy; • subject us to the risk of increased sensitivity to interest rate increases on any future indebtedness with variable interest rates; • require the dedication of a substantial portion of our cash flow from operations to service our indebtedness, thereby reducing the amount of our cash flow available for other purposes, including working capital, business development activities, any future clinical trials and / or research and development, capital expenditures and other general corporate purposes; • limit our flexibility in planning for, or reacting to, changes in our business and our industry; and • put us at a disadvantage compared to our competitors who have less debt. Any of these factors can adversely affect our business, financial condition and results of operations. In addition, if we incur additional indebtedness, the risks related to our business and our ability to service or repay our indebtedness would increase. ~~In 2022, we issued the 2027 Convertible Notes, and in the future, we may sell additional shares of our common stock or equity- linked securities to raise capital. A substantial number of shares of our common stock is reserved for issuance upon the exercise of restricted stock units and stock options, and upon conversion of the 2027 Convertible Notes. We cannot predict the effect, if any, that conversions of the 2027 Convertible Notes or of any future issuances of common stock or equity- linked securities, may have on the market price of our common stock. The issuance and sale or conversion of substantial amounts of common stock or equity- linked securities, or the perception that such issuances and sales may occur, could adversely affect the trading price of the 2027 Convertible Notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity- linked securities.~~ We have incurred net losses in many years. We may incur operating losses in future years. Any such losses may have an adverse impact on our total assets, shareholders' equity and working capital. We have significant amounts of long- lived assets which depend upon future positive cash flows to support the ~~values~~ **value** recorded in our balance sheet. We are subject to increased risk of future impairment charges should actual financial results differ materially from our projections. Our consolidated balance sheet contains significant amounts of long- lived assets, including intangible assets representing the product rights which we have acquired. We review the carrying value of our long- lived assets when indicators of impairment are present, as was the case in the third quarter ~~of 2022~~ and ~~the~~ fourth quarter of ~~2021~~ **2023** . Conditions that could indicate impairment of long- lived assets include, but are not limited to **, our market capitalization declining below the book value of our equity** , a significant adverse change in market conditions, significant competing product launches by our competitors, significant adverse change in the manner in which the long- lived asset is being used, and adverse legal or regulatory outcomes. **During the third quarter of 2023, we determined that our book value of our equity exceeded our market capitalization, which management determined represented an indicator of impairment with respect to our long- lived assets. Applying the relevant accounting literature, management first assessed the recoverability of our long- lived assets. In performing this assessment, management concluded it was appropriate to group its assets at the entity level,**

most notably attributed to the significant shared operating cost structure which characterizes Assertio. We determined the carrying value of this asset group was not recoverable. Management then assessed and concluded that the fair value of the asset group was less than its carrying value and so recognized an impairment loss of approximately $ 238. 8 million, which was allocated to the intangible assets of the group and is classified within Loss on impairment of intangible assets in the Consolidated Statement of Comprehensive (Loss) Income. In the fourth quarter of 2023, our market capitalization further declined below the book value of our equity, which management determined represented an indicator of impairment. A similar assessment of recoverability and impairment was performed, except that management changed its determination of long- lived asset groups from the entity level to the product level. The asset group reassessment, which will be applied prospectively, was concluded to be necessary by management because of strategic changes to our operating cost structure in the form of reduced levels of shared costs, attributed primarily by the fourth quarter of 2023 and revised, expected go- forward performance of INDOCIN. Management concluded that the fair values of the INDOCIN and Otrexup asset groups were less than their carrying values and recognized an impairment loss for these asset groups of approximately $ 36. 0 million and $ 4. 8 million, respectively. In performing our impairment tests, which assess the recoverability of our assets, we utilize our future projections of cash flows. Projections of future cash flows are inherently subjective and reflect assumptions that may or may not ultimately be realized. Significant assumptions utilized in our projections include, but are not limited to ~~, grouping long- lived assets at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows of other assets and liabilities~~ , our evaluation of the market opportunity for our products, the current and future competitive landscape and resulting impacts to product pricing, future regulatory actions, planned strategic initiatives and the realization of benefits associated with our existing patents. Given the inherent subjectivity and uncertainty in projections, we could experience significant unfavorable variances in future periods or revise our projections downward. This would result in an increased risk that our long- lived assets may be impaired **. Any future impairments could have a material adverse effect on our financial condition and results of operations** . Our customer concentration can materially adversely affect our financial condition and results of operations. We sell a significant amount of our products to a limited number of independent wholesale drug distributors. If we were to lose the business of one or more of these distributors, if any of these distributors failed to fulfill their obligations, if any of these distributors experienced difficulty in paying us on a timely basis, or if any of these distributors negotiated lower pricing or extended payment terms, it could have a material adverse effect on our competitive position, business, financial condition, results of operations and cash flows. ~~Our product revenues have typically been lower in the first quarter of the year as compared to the fourth quarter of the preceding year. We believe this arises primarily as a result of wholesalers' reductions of inventory of our products in the first quarter and annual changes in health insurance plans that occur at the beginning of the calendar year. Our wholesalers typically end the calendar year with higher levels of inventory of our products than at the end of the first quarter of the following year. As a result, in such first quarters, net sales are typically lower than would otherwise have been the case as a result of the reduction of product inventory at our wholesalers. Any material reduction by our wholesalers of their inventory of our products in the first quarter of any calendar year as compared to the fourth quarter of the preceding calendar year can adversely affect our operating results and can cause our stock price to decline. Many health insurance plans and government programs reset annual limits on deductibles and out- of- pocket costs at the beginning of each calendar year and require participants to pay for substantially all of the costs of medical services and prescription drug products until such deductibles and annual out- of- pocket cost limits are met. In addition, enrollment in high- deductible health insurance plans has increased significantly in recent years. As a result of these factors, patients may delay filling or refilling prescriptions for our products or substitute less expensive generic products until such deductibles and annual out- of- pocket cost limits are met. Any reduction in the demand for our products, including those marketed by our commercialization partners as a result of the foregoing factors or otherwise, can adversely affect our business, operating results and financial condition.~~ Changes in fair value of contingent consideration obligation **incurred in** ~~assumed as part of~~ the Zyla Merger can adversely affect our results of operations. Contingent consideration obligations arise from the INDOCIN product and relate to the potential future contingent milestone payments and royalties payable under the respective agreements. The contingent consideration is initially recognized at its fair value on the acquisition date and is remeasured to fair value at each reporting date until the contingency is resolved with changes in fair value recognized in earnings. The fair value of the contingent consideration is determined using an option pricing model under the income approach based on estimated INDOCIN product revenues through January 2029 and discounted to present value. The fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement as defined in fair value measurement accounting. The significant assumptions used in the calculation of the fair value included projections of future INDOCIN product revenues, revenue volatility, discount rate, and credit spread. Significant judgment is employed in determining these assumptions as of the acquisition date and for each subsequent period. Updates to assumptions could have a significant impact on our results of operations in any given period. If we are unable to satisfy regulatory requirements relating to internal controls, our stock price could suffer. Section 404 of the Sarbanes- Oxley Act of 2002 requires companies to conduct a comprehensive evaluation of the effectiveness of their internal control over financial reporting. At the end of each fiscal year, we must perform an evaluation of our internal control over financial reporting, include in our annual report the results of the evaluation and have our external auditors also publicly attest to the effectiveness of our internal control over financial reporting. Our ability to produce accurate financial statements and comply with applicable laws, rules and regulations is largely dependent on our maintenance of internal control and reporting systems, as well as on our ability to attract and retain qualified management and accounting personnel to further develop our internal accounting function and control policies. If we fail to effectively establish and maintain such reporting and accounting systems or fail to attract and retain personnel who are capable of designing and operating such systems, these failures will increase the likelihood that we may be required to restate our financial results to correct errors or that we will become subject to legal and regulatory infractions, which may entail civil litigation and

investigations by regulatory agencies including the SEC. In addition, if material weaknesses are found in our internal controls in the future, if we fail to complete future evaluations on time or if our external auditors cannot attest to the effectiveness of our internal control over financial reporting, we could fail to meet our regulatory reporting requirements and be subject to regulatory scrutiny and a loss of public confidence in our internal controls, which could have an adverse effect on our stock price or expose us to litigation or regulatory proceedings, which may be costly or divert management attention. The preparation of financial statements in conformity with U. S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Estimates are used when accounting for amounts recorded in connection with acquisitions, including initial fair value determinations of assets and liabilities as well as subsequent fair value measurements. Additionally, estimates are used in determining items such as product returns, rebates, evaluation of impairment of intangible assets, fair value of contingent consideration obligation and taxes on income. Although management believes these estimates are based upon reasonable assumptions within the bounds of its knowledge of our business and operations, actual results could differ materially from these estimates. Refer to the Critical Accounting Policies and Significant Estimates section within " Item 7. Management' s Discussion and Analysis of Financial Condition and Results of Operations. " The development of drug **and biological product** candidates is inherently difficult and uncertain, and we cannot be certain that any of our future product candidates or those of our collaborative partners will be approved for marketing or, if approved, will achieve market acceptance. Clinical development is a long, expensive and uncertain process and is subject to delays and failures. As a condition to regulatory approval, each future product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that any such product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. Positive or encouraging results of prior clinical trials are not necessarily indicative of the results obtained in later clinical trials. Further, product candidates in later clinical trials may fail to show the desired safety and efficacy despite having progressed in development. In addition, data obtained from pivotal clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Product candidates are subject to the risk that any or all of them may be found to be ineffective or unsafe, or otherwise may fail to receive necessary regulatory clearances. The FDA or other applicable regulatory agencies may determine that our data is not sufficiently compelling to warrant marketing approval and require us to engage in additional clinical trials or provide further analysis, which may be costly and time- consuming. A number of companies in the pharmaceutical **and biological product** industry have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in preclinical studies or earlier clinical trials. If our future product candidates fail at any stage of development, they will not receive regulatory approval, we will not be able to commercialize them and we will not receive any return on our investment in any such product candidates. Other factors could delay or result in the termination of our or our collaborative partner' s future clinical trials and related development programs, including: • negative or inconclusive results; • patient enrollment requirements and rates; • patient noncompliance with the protocol; • adverse medical events or side effects among patients during the clinical trials; • any findings resulting from FDA inspections of clinical operations; • failure to meet FDA preferred or recommended clinical trial design, end points or statistical power; • failure to comply with good clinical practices; • failure of third- party clinical trial vendors to comply with applicable regulatory laws and regulations; • compliance with applicable laws and regulations; • inability of third- party clinical trial vendors to satisfactorily perform their contractual obligations, comply with applicable laws and regulations or meet deadlines; • delays or failures in obtaining clinical materials or manufacturing sufficient quantities of the product candidate for use in clinical trials; • delays or failures in recruiting qualified patients to participate in clinical trials; • unexpected external medical threats such as **epidemics,** ~~the COVID- 19 pandemic~~ **pandemics ,** or ~~future~~ **other disease** outbreaks; and • actual or perceived lack of efficacy or safety of the product candidate. We are unable to predict whether any future product candidates will receive regulatory clearances or be successfully manufactured or marketed. Further, due to the extended testing and regulatory review process required before marketing clearance can be obtained, the time frame for commercializing a product is long and uncertain. Even if product candidates receive regulatory clearance, these products may not achieve or maintain market acceptance. If it is discovered that our or our collaborators' products or technologies have potential adverse effects or other characteristics that indicate they may be ineffective as therapeutics, our product development efforts and our business could be significantly harmed. Even assuming our or our collaborative partners' products obtain regulatory approval, successful commercialization requires: • market acceptance; • a cost- effective commercial- scale production; and • reimbursement under private or governmental health plans. Any material delay or failure in the governmental approval process, the successful production of commercial product or the successful commercialization of any future approved product candidates, or those of our collaborative partners, could adversely impact our business, financial condition and results of operations. We and our collaborative partners customarily depend on third- party contract research organizations, clinical investigators and clinical sites to conduct clinical trials with regard to product candidates, and if they do not perform their regulatory, legal and contractual obligations, or successfully enroll patients in and manage our clinical trials, we and our collaborative partners may not be able to obtain regulatory approvals for future product candidates. We and our collaborative partners customarily rely on third- party contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise conducting clinical trials. We and our collaborative partners do not directly control these third parties and, as a result, we and our collaborative partners may be unable to control the amount and timing of resources that they devote to our or our collaborative partners' clinical trials. Although we and our collaborative partners rely on third parties to conduct clinical trials, we and our collaborative partners are responsible for confirming that each clinical trial is conducted in accordance with its general investigational plan and protocol, as well as the FDA' s and other applicable regulatory agencies' requirements, including good clinical practices, for conducting, recording and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the trial participants are adequately protected. If we, contract research organizations or other third parties assisting us or our collaborative partners

with clinical trials fail to comply with applicable good clinical practices, the clinical data generated in such clinical trials may be deemed unreliable and the FDA, or other applicable regulatory agencies, may require us or our collaborative partners to perform additional clinical trials before approving any marketing applications with regard to future product candidates. We cannot be certain that, upon inspection, the FDA or other applicable regulatory agencies will determine that any of our clinical trials or **those of** our collaborative partners comply with good clinical practices. In addition, clinical trials must be conducted with product produced under the FDA' s cGMP regulations and similar regulations outside of the U. S. Our or our collaborative partners' failure, or the failure of our product manufacturers, to comply with these regulations may require the repeat or redesign of clinical trials, which would delay the regulatory approval process. We and our collaborative partners also customarily rely on clinical investigators and clinical sites to enroll patients and other third parties to manage clinical trials and to perform related data collection and analysis. If clinical investigators and clinical sites fail to enroll a sufficient number of patients in such clinical trials or fail to enroll them on the planned schedule, these trials may not be completed or completed as planned, which could delay or prevent us or our collaborative partners from obtaining regulatory approvals for future product candidates. Agreements with clinical investigators and clinical sites for clinical testing and for trial management services place substantial responsibilities on these parties, which could result in delays in, or termination of, clinical trials if these parties fail to perform as expected. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to clinical protocols or for other reasons, clinical trials may be extended, delayed or terminated, and we and our collaborative partners may be unable to obtain regulatory approval for, or successfully commercialize, product candidates. In addition, clinical trials sometimes need to be amended once the trial is in process in order to ensure enrollment and / or successful prosecution of a trial, and such amendments could introduce significant delays and / or additional costs to our or our collaborative partners' clinical programs. Failure to obtain regulatory approval for our products, our raw materials or future product candidates, will limit our ability to commercialize our products, and our business will suffer. The regulatory process is expensive and time consuming. Even after investing significant time and expenditures on clinical trials, we may not obtain regulatory approval of any future product candidates. Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval, and the FDA may not agree with our methods of clinical data analysis or our conclusions regarding safety and / or efficacy. Significant clinical trial delays could impair our ability to commercialize any future products and could allow our competitors to bring products to market before we do. In addition, changes in regulatory policy for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections. Even if we receive regulatory approval, this approval may entail limitations on the indicated uses for which we can market a product **. We are subject to risks associated with NDAs submitted under Section 505 (b) (2) of the FDCA** . The products we and our collaborative partners develop or acquire generally are or will be submitted for approval under Section 505 (b) (2) of the FDCA, which was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch- Waxman Act. Section 505 (b) (2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For instance, the NDA for Cambia relies on the FDA' s prior approval of Cataflam, the diclofenac initially approved by the FDA. For NDAs submitted under Section 505 (b) (2) of the FDCA, the patent certification and related provisions of the Hatch- Waxman Act apply. In accordance with the Hatch- Waxman Act, such NDAs may be required to include certifications, known as " Paragraph IV certifications, " that certify any patents listed in the Orange Book publication in respect to any product referenced in the 505 (b) (2) application are invalid, unenforceable and / or will not be infringed by the manufacture, use or sale of the product that is the subject of the 505 (b) (2) application. Under the Hatch- Waxman Act, the holder of the NDA which the 505 (b) (2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit triggers a one- time automatic 30- month stay of the FDA' s ability to approve the 505 (b) (2) application. Accordingly, we may invest a significant amount of time and expense in the development of one or more products only to be subject to significant delay and patent litigation before such products may be commercialized, if at all. A Section 505 (b) (2) application may also not be approved until any non- patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or only some of the indications sought by us. If the FDA disagrees with the use of the Section 505 (b) (2) regulatory pathway for future product candidates, we would need to reconsider our plans and might not be able to obtain approval for any such product candidates in a timely or cost- efficient manner, or at all. The FDA may also reject our future Section 505 (b) (2) submissions and may require us to file such submissions under Section 501 (b) (1) of the FDCA, which could be considerably more expensive and time- consuming. The market price of our common stock..... price of the 2027 Convertible Notes. Our common stock is listed on the Nasdaq Capital Market. There are a number of continued listing requirements that we must satisfy in order to maintain our listing on The Nasdaq Capital Market, including the requirement to maintain a minimum bid price of at least $ 1. 00 (the " Bid Price Rule "). If a deficiency with respect to this requirement continues for a period of 30 consecutive business days, Nasdaq may require us to satisfy a minimum bid price per share of our common stock of at least $ 1. 00 for a period in excess of ten consecutive business days, but generally no more than 20 consecutive business days, before determining that we have demonstrated an ability to maintain long- term compliance with the Bid Price Rule. ~~Although~~ **As previously disclosed, on February 21, 2024, we received notification from Nasdaq indicating that our common stock is subject to potential delisting from The Nasdaq Capital Market because** we are ~~currently~~ **not** in compliance with the Bid Price Rule **. It did not result in the immediate delisting of our common stock. We have until August 19** . **2024 to regain compliance and, if** we **do not, we may be eligible for an additional 180- day calendar period in which to regain compliance. If we do not regain**

compliance with the Bid Price Rule by the applicable deadline, Nasdaq will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal Nasdaq' s delisting determination to a Nasdaq Listing Qualifications Panel (the " Panel "). We expect that our common stock would remain listed pending the Panel' s decision. However, there can be no assurance that, if we do appeal the delisting determination by Nasdaq to the Panel, that such appeal would be successful. We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Bid Price Rule, which could include, if necessary, seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule. We have **also** been unable to comply with ~~this~~ **the Bid Price** ~~rule~~ **Rule** in the past and for periods in 2021 our continued listing on ~~the~~ **The** Nasdaq Capital Market required the grant of a grace period from Nasdaq and the implementation of a one- for- four reverse stock split. If we fail to comply with the Bid Price Rule in the future, there can be no assurance that we will be granted such grace periods or that we will be able to receive the necessary shareholder approval to implement an additional reverse stock split. In particular, we may encounter difficulties obtaining such shareholder approval due to our heavily retail investor shareholder base, which may also affect our ability to obtain shareholder approval of other significant corporate actions. Any delisting of our common stock would likely adversely affect the market liquidity and market price of our common stock and our ability to obtain financing for the continuation of our operations and / or result in the loss of confidence by investors. If we were delisted from The Nasdaq Capital Market, it would constitute a " fundamental change " under the 2027 Convertible Notes, which would require us to offer to repurchase the 2027 Convertible Notes and would allow the holders of the 2027 Convertible Notes to convert their 2027 Convertible Notes into our common stock at an increased conversion rate, which would make conversion of the 2027 Convertible Notes more dilutive. ~~We~~ **The market price of our common stock historically has been volatile. Our results of operations have and may continue to fluctuate and affect our stock price. The trading price of our common stock has been, and is likely to continue to be, volatile and could be subject to wide fluctuations in response to various factors, some of which** are **The market price of our common stock historically has been volatile.Our results of operations have and may continue to fluctuate and affect our stock price.The trading price of our common stock has been,and is likely to continue to be,volatile and could be subject to wide fluctuations in response to various factors,some of which are beyond our control.Factors affecting our operating results and that could adversely affect our stock price include:• the degree of commercial success and market acceptance of our products** ,including the coverage of our products by payors and pharmacy benefit managers;• our ability to successfully develop and execute our sales,marketing and ~~promotion strategies using our sales force and~~ non- personal **and digital** promotion **strategies** ~~model capabilities~~ ,including developing and maintaining relationships with customers,physicians,payors and other constituencies ~~,and our ability to capitalize on opportunities that exist in the marketplace~~ ;• the entry and sales of generics of our products **(including the INDOCIN products which are not patent protected and may face generic competition at any time)** and / or other products competitive with any of our products (including **compounded** indomethacin suppositories **that** ~~compounded by hospitals and other institutions,including~~ a 503B compounder ~~which~~ **recently began selling in what** we believe ~~is~~ **to be** ~~violating~~ **violation of** certain provisions of the FDCA ~~);• the timing~~ and **which compete with our** ~~impact of additional generic approvals and uncertainty around the recent approvals and launches of generic~~ INDOCIN ~~products (which are not patent protected and now face generic competition as a result of the August 2023 approval and launch of generic indomethacin~~ suppositories ~~and January 2024 approval of a generic indomethacin oral suspension product~~);• our ability to successfully execute our business strategy,business development,strategic partnerships,and investment opportunities to build and grow for the future,including through product acquisitions,commercialization agreements,licensing or technology agreements,equity investments,and business combinations;• ~~our ability to attract and retain executive leadership and key employees,including in connection with our ongoing search for a permanent CEO;•~~ the outcome of,and our intentions with respect to,any litigation or ~~government~~ investigations,including ~~pending and potential future shareholder litigation relating to the Spectrum Merger and / or the recent approval and launch of generic indomethacin suppositories,~~ antitrust litigation,opioid- related ~~government~~ investigations,opioid- related litigation and related claims for negligence and breach of fiduciary duty against our former insurance broker, ~~as well as Spectrum' s legacy shareholder and other litigation,~~ and other disputes and litigation,and the costs and expenses associated therewith ~~;• the timing,cost and results of our clinical studies and other research and development efforts,including the extent to which data from the ROLVEDON same- day dosing trial,if and when completed,may support our ongoing commercialization efforts~~ ;• filings and other regulatory or governmental actions,investigations or proceedings related to our products and any future product candidates and those of our commercialization and collaborative partners;• developments concerning proprietary rights,including patents,infringement allegations,inter parties review proceedings and litigation matters;• legal and regulatory developments in the U.S.;• actions taken by industry stakeholders affecting the market for our products;• our ability to generate sufficient cash flow from our business to fund operations and make payments on our indebtedness;• our and our commercialization and collaborative partners' compliance or noncompliance with legal and regulatory requirements and with obligations under our collaborative agreements;• adverse events related to our products,including recalls;• interruptions of manufacturing or supply,or other manufacture or supply difficulties;• variations in revenues obtained from commercialization and collaborative agreements,including contingent milestone payments,royalties,license fees and other contract revenues,including nonrecurring revenues,and the accounting treatment with respect thereto;• adverse events or circumstances related to our peer companies or our industry or the markets for our products;• adoption of new technologies by us or our competitors;• our compliance with the terms and conditions of the agreements governing our indebtedness;• sales of large blocks of our common stock;and • variations in our operating results,earnings per share,cash flows from operating activities,deferred revenue,and other financial metrics and non- financial metrics,and how those results are measured,presented and compare to our financial and operating projections and analyst expectations.As a result of these and other such factors,our stock price may continue to be volatile and investors may be unable to sell their shares at a price equal to,or above,the price

paid.Any significant drops in our stock price ~~,including those we experienced in 2023,~~ could give rise to shareholder lawsuits,which are costly and time- consuming to defend against and which may adversely affect our ability to raise capital while the suits are pending,even if the suits are ultimately resolved in our favor.In addition,if the market for pharmaceutical stocks or the stock market in general experiences uneven investor confidence,the market price of our common stock could decline for reasons unrelated to our business,operating results or financial condition.For example,if one or more securities or industry analysts downgrades our stock or publishes an inaccurate research report about our company,the market price for our common stock would likely decline.The market price of our common stock might also decline in reaction to events that affect other companies within,or outside,our industry even if these events do not directly affect us. ~~Fluctuations~~ **A decrease** in the market price of our common stock ~~may also~~ **would likely adversely** impact the trading price of the 2027 Convertible Notes **.The market price of our common stock could also be affected by possible sales of our common stock by investors who view the 2027 Convertible Notes as a more attractive means of equity participation in us and by hedging or arbitrage trading activity that we expect to develop involving our common stock.This trading activity could , in turn,affect the trading price of the 2027 Convertible Notes.** a " smaller reporting company **.** " ~~as defined~~ **As of December 31, 2023, we are no longer a smaller reporting company, but** in **accordance with the** SEC **' s transition** rules, ~~and~~ we **continue to** take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies including, but not limited to, not being required to comply with reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If investors find our common stock less attractive as a result of our reduced reporting requirements, there may be a less active trading market for our common stock and our stock price may be more volatile. We may also be unable to raise additional capital as and when we need it. Our business could be impacted as a result of actions by activist shareholders, including as a result of a potential proxy contest for the election of directors at our annual meeting. The Company was subjected to a proxy contest in the run **-** up to its 2016 Annual Meeting of Shareholders, which resulted in the negotiation of changes to the Board of Directors and substantial costs being incurred. A future proxy contest would require us to incur significant legal fees and proxy solicitation expenses and require significant time and attention by management and the Board of Directors. The potential of a proxy contest could interfere with our ability to execute our strategic plan, give rise to perceived uncertainties as to our future direction, adversely affect our relationships with customers, suppliers, investors, prospective and current team members and others, result in the loss of potential business opportunities, or make it more difficult to attract and retain qualified personnel, any of which could materially and adversely affect our business and operating results. We may also be subject, from time to time, to other legal and business challenges in the operation of our company due to actions instituted by activist shareholders. Responding to such actions could be costly and time-consuming. We have in the past and may in the future be subject to unsolicited attempts to gain control of our company. Responding to any such attempt would distract management attention away from our business and would require us to incur significant costs. Moreover, any unsolicited takeover attempt may disrupt our business by causing uncertainty among current and potential employees, producers, suppliers, customers and other constituencies important to our success, which could negatively impact our financial results and business initiatives. Other disruptions to our business include potential volatility in our stock price and potential adverse impacts on the timing of, and our ability to consummate, acquisitions of products and companies. **In 2022, we issued the 2027 Convertible Notes, and in the future, we may sell additional shares of our common stock or equity- linked securities to raise capital. A substantial number of shares of our common stock is reserved for issuance upon the exercise of restricted stock units and stock options, and upon conversion of the 2027 Convertible Notes. We cannot predict the effect, if any, that conversions of the 2027 Convertible Notes or of any future issuances of common stock or equity- linked securities, may have on the market price of our common stock. The issuance and sale or conversion of substantial amounts of common stock or equity- linked securities, or the perception that such issuances and sales may occur, could adversely affect the trading price of the 2027 Convertible Notes and the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-linked securities.**