Risk Factors Comparison 2023-04-12 to 2022-04-15 Form: 10-K

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

The Company is not required to provide the information called for in this item due to its status as a Smaller Reporting Company, however we describe below some of the risks we believe are material to our business. You should carefully consider the following risks in evaluating us and our business. You should also refer to the other information set forth in this report, including the information set forth in " Business " and " Management' s Discussion and Analysis of Financial Condition and Results of Operations " as well as in our consolidated financial statements and the related notes. Our business prospects, financial condition or results of operations could be adversely affected by any of the following risks. Regulatory and Litigation Risks Laws and regulations regarding our business may prohibit or restrict our ability to sell our products in some markets or require us to make changes to our business model in some markets. Our products, business practices and manufacturing activities are subject to extensive government regulations and could be subject to additional laws and regulations. Taxation and transfer pricing could adversely affect our results of operations and financial condition We are subject to foreign tax and intercompany pricing laws, including those relating to the flow of funds between our U. S. parent company and our foreign subsidiaries. These pricing laws are designed to ensure that appropriate levels of income and expense are reported by our U. S. and foreign entities, and that they are taxed appropriately. Regulators in the United States and in foreign markets closely monitor our corporate structures, intercompany transactions, and how we effectuate intercompany fund transfers. Our effective tax rate could increase, and our results of operations and financial condition could be materially adversely affected if regulators challenge our corporate structures, transfer pricing methodologies or intercompany transfers. We are eligible to receive foreign tax credits in the United States for certain foreign taxes actually paid abroad. In the event any audits or assessments are concluded adversely to us, we may not be able to offset the consolidated effect of foreign income tax assessments through the use of U. S. foreign tax credits. Because the laws and regulations governing U. S. foreign tax credits are complex and subject to periodic legislative amendment, we may not be able to take advantage of any foreign tax credits in the future. In addition, changes in the amount of our total and foreign source taxable income may also limit our ability to take advantage of foreign tax credits in the future. The various customs, exchange control and transfer pricing laws are continually changing, and are subject to the interpretation of governmental agencies. We collect and remit value- added taxes and sales taxes in jurisdictions and states in which we have determined that nexus exists. Despite our efforts to be aware of and to comply with such laws and changes to the interpretations thereof, we may not be able to continue to operate in compliance with such laws. We may need to adjust our operating procedures in response to these interpretational changes, and such changes could have a material adverse effect on our results of operations and financial condition. Changes in consumers behavior Consumer behavior in recent years shows an increasing trend in the Health- Medicines sector, especially during the period of health crisis. It is observed that shopping habits and consumer behavior in general have changed in the midst of the coronavirus pandemic. The ~~ongoing~~ coronavirus pandemic and the responses thereto around the world could adversely impact our business and operating results. Consumers have turned to basic necessities and digital channels and e- commerce while physical networks are underperforming. 13Management of further developments In recent years, the Company has been increasing its turnover, while expanding its range of products and its own branded nutraceutical products, has acquired the latest technology drug storage systems to ensure quality and accuracy (zero error rates) in their distribution. The further increase of the Company ~~'~~ **’** s operations may lead, among other things, to increased capital needs, new investments in equipment and information systems, and requirements for capacity building. Failure to raise new capital will have a significant impact on the non- implementation of the required investments necessary to increase sales. Under these conditions, the growth of the Company ~~'~~ **’** s activity, its financial results and its financial situation will be negatively affected. Currency exchange rate fluctuations could adversely affect our results of operation and financial condition In ~~2021~~ **2022** , we recognized 100 % percent of our net sales in markets outside the United States, the majority of which were recognized in each market' s respective local currency. We purchase inventory from companies in foreign markets, some of them in U. S. dollars. In preparing our financial statements, we translate net sales and expenses in foreign countries from their local currencies into U. S. dollars using average **annual** exchange rates. Because our sales are in foreign countries, exchange rate fluctuations may have a significant effect on net sales and earnings. Our reported earnings have been significantly affected by fluctuations in currency exchange rates, with net sales and earnings generally increasing with a weaker U. S. dollar and decreasing with a strengthening U. S. dollar. Geopolitical issues, conflicts and other global events could adversely affect our results of operations and financial condition Because our business is conducted outside of the United States, it is subject to global political issues and conflicts such as the current war in the Ukraine. Such political issues and conflicts could have a material adverse effect on our results of operations and financial condition if they escalate in areas in which we do business. In addition, changes in and adverse actions by governments in foreign markets in which we do business could have a material adverse effect on our results of operations and financial condition. **Climate change and related legislation or regulations may adversely impact our business, including potential financial, operational and physical impacts. The nature of our business has not required any material capital expenditures to comply with federal, state or local provisions enacted or adopted regulating the discharge of materials into the environment. No material capital expenditures to meet such provisions are anticipated. Such regulatory provisions did not have a material effect upon our results of operations or competitive position during the year ended December 31, 2022. Cybersecurity risks and the failure to maintain the integrity of data could expose us to data loss, litigation and liability, which could adversely affect our results of operations and financial condition. We collect and retain large volumes of data from employees and independent consultants, including credit card numbers and**

other personally identifiable information, for business purposes, including transactional and promotional purposes. Our various information technology systems enter, process, summarize and report such data. The integrity and protection of this data are critical to our business. We are subject to significant security and privacy regulations, as well as requirements imposed by the credit card industry. Similarly, a failure to adhere to the payment card industry' s data security standards could cause us to incur penalties from payment card associations, termination of our ability to accept credit or debit card payments, litigation and adverse publicity, any of which could have a material adverse effect on our business and financial condition. Maintaining compliance with these evolving regulations and requirements could be difficult and may increase costs. In addition, a penetrated or compromised data system or the intentional, inadvertent, or negligent release or disclosure of data could result in theft, loss or fraudulent or unlawful use of company, employee, consultant or guest data which could adversely affect our reputation, disrupt our operations, or result in remedial and other costs, fines or lawsuits, which could have a material adverse effect on our results of operations and financial condition. Although we take measures to protect the security, integrity and confidentiality of our data systems, we experience cyber- attacks of varying degrees and types on a regular basis. Our infrastructure may be vulnerable to these attacks, and in some cases, it could take time to discover them. Breaches of our data systems, or those of our vendors, whether from circumvention of security systems, denial- of- service attacks or other cyber- attacks, hacking, " phishing " attacks, computer viruses, ransomware or malware, employee or insider error, malfeasance, social engineering, vendor software supply chain compromises, physical breaches or other actions, could result in material interruptions or malfunctions in our or such vendors' websites, applications, data processing, or disruption of other business operations. For various reasons or circumstances, our employees may work remotely from time to time. For example, many of our employees have worked remotely in response to the spread of the COVID- 19 pandemic. During such times, remote access heightens the risk of a cyber- attack. Additionally, outside parties may attempt to fraudulently induce employees, users, or customers to disclose sensitive information to gain access to our data or our users' or customers' data. Any such breach or unauthorized access could result in the unauthorized disclosure, misuse or loss of sensitive information and lead to significant legal and financial exposure, regulatory inquiries or investigations, loss of confidence by our sales force, disruption of our operations and damage to our reputation. These risks are heightened as we work with third-party partners and as our sales force uses social media, as the partners and social media platforms could be vulnerable to the same types of breaches. We may be required to expend significant capital and other resources to protect against and remedy any potential or existing security breaches and their consequences. A cyber- attack could also lead to litigation, fines, other remedial action, heightened regulatory scrutiny and diminished customer confidence. In addition, our remediation efforts may not be successful, and we may not have adequate insurance to cover these losses. The unavailability of the information systems or the failure of these systems to perform as anticipated for any reason could disrupt our business and could have a material adverse effect on our business, results of operations, cash flows and financial condition. Moreover, cyber- attacks against the Ukrainian government and other countries in the region have been reported in connection with the recent conflicts between Russia and Ukraine. To the extent such attacks have collateral effects on global critical infrastructure or financial institutions or us, such developments could adversely affect our business, operating results and financial condition. At this time, it is difficult to assess the likelihood of such threat and any potential impact at this time. Inflation and rising interest rates In 2022, EU annual inflation reached the highest level ever measured at 9. 2 %. Compared with 2021, when the annual value was 2. 9 %, it more than tripled. The annual average change in the harmonized index of consumer prices (HICP) in the EU during the period 2013- 2022 was 2. 1 %. Annual inflation also increased in these three economies: the United States hit 8. 7 % (just below the EU), Japan' s inflation reached 2. 5 %, while China was the lowest of the four with 2. 0 %. The high inflation has adversely affected our business due to the higher costs of purchasing raw materials, the higher transportation costs and the significantly increased operating costs. Moreover, the significant rise in the interest rates during 2022 may also adversely affect our business since most of our loan facilities carry floating interest rates and this may cause increased financing outflows. 14Inflation Reduction Act of 2022 The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out- of- pocket spending cap for Medicare Part D beneficiaries from $ 7, 050 to $ 2, 000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D price caps for certain high- cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.