Risk Factors Comparison 2024-03-26 to 2023-03-31 Form: 10-K

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Our business is subject to a number of risks, the most important of which are discussed below. You should consider carefully the following risks in addition to the other information contained in this report and our other filings with the SEC before deciding to buy, sell or hold our common stock. If any of the following risks actually occur, our business, financial condition, results of operations and the market price of our common stock could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment. The risks and uncertainties described below are not the only ones facing our Company, but those that we consider to be material. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. Please also read carefully the section in this report above entitled " Special Note Regarding Forward- Looking Statements. " Risks Relating to Our Business There is ~~uncertainty~~ **substantial doubt** about our ability to continue as a going concern. We have sustained operating losses for the majority of our corporate history. In fiscal ~~2022~~ **2023** , our expenses exceeded our revenues, as we continue to invest in our ~~Avenova and DERMAdoctor~~ commercialization efforts. We will need to generate significant revenues to achieve and maintain profitability, which we have not been able to achieve to date. Our operating cash flow currently is not sufficient to support our ongoing operations, and we expect to continue incurring operating losses and negative cash flows until revenues reach a level sufficient to support ongoing growth and operations. Accordingly, our current cash resources are not sufficient to fund operations at the expected level of activity beyond the third quarter of ~~2023~~ **2024** . As such, additional funding or substantial revenue growth will be needed in both the short- and long- term in order to pursue our business plan. We are continuing to evaluate our current business plan and potential changes to our business and strategic direction. If we do not raise additional capital or our revenues do not reach sufficient levels in the near term, then we may need to implement additional cost reduction measures and changes to our current business plan and strategic direction. Such changes may include altering our existing operations and / or ~~pursing~~ **pursuing** a strategic transaction, such as a divestiture of certain business or product lines and related assets **. By way of example, as part of our strategic direction, we recently sold DERMAdoctor for $ 1. 1 million** . As a result of these circumstances, our financial statements include explanatory disclosures expressing substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. Future reports on our financial statements may continue to include such disclosures. If we cannot continue as a going concern, our stockholders may lose their entire investment in our securities. We require additional capital to finance our operations as currently conducted, which may not be available to us on acceptable terms or at all and may result in dilution to our existing stockholders. Our current cash resources are not sufficient to fund operations at the expected level of activity beyond the third quarter of ~~2023~~ **2024** , and we therefore require additional capital to fund our operations. As of December 31, ~~2022~~ **2023** , our cash and cash equivalents were $ ~~5~~ **3** . ~~4~~ **1** million and we had an accumulated deficit of $ ~~158~~ **174** . ~~2~~ **8** million. If we raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures. If we are unable to obtain adequate financing on commercially reasonable terms or at all when needed, we may have to implement additional cost reduction measures and / or make changes to our current business, which may have a material adverse effect on our business, financial condition, and results of operations. Our ~~business may be adversely affected by the continuing coronavirus outbreak. The COVID- 19 pandemic has had and continues to have widespread, evolving, and unpredictable impacts on global society, economies, financial markets and business practices. Overall, the impact of COVID- 19 to date has been minimal on the sales of Avenova Spray and the sales of DERMAdoctor products as an increase in online sales has made up for the decrease in revenue from other channels. DERMAdoctor shifted from brick- and- mortar retail partners to online direct- to- consumer marketing during pandemic related shutdowns. Although we and DERMAdoctor have not experienced a material disruption in our supply chain to date due to COVID- 19, as the pandemic continues and regions face resurgence of COVID- 19, including variants of the virus, and outbreaks of other contagious diseases and related uncertainties, the availability of raw materials, goods and / or services from our suppliers could be disrupted and / or not provided in a timely manner or in the quantities that we require in order to operate our business in the ordinary course, which could materially and adversely affect our product sales, customer service levels and our overall business. In addition, any increases in the costs of goods and services for our business that could result from such disruptions in our supply chain or as a result of inflation in the overall costs of goods and services may adversely affect our profit margins if we are unable to pass along any higher costs in the form of price increases or otherwise achieve cost efficiencies in our operations. Our~~ future success is largely dependent on the successful commercialization of our products, particularly Avenova Spray ~~and our DERMAdoctor products~~ . If we are unable to establish and maintain adequate sales, marketing and distribution capabilities or enter into or maintain agreements with third parties to do so, we may be unable to successfully commercialize our products, ~~including~~ **specifically** Avenova Spray ~~and our DERMAdoctor products~~ . While we believe we are working to create an efficient commercial organization, we may not be able to correctly judge the size and experience of the sales and marketing force and the scale of distribution necessary to be successful. Establishing and maintaining sales, marketing, and distribution capabilities are expensive and time- consuming. Such expenses may be

disproportionate compared to the revenues we may be able to generate on sales of Avenova **Spray** ~~branded, and / or our DERMAdoctor branded products~~ , which could cause our commercialization efforts to be unprofitable or less profitable than expected. Acceptance and use of Avenova **Spray** ~~and / or DERMAdoctor branded products~~ by physicians, retail partners, wholesale customers and other customers may depend on a number of factors including: (i) perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our products ; (ii) published studies demonstrating the cost- effectiveness of our products relative to competing products; (iii) availability of reimbursement for our products from government or commercial payers ~~as relates to Avenova Spray~~ ; and (iv) effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. The failure of any of our products to find market acceptance would harm our business and could require us to seek additional financing to fund our operations. Goodwill, intangible and other assets from our **2021** DERMAdoctor Acquisition have become **fully** impaired **,** which adversely impacted our profitability in **2023 and** 2022 **.** ~~, and we may be required to record additional charges to earnings if there is further impairment in the future~~ We are required under U. S. Generally Accepted Accounting Principles (" GAAP ") to test our goodwill for impairment annually or more frequently if indicators for potential impairment exist. Additionally, at least annually at year end, or more frequently at interim periods, we periodically review our intangible and other long- lived assets for impairment. During the fourth ~~quarter~~ **quarters** of **2023 and** 2022, we performed our annual testing for goodwill, intangible and other long- lived asset impairment which resulted in us recording ~~a~~ goodwill, intangible and other asset impairment ~~charge~~ **charges** of **$ 2. 6 million** ~~an~~ **and** ~~aggregate of~~ $ 6. 7 million **,** relating to our DERMAdoctor business for the ~~year~~ **years** ended December 31, **2023 and** 2022 **, respectively** , which significantly increased our net losses for ~~the~~ **each** year ~~. In the future, we may be required to record an additional significant charge to our earnings in our consolidated financial statements during the period in which any impairment of our goodwill or intangible and other long- lived assets is determined. This could have a material adverse impact on our business, financial condition, results of operations and stock price~~ . We face substantial competition in the eyecare ~~and the skincare markets~~ **market** in which we operate. Avenova Spray faces intense competition in the eyecare market, which is focused on cost- effectiveness, price, service, product effectiveness and quality, patient convenience and technological innovation. There is substantial competition in the eyecare market from companies of all sizes in the United States and abroad, including, among others, large companies such as Allergan plc and Shire plc, and against products such as Restasis, Xiidra, eye wipes, baby shampoo and soap. There are also over- the- counter products that contain hypochlorous acid that compete with Avenova Spray. **The** ~~For our DERMAdoctor products that operate in the skincare and beauty industries, we also face vigorous competition from companies globally, including large multinational consumer products~~ companies that ~~have many skincare brands under ownership and standalone skincare brands, including those that may target the latest trends or specific distribution channels. The skincare and beauty industries are highly competitive and subject to rapid changes due to consumer preferences and industry trends. Competition in the skincare industry is generally based on the introduction of new products, pricing of products, quality of products and packaging, brand awareness, perceived value and quality, innovation, in- store presence and visibility, promotional activities, advertising, editorials, e- commerce and mobile- commerce initiatives and other activities. We must compete with a high volume of new product introductions and existing products by diverse companies across several different distribution channels. Our skincare and other beauty products face, and will continue to face, competition for consumer recognition and market share with products that have achieved significant national and international brand name recognition and consumer loyalty, such as those offered by global prestige beauty companies like Avon Products, Inc., Elizabeth Arden, Inc., The Estée Lauder Companies, Inc., Johnson & Johnson, Inc., L' Oréal Group, Shiseido, Coty, Mary Kay, Inc. and The Procter & Gamble Company, each of which have launched skincare brands. In addition, we compete with brands including Dr. Dennis Gross, Kate Somerville, Murad, Perricone M. D., Dr. Brandt, Clarins, Clinique, Dermalogica, Exuviance, La Roche- Posay and Vichy. Additionally, competition may increase as existing competitors enhance their offerings or additional companies enter our markets or modify their existing products to compete directly with our products. These companies that~~ we compete against in the eyecare ~~, skincare and beauty industries~~ **industry** may have substantially greater financial, technical and marketing resources, longer operating histories, greater brand recognition and larger customer bases than we do and may be able to respond more effectively to changing business and economic conditions than we can ~~. Larger competitors in the skincare and beauty industry have substantially greater financial resources for new product research, development and commercialization, both in the U. S. and / or internationally, on a scale that our operations and financial resources are not able to match making it difficult for us to compete with these companies. Additionally, these larger competitors are able to manufacture and maintain product inventories for longer periods of time for the commercialization of their products then we are able to due to our more limited capital resources and liquidity~~ . If our competitors respond more quickly to new or emerging technologies and changes in customer requirements, our products may be rendered obsolete or non- competitive. In addition, if our competitors develop more effective or affordable products, or achieve earlier intellectual property protection or product commercialization than we do, our operating results will materially suffer. Competition may increase further as existing competitors enhance their offerings or additional companies enter our markets or modify their existing products to compete directly with our products. We may not be able to sustain growth as competitive pressures, including pricing pressure from competitors, increase. Our ability to compete depends on the continued strength of our brand and products, the success of our marketing, innovation and execution strategies, the continued diversity of our product offerings, the successful management of new product introductions and innovations, strong operational execution, including in order fulfillment, and our success in entering new markets and expanding our business in existing geographies. If we are unable to continue to compete effectively, it could have a material adverse effect on our business, results of operations and financial condition. We are dependent on third parties to **manufacture,** supply ~~raw materials used in our products~~ and **distribute** ~~to manufacture~~ our products. Any interruption or failure by these suppliers or other disruptions to our supply chain may materially adversely affect our business, financial condition, results of operations and cash flows. Our ability to make, move, and sell our products is critical to our success. **Historically,** ~~Prior to the DERMAdoctor Acquisition~~ we

have ~~historically~~ predominately relied on a single product, Avenova Spray, for our primary revenue stream, which is comprised of our proprietary, stable and pure form of hypochlorous acid. ~~In acquiring DERMAdoctor, we greatly expanded our product offerings and operations, as DERMAdoctor has an extensive global platform, currently selling over 30 dermatologist- developed products in the U. S. and various other countries, with over 40 commercial relationships that supply its products from around the globe. While product sales in the United States have historically driven DERMAdoctor' s revenue, it has strategically sought international opportunities for the sale and distribution of its products. DERMAdoctor' s products are currently offered internationally in China, the Middle East, Europe, Canada, and Central and South America. With this larger operational business and range of product offerings around the globe, comes additional opportunity for us, as well as corresponding additional operating costs and risks in certain areas. A key risk area, which is emphasized further by the current pandemic environment and conflict between Russia and Ukraine, is that of supply chain risk. Our subsidiary, DERMAdoctor, also uses third party contract manufacturers and suppliers, some internationally, to obtain substantially all raw materials, components, and packaging products and to manufacture finished products.~~ Damage or disruption to our supply chain, including third- party manufacturing, assembly or transportation and distribution capabilities, due to weather, including any potential effects of climate change, natural disaster, fire or explosion, terrorism, pandemics ~~(such as the COVID- 19 pandemic)~~, strikes, government action, armed conflict, war (such as the ~~conflict~~ **conflicts** between **Israel and Hamas,** Russia and Ukraine **, and China and Taiwan**) or other reasons beyond our control or the control of our suppliers and business partners, could impair our ability to manufacture or sell our products. Failure to take adequate steps to mitigate the likelihood or potential impact of such events, or to effectively manage such events if they occur, particularly when a product is sourced from a single supplier or location, could adversely affect our business or financial results. ~~Further, we rely on third parties to supply raw materials, components, and packaging products, to manufacture finished products, and distribute our products.~~ Any interruption or failure by our suppliers, distributors and other partners to meet their obligations on schedule or in accordance with our expectations, misappropriation of our proprietary information, including trade secrets and know- how, or any termination by these third parties of their arrangements with us, which, in each case, could be the result of one or many factors outside of our control, could delay or prevent the manufacture or commercialization of our products, disrupt our operations or cause reputational harm to our company, particularly with wholesale customers, any or all of which could have a material adverse effect on our business, financial condition, results of operations and cash flows. ~~DERMAdoctor' s operating results are dependent on sales to a few significant retail partners and wholesale customers and the loss of, or substantial decline in, sales or increase in costs to sell our products to one or more of these retail partners and / or wholesale customers could have a material adverse effect on our expected future revenues and profitability. Retail partners and wholesale partners that purchase our DERMAdoctor products account for most of net sales revenue, and the loss of all or a portion of the sales to any one of these customers could have a material adverse effect on the results of operations generated by the DERMAdoctor business. A small group of retail partners and wholesale customers accounted for most of DERMAdoctor' s gross sales revenue for 2022, which we expect to continue for the foreseeable future. Although DERMAdoctor developed long- standing relationships with its major retail partners and wholesale customers, it generally does not, consistent with industry norms, have written agreements or advance commitments that require these retail partners or wholesale customers to buy from DERMAdoctor or to purchase a minimum amount of DERMAdoctor products. As a result, these retail partners and wholesale customers are not contractually committed to purchase specified quantities of DERMAdoctor products from us at specific times, and, therefore, the product quantities and the purchasing cycles for such products are difficult to predict and may fluctuate each year. Wholesale customers generally place large orders shortly before such products are needed. Therefore, our DERMAdoctor business relies on both having available capital resources to produce such products and its third- party suppliers and manufacturers to be able to quickly respond to DERMAdoctor product needs. If we do not have the capital resources and / or such supply chain is interrupted, it could cause a material adverse effect on our business, reputation with our wholesale customers and our financial condition and results of operations. In fiscal 2022, we experienced a decline from our retail partners and wholesale customers in amount and frequency of sales of DERMAdoctor products in the fourth quarter of 2022 compared to sales from the fourth quarter in 2021, and we expect that this may continue into 2023 with inflationary and / or recessionary conditions in the U. S. and internationally adversely impacting consumer demand for discretionary premium products such as those in the beauty and skincare industry. Additionally, certain of our online retail partners increased the fulfillment fees they charged us for sales of our products through their platform, which increased our cost of sales and adversely impacted our gross profit in 2022.~~ If we underestimate or overestimate demand for our products and do not maintain appropriate inventory levels, our net revenues or working capital could be negatively impacted. Our ability to manage our inventory levels to meet demand for our products is important for our business. If we overestimate or underestimate demand for any of our products, ~~including our DERMAdoctor products,~~ we may not maintain appropriate inventory levels, we could have excess inventory that we may need to hold for a long period of time, write down, sell at prices lower than expected or discard, which could negatively impact our reputation, net sales, working capital or cash flows from working capital, or cause us to incur excess and obsolete inventory charges. We ~~also could have inadequate inventories which could hinder our ability to meet demand, including those of our wholesale and other customers and our retail partners of DERMAdoctor and Avenova branded products. We have sought and continue to seek to improve our payable terms, which could adversely affect our relations with our suppliers. In addition, we have significant working capital needs to meet customer demand for DERMAdoctor products, as the nature of the DERMAdoctor business requires us to produce and maintain certain inventory levels to fulfill our customer and retail partner demand. We~~ generally finance our working capital needs through our cash and cash flows from operations, and if we do not have enough cash and cash flows from our operations, then we may not be able to produce the inventories required to meet demand, which could result in a loss of sales, the loss of wholesale customers and / or retail partners and adversely impact our reputation. ~~Potential disruptions~~ **We have sought and continue** to **seek to improve** our ~~distribution facility~~ **payable terms, which** could **also** ~~cause interruptions or delays in our business and~~

adversely affect our **relations with** ~~net sales and results of operations. Our ability to meet the needs of our consumers and retail customers depends on the proper operation of our Riverside, Missouri distribution facility, where a significant portion of our inventory that is not in transit is housed. Although we currently insure our inventory, our insurance coverage may not be sufficient to cover the full extent of any loss or~~ **our suppliers** ~~damage to our inventory or distribution facility, and any loss, damage or disruption of this facility, or loss or damage of the inventory and contents stored there, could materially and adversely affect our business, financial condition and results of operations. A natural disaster or other catastrophic event, such as a fire, flood, severe storm, break- in, terrorist attack or other comparable event could cause loss of inventory and interruptions or delays in our business and could render us unable to accept or fulfill customer orders in a timely manner, or at all. Our warehouse is located in an area that has historically been subject to severe storms and tornados. This increases our susceptibility to the risk that severe weather conditions could harm the operations of our distribution facility. In the event that a storm, tornado, fire, natural disaster, or other catastrophic event were to destroy a significant part of the facility or interrupt our operations for an extended period of time, our net sales could be reduced, and our results of operations could be harmed~ . Significant disruptions of information technology systems or breaches of information security could adversely affect our businesses. We rely upon information technology systems to operate our businesses. In the ordinary course of business, we collect, store and transmit large amounts of confidential information (including, but not limited to, personal information and intellectual property), and we deploy and operate an array of technical and procedural controls to maintain the confidentiality and integrity of such confidential information. We also have outsourced aspects of our operations to third parties, including significant elements of our information technology infrastructure and, as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. The size and complexity of our information technology and information security systems, and those of our third- party vendors with whom we contract, make such systems potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. Such attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, " hacktivists, " nation states and others. While we have invested in the protection of data and information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches. Any such interruption or breach of our systems could adversely affect our business operations and / or result in the loss of critical or sensitive confidential information or intellectual property, and could result in financial, legal, business and reputational harm to us. Adverse U. S. or international economic and political conditions could negatively affect our business, financial condition and results of operations. Our business is sensitive to general economic conditions and consumer spending. Therefore, we face risks associated with U. S. and international economic conditions, including a recession or other economic downturn, and are subject to events beyond our control including armed conflict, war, public health crises (such as the COVID- 19 pandemic), trade disputes, economic sanctions, and their collateral impacts. In particular, consumer spending on discretionary premium items ~~such as skincare and beauty products~~ , as well as eyecare products ~~,~~ is influenced and may be impacted by general economic conditions, wage and salary levels, trends in consumer confidence and spending, interest rates, inflation, and the availability of discretionary income and consumer credit. ~~Accordingly~~ **Further** , adverse U. S. or international economic conditions, including recessionary conditions, or periods of inflation or high energy prices may contribute to higher unemployment levels, decreased consumer spending, reduced credit availability and declining consumer confidence and demand, poses a risk to our business ~~. A further and future decline in consumer spending or in retailer and consumer confidence and demand for discretionary premium products such as our beauty and skincare products, would have a significant negative impact on our net sales and our profitability~~ . These economic conditions could cause some of our retail customers or suppliers to experience cash flow or credit problems and impair their financial condition, which could disrupt our business and adversely affect product orders, payment patterns and default rates and increase our bad debt expense. In addition, deterioration in global financial markets could make future financing difficult or more expensive, which could have a material adverse effect on our ability to finance the acquisition of inventory for sale to our customers. **Additional concerns include** ~~Abrupt~~ **abrupt** political change, terrorist activity, and armed conflict and any escalation or expansion thereof, **including but not limited to the dispute between Israel and Hamas, Russia and Ukraine, and China and Taiwan, which** pose a risk of further general economic disruption ~~. In February 2022, armed conflict escalated between Russia and Ukraine and has been ongoing since such time. The sanctions imposed by the U. S. and other countries against Russia following Russia' s invasion of Ukraine to date include restrictions on selling or importing goods, services, or technology in or from affected regions and travel bans and asset freezes impacting connected individuals and political, military, business and financial organizations in Russia. The U. S. and other countries could impose wider sanctions and take other actions should the conflict continue to escalate. It is not possible to predict the broader consequences of this conflict, which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, currency exchange rates and financial markets, all of which could impact our business, financial condition and results of operations~ . Risk Related to Government Regulation We expect continuous revenue from sales of Avenova Spray, which is classified as a cleared medical device by the FDA, but we cannot guarantee that the FDA will continue to allow us to market and sell Avenova Spray as a cleared medical device, which marketing inability would halt our sales and marketing of Avenova Spray and cause us to lose revenue and materially and adversely affect our results of operations and the value of our business. Our ability to continue commercializing Avenova Spray and generating revenue from Avenova Spray depends upon, among other things: ● the FDA allowing us to continue marketing Avenova Spray as an FDA cleared medical device; ● acceptance in the medical community; ● the safety of Avenova Spray' s predicate devices; ● the number of patients who use Avenova Spray; ● coverage or reimbursement by third- party payors of Avenova Spray; ● our ability to successfully market Avenova Spray to both doctors and patients; and ● the amount and nature of competition from competing companies with similar products. Revenue from the Avenova brand will be subject to, among other things, regulatory and commercial and

market uncertainties that may be outside of our control. The clearance that we have received from the FDA for our Avenova Spray, NeutroPhase, PhaseOne and other products is subject to strict limitations on the indicated uses for which the products may be marketed. The labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping for all our products, including those that are not subject to FDA clearance, are subject to extensive regulatory requirements. In addition, there can be no assurance that government regulations applicable to our products will not change and thereby prevent the marketing of some or all our products for a period of time or permanently. The FDA' s policies may change and additional government regulations may be enacted that could modify, prevent or delay regulatory approval of our products. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U. S. or in other countries. We cannot guarantee that Avenova Spray, our other cleared products, or products that may be approved or cleared for marketing in the future, will not be materially adversely impacted by a change in industry standards or regulations. If changes to industry standards, practices or regulations applicable to Avenova Spray or our other cleared products that we may market and sell in the future cause a delay in continued commercialization or if we cannot make a change to satisfy the industry standards, practices or regulations, we may not be able to meet market demand which may have a materially adverse effect on our business, financial condition, results of operations, and prospects. Additionally, the FDA may request that we submit another 510 (k) premarket submission that compares to another predicate device. If we are unable to find an adequate predicate device that is substantially equivalent to Avenova Spray for the treatment claims that we use to sell and market Avenova Spray, we may not be able to obtain the necessary FDA clearance to continue to market and sell Avenova Spray without performing comprehensive clinical trials. In such event, we would need to seek premarket approval from the FDA for the applicable product before we could continue to sell and market Avenova Spray in the United States, which would be significantly more time consuming, expensive, and uncertain. ~~Our commercialized products such as~~ Avenova **Spray is** ~~and DERMAdoctor branded products are~~ not approved by the FDA as a drug, and we rely solely on the 510 (k) clearance for Avenova Spray and certain of our other products as a medical device. Our business and future growth depend on the development, use and sale of products that are subject to FDA regulation, clearance and approval. Under the U. S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off- label uses. This means that we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA. ~~Our products, particularly our DERMAdoctor products, are also subject to regulation by the CPSC and the FTC. These laws and regulations principally relate to the ingredients, proper labeling, advertising, packaging, marketing, manufacture, safety, shipment and disposal of such products.~~ As Avenova Spray is a medical device, we may only make very limited claims that pertain to its cleared intended use. Without claims of efficacy, market acceptance of our products may be slow. The 510 (k) status of Avenova Spray also affects our ability to obtain formal insurance reimbursement by payors and affects our ability to obtain Medicare coverage ~~. The FDA does not currently require pre- market approval for products intended to be sold as non- prescription skincare products, so long as they are not marketed for the treatment or prevention of a disease, or as affecting the structure or function of the human body. However, the FDA may in the future require pre- market approval, clearance, or registration / notification of skincare products. Moreover, such products could also be regulated as both drugs and skincare simultaneously, as the categories are not mutually exclusive. If the FDA determines that any of our products intended to be sold as skincare should be classified and regulated as drug products, and we are unable to comply with applicable drug requirements, we may be unable to continue to market those products. Any inquiry into the regulatory status of our skincare products and any related interruption in the marketing and sale of these products could damage our reputation and image in the marketplace~~ . There is significant risk that the FDA or other federal or state law enforcement authorities may determine that the nature and scope of our sales and marketing activities constitutes the promotion of our products for non- FDA- approved uses in violation of applicable law and as the sale of unapproved drugs, which is prohibited under applicable law. We face the risk that the FDA may take enforcement action against us for the way that we promote and sell our products. This risk may grow with the increased visibility of Avenova Spray online, as well as the FDA' s increased focus on antimicrobial products in the wake of the COVID- 19 pandemic. We also face the risk that the FDA or other regulatory authorities might pursue enforcement actions based on past activities that we have discontinued or changed, including sales activities, arrangements with institutions and doctors, educational and training programs and other activities. Government investigations concerning the promotion of unapproved drug products, off- label ~~uses~~ **use** and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and be required to substantially limit and change our sales and promotion activities. Developments after a product reaches the market may adversely affect sales of our products. Even after obtaining regulatory clearances, certain developments may decrease demand for our products, including the re- review of products that are already marketed; new scientific information and evolution of scientific theories; the recall or loss of regulatory clearance of products that are already marketed; changing government standards or public expectations regarding safety, efficacy, or labeling changes; and greater scrutiny in advertising and promotion. If previously unknown side effects are discovered or if there is an increase in negative publicity regarding known side effects of a product, it could significantly reduce demand for the product or require us to take actions that could negatively affect sales, including removing the product from the market, restricting its distribution or applying for labeling changes. In addition, some health authorities appear to have become more cautious when examining new products and are re- reviewing select products that are already marketed, adding further to the uncertainties in the regulatory processes. There is also greater regulatory scrutiny, especially in the United States, on advertising (in particular, direct to consumer advertising), promotion and pricing of pharmaceutical products. Certain regulatory changes or decisions could make it more difficult for us to sell our products. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory clearance, product recalls, seizure of products, operating restrictions, injunctions, warning letters, criminal

prosecution and other enforcement actions. Any of these events could prevent us from marketing our products and our business may not be able to continue past such concerns. If any of the above occurs to Avenova Spray, ~~or our DERMAdoctor products,~~ our business, results of operations, financial condition and cash flows could be materially adversely affected. We do not have our own manufacturing capacity, and we rely on partnering arrangements or third- party manufacturers for the manufacture of our products and potential products. The FDA and other governmental authorities require that all our products ~~, including those of DERMAdoctor,~~ be manufactured in strict compliance with federal Quality Systems Regulations (" QSR ") and other applicable government regulations and corresponding foreign standards. We do not currently operate manufacturing facilities for **the** production of our products. As a result, we have partnered with third parties to manufacture our products or rely on contract manufacturers to supply, store and distribute our products and help us meet legal requirements. As we have limited control over our commercial partners, any performance failure on their part (including failure to deliver compliant, quality components or finished goods on a timely basis ~~or properly branded products~~) could affect the commercialization of our products, producing additional losses and reducing or delaying product revenues. If any of our commercial partners or manufacturers have violated or is alleged to have violated any laws or regulations during the performance of their obligations to us, it is possible that we could suffer significant financial, operational and reputational harm or other negative outcomes, including ~~costly corrective actions, including suspending manufacturing operations, changing product formulations, suspending sales of nonconforming products, or initiating product recalls, change product labelling, packaging or advertising or take other corrective action and~~ possible legal consequences. Our products require precise, high- quality manufacturing. The failure to achieve and maintain high manufacturing standards could result in patient injury or death, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm our business. Contract manufacturers and partners often encounter difficulties involving production yields, quality control and quality assurance, as well as shortages of qualified personnel. Accordingly, we and our third- party manufacturers are also subject to periodic unannounced inspections by the FDA to determine compliance with the FDA ~~'~~ **,** s requirements, including primarily ~~current~~ cGMP, the QSR, medical device reporting regulations ~~(where applicable for Avenova Spray), proper and compliant labeling~~ and other applicable government regulations and corresponding foreign standards, including ISO 13485. The results of these inspections can include inspectional observations on FDA' s Form 483, untitled letters, warning letters, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA- cleared products are ineffective, make additional therapeutic claims that are not commensurate to the accepted labeling claims, or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including preventing us from manufacturing any or all of our products or performing laboratory testing on human specimens, which could materially adversely affect our business. In addition, a prolonged interruption in the manufacturing of one or more of our products as a result of non- compliance could decrease our supply of products available for sale, which could reduce our net sales, gross profits and market share, as well as harm our overall business, prospects, financial condition and results of operations. Avenova Spray' s FDA- clearance and our other products that have been cleared by the FDA or products that we may obtain FDA- clearance in the future, if at all, are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities. In addition, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements where applicable for Avenova Spray, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearance to one or all of our products that may be cleared in the future, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. If we were to lose, or have restrictions imposed on, FDA clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be materially adversely impacted. Risks Relating to Owning Our Common Stock The price of our common stock may fluctuate substantially, which may result in losses to our stockholders. The stock prices of our company and many other companies in our market segments have generally experienced wide fluctuations in response to various factors, some of which are beyond our control, including those that are unrelated to our operating performance. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The market price of our common stock is likely to be volatile and could fluctuate in response to, among other things: ● the announcement of new products by us or our competitors ; ● the announcement of partnering arrangements by us or our competitors ; ● our ability to effectively manage our future growth; ● actual or anticipated variations in quarterly operating results; ● our cash position; ● our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ● adverse developments concerning our suppliers or distributors; ● adverse developments concerning our customers, including the reduction in products purchased and / or loss of customers; ● our inability to obtain adequate supplies and components for our products or inability to do so at acceptable prices; ● the failure to increase net sales or increases in our operating expenses; ● changes in our earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts ~~'~~ **,** earnings estimates; ● the sale of a substantial

number of shares of common stock by any large stockholder, especially within a short period of time; ● general, economic and market conditions, including volatility in the financial markets, a decrease in consumer confidence and other factors unrelated to our operating performance or the operating performance of our competitors; and ~~● other events or factors, many of which are beyond our control.~~ Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under Section 382 of the Internal Revenue Code of 1986, as amended (the " Code "), if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change net operating loss (" NOL ") carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post- change income may be limited. Since our formation, we have raised capital through the issuance of capital stock on many occasions which, combined with the purchasing stockholders' subsequent disposition of those shares, may have resulted in one or more changes of control, as defined by Section 382 of the Code. We have not currently completed a study to assess whether any change of control has occurred, or whether there have been multiple changes of control since our formation, due to the significant complexity and cost associated with such study. If we have experienced a change of control at any time since our formation, our NOL carryforwards and tax credits may not be available, or their utilization could be subject to an annual limitation under Section 382. In addition, since we may need to raise additional funding to finance our operations, we may undergo further ownership changes in the future. If we earn net taxable income, our ability to use our pre- change NOL carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. If we are unable to comply with the continued listing requirements of the NYSE American, then our common stock would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our common stock and subject us to additional trading restrictions. Our ~~common~~ **Common** ~~stock~~ **Stock** is currently listed on the NYSE American ~~LLC (" NYSE American ") and the continued listing of our common stock on the NYSE American is contingent on our continued compliance with a number of listing requirements~~. If we are unable to comply with the continued listing requirements of the NYSE American, our ~~common~~ **Common** ~~stock~~ **Stock** would be delisted from the NYSE American, which would limit investors' ability to effect transactions in our ~~common~~ **Common** ~~stock~~ **Stock** and subject us to additional trading restrictions. In order to maintain our listing, we must maintain certain share prices, financial and share distribution targets, including maintaining a minimum amount of stockholders' equity and a minimum number of public stockholders ~~, as well as satisfy other listing requirements of the NYSE American~~. In addition to these objective standards, NYSE American may delist the securities of any issuer for other reasons involving the judgment of NYSE American. **Historically** ~~For example~~, **our stockholders' equity has at times been below** the ~~NYSE American~~ **minimum requirements of Section 1003 (a) of the** Company Guide **though we have met all such minimum requirements since September 30, 2020. In accordance with Section 1009 (h) of** the ~~"~~ Company Guide **, if we are again determined to be below** ~~") provides that the NYSE American may suspend or remove from listing~~ any ~~common stock selling for a substantial period~~ of ~~time at a low price per share, if~~ the ~~issuer shall fail to effect a reverse split of such shares within a reasonable time after being notified that NYSE American deems such action to be appropriate under all the circumstances. On October 3, 2022, we received a letter from the NYSE American stating that we were not, at that time, in compliance with certain NYSE American~~ continued listing standards **in the future** ~~(" Deficiency Letter "). Specifically~~, **the NYSE American will take the appropriate action which, depending on the circumstances, may include initiating its compliance procedures or initiating delisting proceedings. If our Common Stock is delisted, this could, among** ~~the~~ **other** ~~Deficiency Letter indicated that we were not~~ **things, substantially impair our ability to raise additional funds ; result** in **a loss of institutional investor interest and fewer financing opportunities for us ; and / or result in potential breaches of representations or covenants of our warrants, subscription agreements or other agreements pursuant to which we made representations or covenants relating to our** compliance with **applicable** ~~Section 1003 (f) (v) of the Company Guide because the NYSE American staff determined that our common stock has been selling for a low price per share for a substantial period of time. We regained compliance with the NYSE American~~ listing requirements ~~that were set forth in this Deficiency Notice by effecting our Reverse Stock Split~~. **Claims related** ~~There is no assurance that we will be able~~ to ~~maintain compliance~~ **any such breaches,** with ~~the NYSE American continued listing rules~~ **or without merit, could result in costly litigation, significant liabilities** and ~~/~~ **diversion of** ~~or our continue its listing~~ **management' s time and attention and could have a material adverse effect** on ~~the NYSE American in the future~~ **our financial condition, business and results of operations**. If the NYSE American delists our common stock from trading on its exchange and we are not able to list our securities on another national securities exchange, we expect the common stock would qualify to be quoted on an over- the- counter market. If this were to occur, we could face significant material adverse consequences, including: ● a limited availability of market quotations for our securities; ● reduced liquidity for our securities; ● substantially impair our ability to raise additional funds; ● result in a loss of institutional investor interest and a decreased ability to issue additional securities or obtain additional financing in the future; ● a determination that our common stock is a " penny stock, " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities; ● a limited amount of news and analyst coverage; and ~~● potential breaches of representations or covenants of our agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements, which, regardless of merit, could result in costly litigation, significant liabilities and diversion of our management' s time and attention and could have a material adverse effect on our financial condition, business and results of operations.~~ We may issue additional shares of our common stock, other series or classes of preferred stock or other equity securities without your approval, which would dilute your ownership interests and may depress the market price of your shares. We may issue additional shares of our common stock, other series or classes of preferred stock, in addition to our Series B Non- Voting Convertible Preferred Stock (the " Series B Preferred Stock " and together with the Series C Preferred Stock, the " Preferred Stock ") and Series C Preferred Stock, units, warrants or other equity securities of equal or senior rank in the future in order to fund our operations, provide working capital

and for other purposes, including in connection with, among other things, future acquisitions, repayment of outstanding indebtedness, repricing of warrants or other outstanding securities or pursuant to our 2017 Omnibus Incentive Plan. These issuances of additional securities shall occur without stockholder approval in most circumstances. Our issuance of additional shares of our common stock, preferred stock or other equity securities of equal or senior rank could have the following effects: ● your proportionate ownership interest in NovaBay will decrease; ● the relative voting strength of each previously outstanding share of common stock may be diminished; and / or ● the market price of your shares of common stock may decline. We may require additional capital funding that may not be available to us or, if received, may not be available to us on favorable terms, which may impair the value of our common stock, Series B Preferred Stock and Series C Preferred Stock. If our working capital needs exceed our current expectations, or we expand more rapidly than currently anticipated, we may need to raise additional capital through public or private equity offerings or debt financings. Our future capital requirements depend on many factors including our cash position, revenue and our overall operating expenses. We do not know whether additional financing will be available when needed or will be available on terms favorable to us. If we cannot raise needed funds on acceptable terms, we may not be able to develop new products or enhance our existing products, be able to fully fund the commercialization and sale of our products, take advantage of future opportunities or respond to competitive pressures or unanticipated requirements. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution and the new equity securities may have greater rights, preferences or privileges than our existing common stock, Series B Preferred Stock and Series C Preferred Stock. **Our** ~~As a result of the conversion of the Series B Preferred Stock, the conversion of the Series C Preferred Stock, the exercise of the 2022 Warrants, the exercise of the September 2022 Warrants and the exercise of our other common stock purchase warrants previously issued, our~~ stockholders will experience significant dilution **as a result of the conversion of the Series B Preferred Stock, the conversion of the Series C Preferred Stock and the potential exercise of outstanding common stock purchase warrants** . We have a significant number of Company securities that are or will be convertible and / or exercisable into shares of our common stock. **As of December 31, 2023,** ~~These~~ **these** Company securities include ~~2~~ **5** , ~~250~~ **607 shares of Series B Preferred Stock that are convertible into 22, 428, 000 shares of common stock, 1, 097** shares of Series C Preferred Stock that are convertible into ~~357~~ **4** , ~~750~~ **388, 000** shares of common stock (subject to potential increase or other adjustment in the number of shares due to applicable anti- dilution adjustments), **notes** ~~the 2022 Warrants issued in the 2022 Private Placement that are exercisable into 1, 031, 752 shares of common stock, the 11, 620 shares of Series B Preferred Stock~~ that are convertible into 1, ~~847~~ **454** , ~~580~~ **021** shares of common stock **and common stock** ~~(subject to potential increase or other adjustment in the number of shares due to applicable anti- dilution adjustments), the September 2022 Warrants~~ **warrants** ~~issued in the 2022 Warrant Reprice Transaction that are~~ exercisable for **7** ~~an aggregate of 327~~ , ~~860~~ **382, 447** shares of common stock **. As** ~~, and all~~ of ~~our other outstanding~~ **December 31, 2023, we had 11, 230, 150 shares of** common stock **issued** ~~purchase warrants that are exercisable for an~~ **and outstanding** ~~aggregate of 945, 907 shares of common stock (collectively, the " Other Warrants ")~~ . ~~As~~ **Subsequent to December 31, 2023, as** of March ~~27~~ **21** , ~~2023~~ **2024** , we had ~~2~~ **30** , ~~035~~ **098** , ~~444~~ **150** shares of common stock issued and outstanding. Accordingly, upon the conversion or exercise (as applicable) of some or all of the Series B Preferred Stock, the Series C Preferred Stock, ~~the 2022~~ **convertible notes and common stock** ~~Warrants~~ **warrants** ~~, the New Reprice Warrants, the Other Warrants~~ , as well as the exercise of stock options and other equity based awards that have been or will be issued and / or granted by us, the percentage ownership and voting power held by our existing stockholders will be significantly reduced and our stockholders will experience significant dilution. Offers or availability for sale of a substantial number of shares of our common stock, including as a result of the conversion of the Series B Preferred Stock and the Series C Preferred Stock and / or the exercise of **outstanding** ~~the 2022 Warrants~~ **warrants** ~~, the September 2022 Warrants and the Other Warrants~~ may cause the price of our publicly traded securities to decline and make it more difficult for us to raise capital in the future. Sales of a significant number of shares of our common stock in the public market could depress the market price of our common stock and make it more difficult for us to raise funds through future offerings of common stock. For example, sales of shares of common stock that are issuable upon conversion of the Series B Preferred Stock and the Series C Preferred Stock and / or the exercise of **outstanding** ~~the 2022 Warrants~~ **warrants** ~~, the September 2022 Warrants and the Other Warrants~~ may cause the price of our publicly traded securities to decline. The shares of common stock underlying the shares of Series B Preferred Stock ~~and ,~~ Series C Preferred Stock ~~, the 2022 Warrants, the September 2022 Warrants~~ and ~~other~~ outstanding warrants represent, in the aggregate, approximately ~~222~~ **114** % of the total number of shares of common stock outstanding as of March ~~27~~ **21** , ~~2023~~ **2024** . Upon conversion or exercise, as the case may be, of those securities, the shares of common stock we issue upon such conversion or exercise could be sold into the public market, and such sales could be significant and have an adverse impact on the price of our common stock. Additionally, such conversion or exercise could make it more difficult for us to raise additional financing through the sale of equity or equity- related securities in the future at a time and / or at a price that we deem reasonable or appropriate, or at all. If we offer common stock or other securities in the future and the price that we sell those securities for is less than the current conversion price of our Series ~~B~~ **C** Preferred Stock ~~or~~ **, then we will be required to issue additional shares of common stock to the holders of** the Series C Preferred Stock ~~, then we will be required to issue additional shares of common stock to the holders of the Series B Preferred Stock and the Series C Preferred Stock, as the case may be,~~ upon conversion, which will be dilutive to all of our other stockholders. The ~~Certificate of Designation of Preferences, Rights and Limitations of the Series B Preferred Stock (the " Series B Certificate of Designation ") and the~~ Certificate of Designation of Preferences, Rights and Limitations of the Series C Preferred Stock (" Series C Certificate of Designation ") ~~both~~ contain ~~,~~ anti- dilution provisions that require the lowering of the conversion price, as then in effect, to the purchase price of equity or equity- linked securities issued by us in subsequent offerings, if lower than the current conversion price. A reduction in the conversion price of ~~either~~ **the** ~~series~~ **Series** ~~of~~ **C** ~~preferred~~ **Preferred** ~~stock~~ **Stock** will result in a greater number of shares of common stock being issuable upon conversion of such preferred stock for no additional consideration, causing greater dilution to our stockholders. **The Series B Preferred Stock**

had a similar anti- dilution provision until such provision was eliminated on January 29, 2024 due to more than 75 % of the Series B Preferred Stock originally issued being converted into common stock. For example, the consummation of the ~~2022~~ **2023 Private Placement and the 2023** Warrant Reprice Transaction **each** triggered the anti- dilution protection in the Series B **and Series C** Certificate of Designation, ~~and as a result~~ **resulting in** ~~there are~~ an **aggregate** additional ~~1~~ **31** , ~~847~~ **496** , ~~580~~ **010** shares of common stock that ~~are~~ **were** issuable upon conversion of the ~~11, 620 shares of~~ Series B **and Series C** Preferred Stock ~~outstanding as of the date of this report~~ . Furthermore, as there is no floor on the conversion price for the Series ~~B Preferred Stock or the Series~~ C Preferred Stock, and, therefore, we cannot determine the total number of shares issuable upon conversion that may occur in the future. In addition, it is possible that we may not have a sufficient number of authorized and available shares of common stock in the future to satisfy the conversion of ~~the Series B Preferred Stock and / or~~ Series C Preferred Stock, as the case may be, if we enter into a future transaction that reduces the applicable conversion price of such securities. We have not paid dividends or repurchased stock in the past and do not expect to pay dividends or repurchase stock in the future, and any return on investment may be limited to the value of our stock. We have never paid cash dividends on, or repurchased shares of, our common stock and do not anticipate paying cash dividends or repurchasing shares of our common stock in the foreseeable future. In addition, we do not anticipate paying any dividends or repurchasing any shares of our Preferred Stock; however, if we pay dividends on our shares of common stock, we are required to pay dividends on our Preferred Stock on an as converted basis. The payment of dividends on, or the repurchase of shares of, our common stock or Preferred Stock will depend on our earnings, financial condition and other business and economic factors affecting us at such time as our Board of Directors may consider relevant. If we do not pay dividends or repurchase stock, holders of our common stock will experience a return on their investment in our shares only if our stock price appreciates. Risks Related to Potential Litigation The pharmaceutical and biopharmaceutical industries are characterized by patent litigation, and any litigation or claim against us may impose substantial costs on us, place a significant strain on our financial resources, divert the attention of management from our business and harm our reputation. There has been substantial litigation in the pharmaceutical and biopharmaceutical industries with respect to the manufacture, use and sale of new products that are the subject of conflicting patent rights. For the most part, these lawsuits relate to the validity, enforceability, and infringement of patents. We rely upon patents, trade secrets, know- how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position, and we may initiate claims to defend our intellectual property rights as a result. Other parties may have issued patents or be issued patents that may prevent the sale of our products or know- how or require us to license such patents and pay significant fees or royalties to produce our products. In addition, future patents may be issued to third parties which our technology may infringe. Because patent applications can take many years to issue and because patent applications are not published for a period of time, or in some cases at all, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. Intellectual property litigation, regardless of outcome, is expensive and time- consuming, would divert management ~~'~~ **’** s attention from our business and could have a material negative effect on our business, operating results, or financial condition. If a dispute involving our proprietary technology were resolved against us, it could mean the earlier entry of some or all third parties seeking to compete in the marketplace for a given product, and a consequent significant decrease in the price we could charge for our product. If such a dispute alleging that our technology or operations infringed third- party patent rights were to be resolved against us, we might be required to pay substantial damages, including treble damages and attorney ~~'~~ **’** s fees if we were found to have willfully infringed a third party ~~'~~ **’** s patent, to the party claiming infringement, to develop non- infringing technology, to stop selling any products we develop, to cease using technology that contains the allegedly infringing intellectual property or to enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. If our product or products cause an unexpected reaction to a patient or patient (s) or customer (s) in certain ways that may have caused or contributed to serious injury, we may be subject to product liability claims, and if product liability lawsuits are brought against us, they could result in costly litigation and significant liabilities. Despite all reasonable efforts to ensure safety, it is possible that we or our distributors will sell our products or products that we currently do not sell but may sell in the future, which are defective, to which patients / customers react in an unexpected manner, or which are alleged to have side effects or otherwise not work for the product’ s intended purpose. The manufacture and sale of such products may expose us to potential liability, including regulatory enforcement actions, and the industries in which our products are likely to be sold have been subject to significant product liability litigation. Any claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management ~~'~~ **’** s time and attention, and could have a material adverse effect on our reputation, financial condition, business and results of operations. We cannot make assurances that any liability insurance coverage that we qualify for, if at all, will fully satisfy any liabilities brought for any event or injury that is attributed to our product or products. If a product liability claim is brought against us, we may be required to pay legal and other expenses to defend the claim and, if the claim is successful, damage awards may not be covered, in whole or in part, by our insurance. We may not have sufficient capital resources to pay a judgment, in which case our creditors could levy against our assets. We may also be obligated to indemnify our collaborators and make payments to other parties with respect to product liability damages and claims. Defending any product liability claims, or indemnifying others against those claims, could require us to expend significant financial and managerial resources. If we are unable to protect our intellectual property, our competitors could develop and market products similar to ours that may reduce demand for our products. Our success, competitive position and potential future revenues will depend in significant part on our ability to protect our intellectual property. We rely on the patent, trademark, copyright and trade secret laws of the U. S. and other countries, as well as confidentiality and nondisclosure agreements, to protect our intellectual property rights. We apply for patents covering our technologies as we deem appropriate. There is no assurance that any patents issued to us, or in- licensed or assigned to us by third parties will not be challenged, invalidated, found unenforceable or circumvented, or that the rights granted thereunder will provide competitive advantages to us. If we or our collaborators or licensors fail to file, prosecute, obtain

or maintain certain patents, our competitors could market products that contain features and clinical benefits similar to those of any products we develop, and demand for our products could decline as a result. Further, although we have taken steps to protect our intellectual property and proprietary technology, third parties may be able to design around our patents or, if they do infringe upon our technology, we may not be successful or have sufficient resources in pursuing a claim of infringement against those third parties. Any pursuit of an infringement claim by us may involve substantial expense and diversion of management attention. We also rely on trade secrets and proprietary know- how that we seek to protect by confidentiality agreements with our employees, consultants, and collaborators. If these agreements are not enforceable, or are breached, we may not have adequate remedies for any breach, and our trade secrets and proprietary know- how may become known or be independently discovered by competitors. We operate in the State of California. California law prevents us from imposing a delay before an employee, who may have access to trade secrets and proprietary know- how, can commence employment with a competing company. Although we may be able to pursue legal action against competitive companies improperly using our proprietary information, we may not be aware of any use of our trade secrets and proprietary know- how until after significant damage has been done to our Company. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the U. S. If our intellectual property does not provide significant protection against foreign or domestic competition, our competitors, including generic manufacturers, could compete more directly with us, which could result in a decrease in our market share. All of these factors may harm our competitive position. ITEM 1B. UNRESOLVED STAFF COMMENTS