Risk Factors Comparison 2022-08-29 to 2021-08-27 Form: 10-K

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The risks described below are not the only ones we face. Additional risks and uncertainties we are not presently aware of or that we currently believe are immaterial may also impair our business operations. Our business could be harmed by any of these risks and uncertainties. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained or incorporated by reference into this annual report on Form 10- K, including our consolidated financial statements and related notes. RISKS RELATED TO OUR BUSINESS Our business could be adversely affected by the effects of widespread public health epidemics. We are susceptible to ongoing outbreaks of ~~an~~ illness or other health issue, such as the recent COVID- 19 Coronavirus outbreak ~~, including outbreaks of variants of the COVID- 19 virus such as the " Delta " variant~~ . The outbreak of the COVID- 19 virus caused ~~the~~ various governments, including the **United States** ~~U. S.~~ , to implement quarantines, various restrictions on travel ~~causing airlines to suspend international~~ and ~~certain domestic flights,~~ shelter in place orders and other restrictions. Governments have also implemented work restrictions that prohibit many employees from going to work, and for businesses that are allowed to remain open, many employees are electing to remain at home to avoid spread of the disease. As a result of this COVID- 19 ~~virus~~ outbreak and potential future pandemic outbreaks, the Company faces significant risks including, but not limited to: a) supply chain disruptions making it difficult for the Company to contract and receive materials needed for production of its products, and needed to ship finished products to our end customers, b) loss of contracts and customers from the financial strains or other disruptions they are experiencing as a result of the pandemic, c) financial risks pertaining to receivables due from customers that may fall into insolvency or otherwise be unable to pay their bills, d) government responses including orders that make it difficult to remain open for business, restrict imports of raw materials or exports of finished goods, refusal to allow the Company' s product to be licensed for sale in their countries, and other seen and unforeseen actions taken by government agencies, e) absenteeism or loss of employees at the Company, or at our partner' s companies, due to health reasons or government restrictions, that are needed to develop, validate, manufacture and perform other necessary functions for our operations, f) equipment failures, loss of utilities and other disruptions that could impact our operations or render them inoperable, g) litigation or government actions against the Company pertaining to existing products **and** new products sold by the Company that are directed at limiting or treating the spread of the pandemic outbreak, h) a local or global recession or depression that could harm the international banking system, limit demand for all products including those made by the Company, i) a drop in demand for our products, that are all medical related, due to patients' reluctance or refusal to visit hospitals, labs, and doctors' offices where our products are used due to their fear of contracting a disease, and many other seen and unforeseen events and circumstances, all of which could negatively impact the Company. We have a history of operating losses. We have historically incurred net losses. There can be no assurance that we will generate net profits in future periods. Further, there can be no assurance that we will be cash flow positive in future periods. In the event that we fail to achieve profitability in future periods, the value of our common stock may decline. In addition, if we are unable to achieve or maintain positive cash flows, we would be required to seek additional funding, which may not be available on favorable terms, if at all. Our operating results may fluctuate adversely as a result of many factors that are outside our control, which may negatively impact our stock price. Our operating results are dependent upon many factors that are substantially outside of our control that could materially and adversely affect our business, results of operations and financial condition. Factors that are beyond our control and that could affect our operating results in the future include: • regulatory clearance; • changes in the level of competition, such as would occur if one of our competitors introduced a new, better performing or lower priced product to compete with one or more of our products; • changes in the reimbursement systems or reimbursement amounts that end- users may rely upon in choosing to use our products; • changes in economic conditions in our domestic and international markets, such as economic downturns, decreased healthcare spending, reduced consumer demand, inflation and currency fluctuations; changes in government laws and regulations affecting our business; reluctance for consumers to visit healthcare providers; • lower than anticipated market penetration of our new or more recently introduced products; • significant quantities of our product or that of our competitors in our distributors' inventories or distribution channels; • changes in distributor buying patterns; • government mandated shelter- in- place or other lock- down orders; • continued spread of the COVID- 19 virus or mutations of the virus; and • changes in the healthcare market including consolidation in our customer base. Fluctuations in our operating results, for any reason, could cause operating losses as a result of significant fixed expenses. We base the scope of our operations and related expenses on our estimates of future revenues. A significant portion of our operating expenses are fixed, and we may not be able to rapidly adjust our expenses if our revenues fall short of our expectations. Our revenue estimates for future periods are based, among other factors, on estimated end- user demand for our products. If end- user consumption is less than estimated, revenues from our distribution partners and other distribution channels would be expected to fall short of expectations, and because such a significant portion of our costs are fixed, could result in operating losses. To remain competitive, we must continue to develop, obtain and protect our proprietary technology rights; otherwise, we may lose market share or need to reduce prices as a result of competitors selling technologically superior products that compete with our products, or selling products at lower prices. Our ability to compete successfully in the diagnostic market depends on continued development and introduction of new products, technology and the improvement of existing technology. If we cannot continue to improve upon or develop, obtain and protect our technology, our operating results could be adversely affected. Our competitive position is heavily dependent on obtaining and protecting our own proprietary technology or obtaining licenses

from others. Our ability to obtain patents and licenses, and their benefits, is uncertain. The Company is required to obtain government or regulatory certification in many countries and the European community to sell its products in those countries or regions. There is no assurance that the Company will be able to retain its certification in the future. This includes the possibility and risk that the Company' s products do not meet the new EU IVDR testing and documentation requirements in the future as described in the above " Research and Development " section of this document. Significant government regulation exists in countries in which we conduct business. A large part of the Company' s sales is to distributors in Europe, China **,** and other countries, which require us to maintain certain certifications to sell our products. Failure to comply with current governmental regulations and quality assurance guidelines could cause the loss of these certifications, which could materially adversely affect the results of the Company. Loss of certifications could lead to temporary manufacturing shutdowns, product recalls, product shortages or delays in product manufacturing and a decline in sales. The Company maintains a manufacturing plant in Mexico which presents risks to the Company including risks associated with doing business outside the United States. The Company has a significant investment in its manufacturing facility in Mexico through its subsidiary, Biomerica de Mexico. In addition, the Company warehouses a significant amount of its inventory at the Mexico facility. There are a number of risks associated with doing business in Mexico, including, exposure to local economic and political conditions, social unrest, including risks of terrorism or other hostilities, export and import restrictions, the potential for shortages of trained labor, and the possible effects of currency exchange rate fluctuations. These risks could lead to additional costs that we cannot foresee at this time and may materially adversely impact our business, results of operations and financial condition. We use hazardous materials in our research and production that may result in unexpected and substantial claims against us relating to handling, storage **,** or disposal. We use hazardous materials in our research and production. The risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, the Company could be held liable for any harm or damages that result and any such liability could exceed the resources of the Company. The Company may incur substantial costs to comply with environmental regulations. If any governmental authorities were to impose new environmental regulations requiring compliance in addition to that required by existing regulations ~~,~~ or alter their interpretation of the requirements of such existing regulations, such environmental and safety regulations could impair our research, development **,** or production efforts by imposing additional, and possibly substantial, costs, restrictions **,** or compliance procedures on our business. In addition, because of the nature of the penalties provided for in some of these environmental and safety regulations, we could be required to pay sizable fines, penalties **,** or damages in the event of noncompliance with regulations and environmental laws. Any environmental or safety violation or remediation requirement could also partially or completely shut down our research and manufacturing facilities and operations, which would have a material adverse effect on our business. The risk of accidental contamination or injury from these hazardous materials cannot be completely eliminated and exposure of individuals to these materials could result in substantial fines, penalties or damages that may not be covered by insurance. **To** ~~In order to~~ remain competitive, we must expend considerable resources to research new technologies and products and develop new markets, and there is no assurance our efforts to develop new technologies, products or markets will be successful or such technologies, products or markets will be commercially viable. We devote a significant amount of financial and other resources to researching and developing new technologies, new products **,** and new markets. The development, manufacture and sale of diagnostic products require a significant investment of resources. The development of new products and markets also requires a substantial investment of resources, such as new employees, offices and manufacturing facilities, consultants **,** and clinical trials. No assurances can be given that our efforts to develop new technologies or products will be successful, that such technologies and products will be commercially viable, or our expansion into new markets will be profitable. There is also no guarantee that our new products, including our InFoods ® IBS products, will get approval and be well accepted into the marketplace. Our operations will be adversely affected if our operating results do not correspondingly increase with our increased expenditures or if our technology, product **,** and market development efforts are unsuccessful or delayed. Furthermore, our failure to successfully introduce new technologies or products and develop new markets could have a material adverse effect on our business and prospects. We rely on a limited number of key distributors that account for a substantial majority of our total revenue. The loss of any key distributor or an unsuccessful effort by us to directly distribute our products could lead to reduced sales. **Our net sales were approximately $ 18, 871, 000 for fiscal 2022 compared to $ 7, 199, 000 for fiscal 2021.** For the fiscal years ended May 31, **2022 and** 2021 ~~and 2020~~ , the Company had two distributors ~~and three distributors, respectively~~ , which accounted for a total of **65 % and** 60 % ~~and 57 %~~ of our net ~~consolidated~~ sales, respectively. Of this, for the fiscal years ended May 31, **2022 and** 2021 ~~and 2020~~ , the largest of the distributors mentioned above accounted for **55 % and** 33 % ~~and 26 %~~ , respectively, of net ~~consolidated~~ sales. ~~At~~ **Total gross receivables on** May 31, **2022 and** 2021 **were approximately $ 927, 000** and **$ 2, 292, 000, respectively. As of May 31,** ~~2020~~ **2022 and 2021** , the Company had **one distributor and** two ~~distributors and three~~ distributors, respectively, which accounted for a total of **50 % and** 73 ~~% and 80~~ %, respectively, of gross accounts receivable. Of the ~~73~~ **50** % as of May 31, ~~2021~~ **2022** , ~~41~~ **50** % was owed by a distributor in **Asia** ~~China. Total gross receivables at May 31, 2021 and 2020 were $ 2, 292, 466 and $ 1, 836, 852, respectively~~ . Adverse changes in our relationships with these distributors and other partners, or adverse developments in their financial condition, performance or purchasing patterns, could adversely affect our business and consolidated financial statements. We extend credit to customers outside the **United States** ~~U. S.~~ which can be difficult to collect. We extend credit to many of our customers including those outside of the **United States** ~~U. S~~ . It is often difficult to obtain adequate credit information on these customers. Further, our ability to collect receivables from these customers through the court systems in those countries can be more difficult than here in the **United States** ~~U. S~~ . Our inability to collect on receivables from customers, in particular those outside of the **United States** ~~U. S.~~ could negatively impact the Company. If we are not able to manage our growth strategy our operating results may be adversely affected. Our business strategy contemplates further growth, which would likely result in expanding into larger facilities, expanding the scope of operating and financial systems and the geographical area of our operations, including further expansion

outside the **United States** ~~U. S.~~, as new products and technologies are developed and commercialized or new geographical markets are entered. Because we have a small executive staff, acquisitions and other future growth may divert management' s attention from core aspects of our business ~~,~~ and place a strain on existing management and our operational, financial and management information systems. Furthermore, we may expand into markets in which we have less experience or incur higher costs. Any and all of these potential growth and expansion strategies and events could impose material risks and cause the Company to incur adverse operating and financial results. Intellectual property risks and third- party claims of infringement, misappropriation of proprietary rights or other claims against us could adversely affect our ability to market our products, require us to redesign our products or attempt to seek licenses from third parties, result in significant costs, and materially adversely affect our operating results. Companies in or related to our industry often aggressively protect and pursue their intellectual property rights. There are often intellectual property risks associated with developing and producing new products and entering new markets, and we may not be able to obtain, at reasonable cost or upon commercially reasonable terms, if at all, licenses to intellectual property of others that is alleged to be part of such new or existing products. We have hired and will continue to hire individuals or contractors who have experience in medical diagnostics and these individuals or contractors may have confidential trade secret or proprietary information of third parties. We cannot assure ~~you~~ that these individuals or contractors will not use this third- party information in connection with performing services for us or otherwise reveal this third- party information to us. Thus, we could be sued for misappropriation of proprietary information and trade secrets. Such claims are expensive to defend and could divert our attention and result in substantial damage awards and injunctions that could have a material adverse effect on our business, financial condition **,** or results of operations. In addition, to the extent that individuals or contractors apply technical or scientific information independently developed by them to our projects, disputes may arise as to the proprietary rights to such data and may result in litigation. The defense and prosecution of patent and trade secret claims are both costly and time consuming. We or our customers may be sued by other parties that claim that our products have infringed their patents or misappropriated their proprietary rights or that may seek to invalidate one or more of our patents. An adverse determination in any of these types of disputes could prevent us from manufacturing or selling some of our products, limit or restrict the type of work that employees involved with such products may perform for us, increase our costs and expose us to significant liability. In addition, the defense of such claims could result in significant costs and divert the attention of our management and other key employees. In addition to the foregoing, we may also be required to indemnify some customers, distributors **,** and strategic partners under our agreements with such parties if a third party alleges or if a court finds that our products or activities have infringed upon, misappropriated or misused another person' s proprietary rights. Further, our products may contain technology provided to us by other parties such as contractors, suppliers **,** or customers. We may have little or no ability to determine in advance whether such technology infringes the intellectual property rights of a third party. Our contractors, suppliers and licensors may not be required or financially able to indemnify us in the event that a claim of infringement is asserted against us, or they may be required to indemnify us only up to a maximum amount, above which we would be responsible for any further costs or damages. Some of the products that we manufacture, sell or use may be covered by claims in issued patents held by other persons or entities, and as such, upon notice from such persons or entity, we may be required to pay a license fee or may be required to cease all manufacture, sale or use of such products, which could negatively impact our financial results or operations. We cannot guarantee that such claims will not be made in the future. We need to continue to raise additional funds to finance our future capital or operating needs, which could have adverse consequences on our operations and the interests of our stockholders. As a company focused on research and development of new products that do not yet generate revenues, we need to continue to raise funds through public or private debt or sale of equity to achieve our business strategy. When we raise funds or acquire other technologies or businesses through issuance of equity, this dilutes the interests of our stockholders. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions in general change. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital. Our inability to raise additional funds to finance our future capital or operating needs could force us to delay, reduce or eliminate our development programs or commercialization efforts. Costs related to development projects and approvals are hard to estimate due to factors that are unknown to us at this time. These future costs could be much higher than anticipated and current operations are unlikely be able to cover these costs. Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of studies and trials may not be predictive of future trial results. Clinical trials are expensive, time consuming and difficult to design and implement. Regulatory agencies may analyze or interpret the results differently than we do. Even if the results of our clinical trials are favorable, the clinical trials for a number of our product candidates may take a significant amount of time to complete. Regulatory authorities, including state and local authorities, may suspend, delay or terminate our clinical trials at any time, require us to conduct additional clinical trials, require a particular clinical trial to continue for a longer duration than originally planned, or require a change to our development plans such that we conduct clinical trials for a product candidate in a different order. There is no assurance that the results of the clinical trials will be positive. A negative clinical trial could affect our ability to obtain regulatory clearances and / or potential licensing partners. There is also no assurance that our clinical trials will not be delayed or will be completed. Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition. Our results of operations and financial conditions may be adversely affected by the financial soundness of our customers, distributors and suppliers. If our customers' or suppliers' operating and financial performance deteriorates, or if they are unable to make scheduled payments or obtain credit, our customers may not be able to pay, or may delay payment of, accounts receivable owed to us, and our suppliers may restrict credit or impose different payment terms or reduce or terminate production of products they supply to us, or may cease all operations. Any inability of customers to pay us

for our products and services, or any demands by suppliers for different payment terms, or inability for such suppliers to continue operations may adversely affect our operating results and financial condition. Additionally, both state and federal government sponsored and private payers, as a result of budget deficits or reductions, may seek to reduce their healthcare expenditures by cutting or eliminating reimbursements for, or cutting purchase of our products. Any reduction in payments by such government sponsored or private payers may adversely affect our earnings and cash flow. We may not achieve market acceptance of our new products among healthcare providers and physicians, and this would have a negative effect on future sales. We believe our ability to introduce new products that gain acceptance among consumers, healthcare providers and physicians is an important part of our ability to grow our revenue in future periods. However, any new products we introduce may not gain market acceptance to the extent we anticipate or project. The acceptance in the medical community for any of our new products is unpredictable at this time. In addition, the Company will need to spend considerable funds in order to introduce new products into the marketplace. Sales, if any, of these products in the future are uncertain. In addition, our competitors may offer different products and product formats at suggested prices that are lower than our products or whose products are more accurate than our products. We can provide no assurances that consumers and the medical community will purchase our products or that they will not prefer to purchase a competitive product. The industry and market segments in which we operate are highly competitive, and intense competition with other providers of diagnostic products may reduce our sales and margins. Our diagnostic tests compete with similar products made by our competitors. There are a large number of multinational and regional competitors making investments in competing technologies and products. We also face competition from our distributors as some have created, and others may decide to create ~~,~~ their own products to compete with ours. A number of our competitors have a potential competitive advantage because they have substantially greater financial, technical, research and other resources, larger, more established marketing, sales, distribution and service organizations; more established relationships with healthcare professionals; and greater experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval for products. Moreover, some competitors offer broader product lines and have greater name recognition than we have. If our competitors' products are more effective than ours or take market share from our products through more effective marketing or competitive pricing, our operating results could be materially and adversely affected. In addition, there has been a trend toward industry consolidation in our markets over the last few years. We may not be able to compete successfully in an increasingly consolidated industry. We expect this trend toward industry consolidation may continue as companies attempt to strengthen or hold their market positions in an evolving industry and as companies are acquired or are unable to continue operations. Our business and products are highly regulated by various governmental agencies. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or other changes to the existing laws and regulations that adversely impact our ability to manufacture and market our products. The testing, manufacture and sale of our products are subject to regulation by numerous governmental authorities in the **United States** ~~U. S.~~, principally the FDA and corresponding state and foreign regulatory agencies. Our future performance depends on, among other matters, if, when and at what cost we will receive regulatory approval for new products, and if we can continue to comply with the many regulatory requirements that enable us to manufacture and sell medical related products and tests. Regulatory review can be a lengthy, expensive and uncertain process, making the timing and costs of clearances and approvals difficult to predict. Meeting all regulatory requirements, laws and mandates, and maintaining compliance with such in order to manufacture and sell medical products can be difficult and expensive. Our results of operations would be negatively affected by failures or delays in the receipt of regulatory approvals or clearances, the loss of previously received approvals or clearances, the placement of limits on the marketing and use of our products, and restrictions on our ability to manufacture our products. Changes in government policy could adversely affect our business and potential profitability. Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include tariffs, embargos, trade wars or modifications to existing legislation, such as U. S. tax policy, or entirely new legislation, such as the Affordable Healthcare Act in the **United States** ~~U. S~~. We cannot predict the many ways that healthcare reform in the **United States** ~~U. S.~~ and internationally, and changing trade legislation and policies could adversely affect our business. It is unclear whether and to what extent, if at all, other anticipated developments, including changes due to new presidential administration priorities, or changes resulting from healthcare reform, such as a change in the number of people with health insurance, may impact us. We are subject to numerous government regulations in addition to FDA regulation, and compliance with laws, including changed or new laws, could increase our costs and adversely affect our operations. There is also the risk that our facilities could fail to get the proper licensing at our next inspection or renewal. In addition to FDA and other regulations referred to above, numerous laws relating to such matters as safe working conditions, manufacturing practices, data privacy, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances impact our business operations. If these laws or their interpretation change or new laws regulating any of our businesses are adopted, the costs of compliance with these laws could substantially increase our overall costs. Failure to comply with any laws, including laws regulating the manufacture and marketing of our products, could result in substantial costs and loss of sales or customers. Because of the number and extent of the laws and regulations affecting our industry, and the number of governmental agencies whose actions could affect our operations, it is impossible to reliably predict the full nature and impact of future legislation or regulatory developments relating to our industry and our products. To the extent the costs and procedures associated with meeting new or changing requirements are substantial, our business, results of operations and financial condition could be adversely affected. Our total revenue could be affected by third- party reimbursement policies and potential cost constraints. The end- users of our products are primarily physicians, labs **,** and other healthcare providers. In the **United States** ~~U. S.~~, healthcare providers such as hospitals and physicians who purchase diagnostic products generally rely on third- party payers, principally private health insurance plans, federal Medicare **,** and state Medicaid, to reimburse all or part of the cost of the procedure. Use of

our products would be adversely impacted if physicians and other healthcare providers do not receive adequate reimbursement for the cost of our products by their patients' third- party payers both in the **United States** ~~U. S.~~ and in foreign markets. Our total revenue could also be adversely affected by changes or trends in reimbursement policies of governmental or private healthcare payers. We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry, both foreign and domestic, to reduce the cost of products and services. Given the efforts to control and reduce healthcare costs in recent years, currently available levels of reimbursement may not continue to be available in the future for our existing products or products under development. Third- party reimbursement and coverage may not be available or adequate in either the **United States** ~~U. S.~~ or foreign markets, current reimbursement amounts may be decreased in the future and future legislation, regulation or reimbursement policies of third- party payers may reduce the demand for our products or adversely impact our ability to sell our products on a profitable basis. Unexpected increases in, or inability to meet, demand for our products could require us to spend considerable resources to meet the demand or harm our reputation and customer relationships if we are unable to meet demand. Our inability to meet customer demand for our products, whether as a result of manufacturing problems or supply shortfalls, could harm our customer relationships and impair our reputation within the industry. In addition, our product manufacturing of certain product lines is concentrated in our two manufacturing sites. Weather, natural disasters (including pandemics), fires, terrorism, political change, governmental restrictions or stay- at- home orders in response to natural disasters (including pandemics), failure to follow specific internal protocols and procedures, equipment malfunction, environmental factors or damage to one or more of our facilities could adversely affect our ability to manufacture our products. This, in turn, could have a material adverse effect on our business. If we experience unexpected increases in the demand for our products, we may be required to expend additional capital resources or engage third- party manufacturers to meet these demands. These capital resources could involve the cost of new machinery or even the cost of new manufacturing facilities. In addition, engaging third- party manufacturers would increase manufacturing costs and reduce margins. This would increase our capital costs or third- party expenses, which could adversely affect our earnings and cash resources. If we are unable to develop or obtain necessary manufacturing capabilities in a timely manner or to engage third- party manufacturers to meet demand, our total revenue could be adversely affected. Failure to cost- effectively increase production volumes, if required, or lower than anticipated yields or production problems, including those encountered as a result of changes that we may make in our manufacturing processes to meet increased demand or changes in applicable laws and regulations, could result in shipment delays as well as increased manufacturing costs, which could also have a material adverse effect on our business, operating results and financial condition. Unexpected increases in demand for our products could also require us to obtain additional raw materials in order to manufacture products to meet the demand. Some raw materials require significant ordering lead time and we may not be able to timely access sufficient raw materials in the event of an unexpected increase in demand, particularly those obtained from a sole supplier or a limited group of suppliers. If one or more of our products is claimed to be defective ~~,~~ or does not meet the performance criteria we claim in our marketing materials we could be subject to product recalls, claims of liability and **harm to patients or users of our products, or** harm to our reputation that could adversely affect our business. A claim of a defect in the design or manufacture of our products could have a material adverse effect on our reputation in the industry and subject us to claims of liability for injuries and otherwise. Further, a claim that one of our products is defective or does not actually meet the performance criteria we claim in our marketing materials, could require a product recall or otherwise have a substantial impact on our revenues and financial performance. Any substantial underinsured loss resulting from such a claim or defect would have a material adverse effect on our operating results and financial conditions and the damage to our reputation or product lines in the industry could have a material adverse effect on our business. We are exposed to business risks which, if not covered by insurance, could have an adverse effect on our results of operations. We face potential product liability exposure, and, if claims brought against us are successful, we could incur substantial liabilities. We face a number of business risks, including exposure to product liability claims, employment law claims, claims that the Company or its officers, directors or employees have engaged in illegal or wrongful acts, claims of violation of environmental laws and many other possible claims. Although we maintain insurance for a number of these risks, we may face claims for types of damages, or for amounts of damages, that are not covered by our insurance. For example, although we currently carry product liability insurance for liability losses, there is a risk that product liability or other claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy. Also, our existing insurance may not be renewed at the same cost and level of coverage as currently in effect ~~,~~ or may not be renewed at all. Further, we do not currently have insurance against many environmental risks we confront in our business. If we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, whether arising out of product liability matters, cybersecurity matters, or from some other matter, that claim could have a material adverse effect on our results of operations. We may rely on third parties to conduct or be part of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to seek or obtain regulatory approval for or commercialize our product candidates. We rely on third- party contract research organizations (" CROs "), universities or / clinical sites (" Vendors "), to coordinate, monitor and conduct of our clinical trials and to manage **, analyze and interpret** data for our clinical programs. We, our Vendors, and our clinical sites are required to comply with current Good Clinical Practices (" GCPs "), regulations and guidelines issued by the FDA and by similar governmental authorities in other countries where we are conducting clinical trials. We have an ongoing obligation to monitor the activities conducted by our Vendors and at our clinical sites to confirm compliance with these requirements. In the future, if we, our Vendors or our clinical sites fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. If our Vendors do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical

protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. Failures in our information technology and storage systems could significantly disrupt our business or force us to expend excessive costs. We utilize complex information technology systems to support our business and store information. We cannot be sure that our systems will meet our future business needs or that necessary upgrades will operate as designed, which could result in excessive costs or disruptions in portions of our business. In particular, any disruptions, delays or deficiencies caused by our enterprise resource planning system could adversely affect our ability to process orders, ship products, provide services and customer support, send invoices and track payments, fulfill contractual obligations or otherwise operate our business. In addition, despite the implementation of security measures, information technology systems are vulnerable to damage from a variety of sources, including computer viruses, unauthorized access, telecommunications or network failures, malicious human acts, terrorism **,** and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses and similar disruptive problems. Cyber security is a great and growing risk to operating companies. Cyber- attacks may result in loss of vital Company documentation and data, or confidential third- party documents held by the Company, that are necessary for the Company to operate. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, could result in a material disruption in our operations and material adverse financial costs to the Company. Furthermore, to the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could face a variety of negative consequences, including regulatory actions or litigation, fines or penalties, adverse publicity, increased cybersecurity protection costs, and lost revenue. There is a risk that our measures to protect our systems from cyber- attack are not sufficient to avoid attacks by new sources and methods. Our business could be negatively affected by the loss of or the inability to hire key personnel. Our future success depends in part on our ability to retain our key technical, sales, marketing and executive personnel and our ability to identify and hire additional qualified personnel. Competition for these personnel is intense, both in the industry in which we operate and where our operations are located. Further, we expect to grow our operations, and our needs for additional management and other key personnel are expected to increase. If we are not able to retain existing key personnel, or timely identify and hire replacement or additional qualified personnel to meet expected growth, our business could be adversely impacted. In addition, the loss of any of our key personnel, particularly key research and development personnel, could harm our business and prospects and could impede the achievement of our research and development, operation or strategic objectives. The Company' s lease obligations and growth expectations could create financial and operating risks. Given the recent growth in the Company' s operations, it is uncertain the current leased facilities will be able to accommodate the Company' s operations in the future. As such, the Company may need to move to new facilities that would require the Company to seek to sublease its current facilities for the remainder of the lease (s) at a potential discount to the existing monthly lease obligation cost. Alternatively, the Company could be required to move a portion of its operations to a new facility which could be disruptive both short term and long term to the Company' s operations and create additional fixed costs. We face risks relating to our international sales, including inherent economic, political **,** and regulatory risks, which could impact our financial performance, cause interruptions in our current business operations and impede our growth strategy. Our products are primarily sold internationally, with the majority of our international sales to our distributors in Asia, Europe and South America. We currently sell and market our products through distributor organizations and sales agents which creates foreign risks include, among others: • compliance with multiple different registration requirements and new and changing registration requirements, our inability to benefit from registration for our products inasmuch as registrations may be controlled by a distributor, and the difficulty in transitioning our product registrations; • compliance with complex foreign and U. S. laws and regulations that apply to our international operations, including U. S. laws such as import / export limitations, the Foreign Corrupt Practices Act, and local laws; • tariffs or other barriers as we continue to expand into new countries and geographic regions, especially related to China as tariffs are changing constantly; • exposure to currency exchange fluctuations against the U. S. dollar; • longer payment cycles, generally lower average selling prices and greater difficulty in accounts receivable collection; • lack of ability to enforce receivables collections contracts in foreign legal courts; • reduced, or lack of, protection for, and enforcement of, intellectual property rights; • political and economic instability in some of the regions where we currently sell our products or that we may expand into in the future; • complex and potentially adverse tax consequences; and • diversion to the **United States** ~~U. S.~~ of our products sold into international markets at lower prices. Currently, most of our international sales are negotiated for and paid in U. S. dollars. Nonetheless, these sales are subject to currency risks, since changes in the values of foreign currencies relative to the value of the U. S. dollar can render our products comparatively more expensive. These exchange rate fluctuations could negatively impact international sales of our products, as could changes in the general economic conditions in those markets. In order to maintain a competitive price for our products internationally, we may have to continue to provide discounts or otherwise effectively reduce our prices, resulting in a lower margin on products sold internationally. Continued change in the values of the Euro, the Mexican peso and other foreign currencies could have a negative impact on our business, financial condition and results of operations. In addition, we have certain supply agreements with foreign vendors whereby we share the foreign currency exchange fluctuation risk. We may, in the future, enter into similar arrangements. Sales of our common stock in the public market could lower the market price for our common stock and adversely impact the trading price of our securities. Future sales by the Company of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the then prevailing market price of our common stock and could make it more difficult for us to raise funds in the future through a public offering of our securities. On July 21, 2020, we filed with the SEC a

“ shelf ” registration statement on Form S- 3. The registration statement registers common shares that may be issued by the Company in a maximum aggregate amount of up to $ 90, 000, 000. Shares of our common stock may be sold from time to time under this registration statement for up to three years from the filing date. On January 22, 2021, we filed a prospectus supplement for the sale of up to $ 15, 000, 000 of shares of our common stock in an at- the- market offering under the shelf registration statement, of which **approximately** $ ~~12~~ **9** , ~~984~~ **600** , ~~273~~ **000** , remains available for sale under the prospectus supplement. The issuance of additional shares of our common stock, or issuances of additional securities, could dilute the ownership interest of our common stockholders and could depress the market price of shares of our common stock and impair our ability to raise capital through the sale of additional equity securities. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price for our common stock. We also have a number of stockholders who own large blocks of our common stock. If one or more of these stockholders were to sell large portions of their holdings in a relatively short time, for liquidity or other reasons, the prevailing market price of shares of our common stock could be negatively affected. The price of our stock may fluctuate unpredictably in response to factors unrelated to our operating performance. The stock market periodically experiences significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These broad market fluctuations may cause the market price of our common stock to drop. In particular, the market price of our common stock has been very volatile and unpredictable and may vary substantially in the future in response to: • announcements by us or our competitors concerning technological innovations; • introductions of new products; • FDA, SEC, Financial Industry Regulation Authority and foreign regulatory actions against the Company; • developments or disputes relating to patents or proprietary rights; • failure to meet the expectations of stock market analysts and investors; • **the Company reporting material weakness in our internal control; •** changes in stock market analyst recommendations regarding our common stock; • changes in healthcare policy in the **United States** ~~U. S.~~ or other countries; • lawsuits or liability claims from shareholders or other parties; • legal disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates, and the results of any proceedings or lawsuits, including patent or shareholder litigation; • sales of our common stock or other securities by us or our stockholders in the future; • trading volume of our common stock **;** • actual or anticipated variations in quarterly operating results; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • effects of natural or man- made catastrophic events, including widespread public health epidemics like the pandemic related to COVID- 19; and • general stock market conditions and other factors unrelated to our operating performance. Trading of our common stock is not significant, therefore sales of a larger volume of the stock could adversely affect the stock price. As of August 26, 2016, our Company' s stock has been traded on the Nasdaq Capital Market. Trading of our stock is limited and liquidation of the Company’ s stock may be difficult as there is a limited market for our stock. Our ability to use our net operating loss carry forwards in the future may be subject to limitation. Although we have Federal income tax net operating loss carryforwards of approximately $ ~~12~~ **17** , ~~957~~ **116** , 000 and California state income tax net operating loss carryforwards of approximately $ ~~6~~ **10** , ~~768~~ **805** , 000, use of these loss carryforwards will depend on future income in relationship to expirations dates of these carryforwards. We ~~do not anticipate declaring any cash dividends on our common stock. We have never declared or paid cash dividends on our common stock and do not plan to pay any cash dividends in the near future. Our current policy is to retain all funds and any earnings for use in the operation and expansion of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future. Further, we may in the future become subject to contractual restrictions on, or prohibitions against, the payment of dividends. Consequently, in the foreseeable future, gains will likely only be experienced from investments in our common stock if the price of our common stock increases. There is no guarantee that our common stock will appreciate in value or even maintain the price at which shares were purchased, and returns may not be realized on investments in our common stock. We~~ face risks related to our intellectual property including our patents (IP). We rely on IP for the current products we sell and for the new products in research, development and in clinical trials. While the Company tries to protect its IP with confidentiality agreements and internal policies, we still face risks that our IP will be stolen or otherwise misappropriated, by parties inside or outside of the **United States** ~~U. S~~. Further, we have filed over 100 patents around the world on much of the research and development done by the Company, and the proposed products to come from this research. The vast majority of these filed patents are still under review and have not yet been allowed or issued. We may not be able to attain patent claims that adequately protect the company from competitors developing similar products or copying our products. Finally, there is a great number of issued patents owned by others that pertain to the product categories in which we operate. While we do not know of any patents with claims that we are violating by manufacturing or selling our current products, there is a risk that certain third **-** party patents will emerge that prohibit us from selling our products or that require us to pay royalty payments. Such third **-** party claims could have a material negative impact on the Company. Any of these IP related risks could cause material damage to future revenues and to the long **-** term enterprise values of the Company.