

Risk Factors Comparison 2024-11-14 to 2023-12-19 Form: 10-K

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

An investment in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, together with all of the other information contained or referred to in this report, before making an investment decision with respect to our common stock. If any of the following events occur, our financial condition, business and results of operations (including cash flows) may be materially adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. ~~SUMMARY OF RISK FACTORS~~ **Summary of Risk Factors**

An investment in our ~~securities~~ ~~common stock~~ involves a high degree of risk. You should carefully consider the risks summarized below. These risks are discussed more fully in the “ Risk Factors ” section immediately following this summary. These risks include, but are not limited to, the following: Risks Related to Our Business and Industry · We might not be able to continue as a going concern. We believe that our cash on hand will be sufficient to fund our operations at least through ~~June 30~~ ~~February 28, 2024~~ ~~2025~~ ~~;~~ ~~.~~ We are still in the early stages of commercialization, refining our technology. Our success depends on our ability to conclude development and market devices that are recognized as accurate, safe, and cost- effective as other options currently available in the market and cleared by FDA. · We are subject to extensive regulation by FDA, which could restrict the sales and marketing of our products and could cause us to incur significant costs ~~;~~ ~~.~~ Risks Related to Ownership of Our Common Stock **and Warrants** · The market price of our common stock may fluctuate, and you could lose all or part of your investment. · We may not be able to maintain a listing of our common stock on the NYSE American. · We do not expect to declare or pay dividends in the foreseeable future. · Future issuances of our common stock or securities convertible into, or exercisable or exchangeable for, our common stock, or the expiration of lock- up agreements that restrict the issuance of new common stock or the trading of outstanding common stock, could cause the market price of our securities to decline and would result in the dilution of your holdings. · Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect the level of return you may be able to achieve from an investment in our common stock. ~~16~~ ~~We~~ ~~17~~ **RISK FACTORS An investment in our common stock involves a high degree of risk. You should carefully read and consider all of the risks described below, together with all of the other information contained or referred to in this report, before making an investment decision with respect to our common stock. If any of the following events occur, our financial condition, business and results of operations (including cash flows) may be materially adversely affected. In that event, the market price of our common stock could decline, and you could lose all or part of your investment. We** need additional financing to support our technology development and ongoing operations, pay our debts and maintain ownership of our intellectual ~~properties~~ ~~property~~ **property**. We are currently operating at a loss and using substantial cash to fund our operation. We believe that our cash on hand will be sufficient to fund our operations through ~~June 30~~ ~~February 28, 2024~~ ~~2025~~ ~~.~~ We may need additional financing to implement our business plan and to service our ongoing operations, pay our current debts (described below) and maintain ownership of our intellectual property. There can be no assurance that we will be able to secure any needed funding, or that if such funding is available, the terms or conditions would be acceptable to us. If we are unable to obtain additional financing when it is needed, we will need to restructure our operations and / or divest all or a portion of our business. We are seeking additional capital through a combination of private and public equity offerings, debt financings and strategic collaborations. Debt financing, if obtained, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, and could increase our expenses and require that our assets secure such debt. Equity financing, if obtained, could result in dilution to our then- existing stockholders and / or require such stockholders to waive certain rights and preferences. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back, eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. There can be no assurance that we will be able to sell that number of shares, if any. We need to continue as a going concern if our business is to succeed. Because we have generated limited revenues **in prior years** and currently operate at a loss, we are completely dependent on the continued availability of financing in order to continue our business. There can be no assurance that financing sufficient to enable us to continue our operations will be available to us in the future. ~~We~~ ~~As of September 30, 2024, we~~ have cash and cash equivalents of \$ ~~8-3, 024-111~~ ~~, 000~~ and a net working capital **deficit** of approximately \$ ~~6-2, 264-053~~ ~~, 000~~ ~~(exclusive of convertible notes payable)~~ ~~as of September 30, 2023~~. We anticipate that we will record losses from operations for the foreseeable future. We believe that we have enough available cash to operate until ~~June 30~~ ~~February 28, 2024~~ ~~2025~~ ~~.~~ As of September 30, ~~2023~~ ~~2024~~, our accumulated deficit was \$ ~~121-138, 841-736~~ ~~, 000~~. We intend to seek additional cash via equity and debt offerings. As a result of not having at least twelve months of cash available and not having any firm commitment for debt or equity financing, substantial doubt about ~~our the Company's~~ ~~ability to continue on a going concern exists~~. We have financed our corporate operations and our technology development through the issuance of convertible debentures, the issuance of preferred stock, the sale of common stock and the exercise of warrants. During the remainder of 2024, we expect to raise additional funds through the issuance of preferred stock, convertible debentures or equity. The proceeds of warrants currently outstanding, to the extent not exercised on a cashless basis, may generate potential proceeds. We cannot provide assurance that any of these warrants will be exercised. As of September 30, ~~2023~~ ~~2024~~, we owed approximately \$ ~~2-4, 980-724~~ ~~, 000~~ and if we do not satisfy these obligations, the lenders may have the right to demand payment in full or exercise other remedies. We owe \$ ~~2-4, 762-724~~ ~~, 000~~ under various convertible promissory notes as of September 30, ~~2023~~ ~~2024~~; ~~including~~ ~~\$ 1, 301, 000 to~~

Clayton Struve who owns 100% of outstanding Series C and D Preferred stock, and \$ 1,461,000 owed to entities controlled by Ronald P. Erickson, our CEO and Chairman. Mr. Erickson and / or entities with which he is affiliated also have accounts payable and accrued liabilities \$ 218,000 as of September 30, 2023 related to accrued interest. We may need additional financing, to service and / or repay these debt obligations. If we raise additional capital through borrowing or other debt financing, we may incur substantial interest expense. If and when we raise more equity capital in the future, it will result in substantial dilution to our current stockholders. ~~17~~**We** have a history of operating losses and there can be no assurance that we can achieve or maintain profitability. We have experienced net losses since inception. As of September 30, ~~2023~~**2024**, we had an accumulated deficit of \$ ~~121,138,841~~**736,000** and net losses in the amount of \$ ~~16,582,000 and \$ 15,289,000 and \$ 20,071,000~~ for the years ended September 30, ~~2024 and 2023 and 2022~~, respectively. There can be no assurance that we will achieve or maintain profitability. If we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Failure to become and remain profitable would impair our ability to sustain operations and adversely affect the price of our common stock and our ability to raise capital. Our operating expenses may increase as we spend resources on growing our business, and if our revenue does not correspondingly increase, our operating results and financial condition will suffer. Our businesses have produced minimal revenues and may not produce significant revenues in the near term, or at all, which would harm our ability to continue our operations or obtain additional financing and require us to reduce or discontinue our operations. You must consider our business and prospects in light of the risks and difficulties we will encounter as a business with an early-stage technology in a new and rapidly evolving industry. We may not be able to successfully address these risks and difficulties, which could significantly harm our business, operating results, financial condition and common stock price per share. We may not be able to generate sufficient revenue from the commercialization of our technology and related products to achieve or sustain profitability. We are in the early stages of commercializing our technology. Failure to develop and sell products based upon our technology could have a material adverse effect on our business, financial condition and results of operations. To date, we have not generated revenue from sales of our technology or products. We believe that our commercialization success is dependent upon our ability to significantly increase the number of customers that will use our products. In addition, demand for our products may not materialize, or increase as quickly as planned, and we may therefore be unable to increase our revenue levels as expected. We are currently not profitable. Even if we succeed in introducing our technology and related products to our target markets, we may not be able to generate sufficient revenue to achieve or sustain profitability. We are subject to extensive regulation by the ~~FDA U. S. Food and Drug Administration~~, which could require us to take significant time and could cause us to incur significant costs. Our KnowU and UBand glucose monitoring products are subject to extensive regulation by FDA. These regulations relate to manufacturing, labeling, sale, promotion, distribution and shipping. Before a new medical device, or a new intended use of a legally marketed device, can be marketed in the United States, it must be cleared or approved by FDA through the applicable premarket review process (510(k), PMA, or de novo classification), unless an exemption applies. The KnowU and UBand glucose monitoring products and substantially equivalent devices of this type that may later receive marketing authorization are similar to products referred to as integrated continuous glucose monitoring (CGM) systems. Integrated continuous glucose monitoring systems are generally classified by FDA as Class II devices and have established special controls outlining requirements for assuring CGM accuracy, reliability, and clinical relevance. FDA also has descriptions of the types of studies and data required to demonstrate acceptable CGM performance. Though it is our current belief that our initial product, the KnowU and UBand glucose monitoring products, are appropriate for a de novo classification request (i. e., a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device that is described in more detail below), we expect similar classification, special controls, and testing. If we receive 510(k) clearance for our KnowU and UBand glucose monitoring products, we may be required to obtain new 510(k) clearances for significant post-market modifications. Each premarket submission and review process can be expensive and lengthy, and entail significant user fees, unless exempt. The classification and special controls for all other products using ~~our the Company's~~ proprietary radio frequency and microwave spectroscopy platform will be dependent on product type and explored as applicable. In addition, regulatory clearance or approval by FDA does not ensure registration, clearance, approval, or certification by regulatory authorities or notified bodies internationally. While the regulatory requirements for marketing in international markets may require that we obtain clearance, approval, or certification by an international specified regulatory body or notified body. Complying with foreign regulatory requirements, including obtaining registrations, clearances, approvals, or certifications, can be expensive and time consuming, and we may not receive regulatory clearances, approvals, or certifications in each country or region in which we plan to market our products or we may be unable to do so on a timely basis. In turn, this could limit our expected international growth and profitability, which could have a material adverse effect on our business, financial condition, and results of operations. ~~18~~**The** clinical trial process is lengthy and expensive with uncertain outcomes. Results of earlier studies may not be predictive of future clinical trial results, or the safety or efficacy profile for such products. Clinical trials are generally required to support an application for clearance of a new device type such as our KnowU and UBand glucose monitoring products. All clinical trials must be conducted in accordance with FDA's Investigational Device Exemption (IDE) regulations, which govern investigational device labeling, prohibit promotion, and specify an array of Good Clinical Practice requirements, which include among other things, recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by FDA. ~~Results~~**Results** of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for FDA to grant approval or clearance of a product. In addition, the commencement or completion of any of our clinical trials may be delayed or halted for numerous reasons, including, but not limited to, the following: · we may be required to submit an investigational device exemption application, or IDE, to FDA, which must become effective prior to commencing certain human

clinical trials of medical devices, and FDA may reject our IDE and notify us that we may not begin clinical trials; · the cost of clinical trials may be greater than we anticipate; · FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold; · patients do not enroll in clinical trials at the rate we expect; · patients do not comply with trial protocols; · patient follow-up is not at the rate we expect; · patients experience adverse side effects; · patients die during a clinical trial, even though their death may not be related to our products; · we may not reach agreement on acceptable terms with prospective contract research organizations (CROs), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; · institutional review boards and third-party clinical investigators may delay or reject our trial protocol; · third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or other FDA requirements; · data collection, monitoring, and analysis is not performed in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans; · regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials; · changes in governmental regulations or administrative actions applicable to our trial protocols, including, for example, recent legislation passed by Congress requiring clinical trial sponsors to increase engagement with FDA on matters related to appropriate representation of racial and ethnic minorities in clinical trial data for pivotal studies; · the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or effectiveness; and · FDA concludes that the results from our trial and / or trial design are inadequate to demonstrate safety and effectiveness of the product.

~~19~~ Additionally -- **Additionally**, the ability of FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, the availability of industry-paid user fees, and statutory, regulatory, and policy changes. Average review times for product approvals at FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. ~~Disruptions~~ **Disruptions** at FDA and other agencies, including those resulting from global concerns (e.g., the ongoing COVID-19 global pandemic), may also slow the time necessary for new products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, if a prolonged government shutdown and / or government employee furloughs were to occur, or if FDA's response to a global issue diverts FDA resources and attention to other regulatory efforts, then the ability of FDA to timely review and process our regulatory submissions could be significantly impacted, which could have a material adverse effect on our business, financial condition, and results of operations. Further, in our operations as a public company, future government shutdowns, furloughs, or public health emergencies could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Any of these occurrences may significantly harm our business, financial condition, and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Moreover, even if our products are cleared in the **United States U.S.**, commercialization of our products in foreign countries would require clearance or approval by regulatory authorities in those countries. Clearance or approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. The safety and efficacy of our products is not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe or effective than initially thought. Given the regulatory environment in which we operate, we lack the breadth of published long-term clinical data supporting the safety and efficacy of ~~The the~~ KnowU and ~~UBand~~ glucose monitoring products and the benefits it offers that might have been generated in connection with other marketing authorization pathways. For these reasons, clinicians may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our product does not improve patient outcomes. Such results would slow the adoption of our product by physicians, would significantly reduce our ability to achieve expected sales, and could prevent us from achieving and maintaining profitability. In addition, because the KnowU and ~~UBand~~ glucose monitoring products have never been marketed, we have limited complaints or patient success rate data with respect to using these products. If future patient studies or clinical testing do not support our belief that our products offer a more advantageous blood glucose monitoring, then market acceptance of our products could fail to increase or could decrease, and our business could be harmed. Moreover, if future results and experience indicate that our product has potentially recurring malfunctions or causes unexpected or serious complications or other unforeseen negative effects, then we could be subject to mandatory or voluntary product recalls, suspension or withdrawal of FDA clearance, as well as significant legal liability or harm to our business reputation and financial results. If we choose to, or are required to, conduct additional clinical studies and the outcome of such studies are not positive, then this could reduce the rate of coverage and reimbursement for the KnowU and ~~UBand~~ glucose monitoring products. This may slow the market adoption of our product by physicians, significantly reduce our ability to achieve expected revenues and prevent us from becoming profitable. We believe that publications of scientific and medical results in peer-reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer-reviewed journals could limit the adoption of our products. Unless specifically stated to be "peer-reviewed," the studies referred to in this filing are not peer reviewed. ~~20~~ **We** are subject to extensive regulation which could restrict the sales and marketing of our products and could cause us to incur significant costs. Medical devices may be marketed only for the indications for which they are approved or cleared. Further, clearances can be revoked if safety or effectiveness problems develop once the device is on the market. ~~The~~ **The** current regulatory requirements to which we are subject may

change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by FDA, which may include any of the following sanctions: · modification to our training and promotional materials; · untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; · customer notification, or orders for repair, replacement or refunds; · voluntary or mandatory recall or seizure of our current or future products; · administrative detention by FDA of medical devices believed to be adulterated or misbranded; · imposing operating restrictions, suspension or shutdown of production; · refusing our requests for clearance, PMA or de novo classification of any new products, new intended uses or modifications to our products; · FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; · withdraws or suspension of 510 (k) clearance that has already been granted, resulting in prohibitions on sales of our products; and · criminal prosecution. The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in stockholders losing their entire investment. Additionally, any relationships we may have with healthcare professionals, clinical investigators, and payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers and payors play a primary role in the recommendation and / or prescription of any product candidates for which we obtain future marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, payors, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell, and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: · the federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the U. S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; ~~21-~~ the federal false claims and civil monetary penalties laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease, or conceal an obligation to pay money to the federal government. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; **22** HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information; · the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program, with specific exceptions, to annually report to Centers for Medicare & Medicaid Services (CMS) starting in 2022 information regarding payments and other transfers of value to physicians, certain other healthcare providers, and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported will be publicly available on a searchable website, with disclosure required annually; and · analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third- party payors, including private insurers. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non- European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. In addition, ~~on June 28, 2018, the State of California enacted~~ the California Consumer Privacy Act, or CCPA, ~~which took effect on January 1, 2020. The CCPA~~ creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, then we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, temporary or permanent debarment, contractual damages,

reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, then they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. 22A-23A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. We may seek regulatory approval of our product candidates outside of the U. S., and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: · differing regulatory requirements and reimbursement regimes in foreign countries; · unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements; · economic weakness, including inflation, or political instability in particular foreign economies and markets; · compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; · foreign taxes, including withholding of payroll taxes; · foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; · difficulties staffing and managing foreign operations; · workforce uncertainty in countries where labor unrest is more common than in the U. S.; · potential liability under the Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations; · challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U. S.; · production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and · business interruptions resulting from geo-political actions, including war and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. We may face difficulties with respect to coverage and reimbursement by various payors. Sales of any medical device depend often, in part, on the extent to which the product will be covered and reimbursed by government payors (e. g., federal and state healthcare programs), third-party payors (e. g., commercial insurance and managed healthcare organizations), and other payors (e. g., foreign government healthcare programs). In the United States, various glucose monitoring products are covered for individuals with both Type 1 and Type 2 diabetes by Medicare and Medicaid in the majority of states and by commercial insurers, subject to satisfaction of certain eligibility and coverage criteria. But significant uncertainty exists as to the coverage and reimbursement status of any newly approved product. For example, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, will be considered cost-effective by payors, that an adequate level of reimbursement will be established even if coverage is available, or that the payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably. Decisions regarding the extent of coverage and reimbursement amount are generally made on a plan-by-plan basis meaning one payor's decision to cover a particular product does not ensure that other payors will also provide similar coverage. As a result, the coverage determination process can require manufacturers to provide scientific and clinical support for the use of a product, and require providers to show medical necessity for use, to each payor separately. This process can be time-consuming, with no assurance that coverage and adequate reimbursement will be applied consistently or even obtained. 23 Payors -- Payors are also increasingly reducing reimbursements for devices through continued implementation of cost-containment programs, including price controls and restrictions on coverage and reimbursement, which could further limit sales of any product. In addition, payors continue to question safety and efficacy while also challenging the prices charged, examining medical necessity and reviewing the cost effectiveness of devices in an effort to avoid coverage and reimbursement. But decreases of this nature surrounding the reimbursement for any product or a decision by a government and third-party payor not to cover a product could result in reduced physician usage and patient demand for the product. Moreover, in international markets, reimbursement and healthcare payment systems vary significantly by country, with many countries have instituted price ceilings on specific products and therapies. The 24 The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of FDA or another governmental authority, could have a negative impact on us. We are subject to FDA's medical device reporting regulations, which require us to report to FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the initial use of the device. If we fail to comply with our reporting obligations, FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, seizure of our products, or, if premarket review is required in the future, delay in clearance of future products. FDA and foreign regulatory bodies have the authority to require the recall of commercialized medical device products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects, or other deficiencies or failures to comply with applicable regulations. We cannot assure you that product defects or other errors will not occur in the future. Recalls involving our products could have a material adverse effect on our business, financial condition, and results of operations. Moreover, medical device manufacturers are required to maintain certain records of recalls and corrections, even if they are not reportable to FDA. We may initiate voluntary withdrawals or corrections for our

devices in the future that we determine do not require notification of FDA. If FDA disagrees with our determinations, then it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability and malpractice claims against us and negatively affect our sales. We may face difficulties from changes to current regulations and future legislation, both in the U. S. as well as in other foreign jurisdictions where we may be operating. Existing regulations and regulatory policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. Legislative changes may impact our future business and operations, including those that may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our business, financial condition, and results of operations. Both before and after a product is commercially released, we have ongoing responsibilities under various laws and regulations. If a regulatory authority were to conclude that we are not in compliance with applicable laws or regulations, or that any of our products are ineffective or pose an unreasonable risk for the end-user, then the authority may ban such devices, detain or seize adulterated or misbranded devices, order a recall, repair, replacement, or refund of such instruments, and require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. A regulatory authority may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The regulatory authority may also recommend prosecution by law enforcement agencies. Any governmental law or regulation, existing or imposed in the future, or enforcement action taken may have a material adverse effect on our business, financial condition, and results of operations. ~~24~~**We** cannot predict the likelihood, nature, or extent of any legislative changes will be enacted or government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. Similarly, we cannot predict whether FDA regulations, guidance, or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, then we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. ~~Our~~**25Our** industry is highly competitive and subject to significant or rapid technological change. Our fields of therapeutic interest is highly competitive and subject to significant and rapid technological change. Accordingly, our success may depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. If our product candidates are approved by FDA, then potential competitors who seek to introduce similar product candidates may seek to take advantage of a shorter and less costly development program for a product that competes with our products. Our ability to compete successfully against currently existing and future alternatives to our product candidates and systems and competitors who compete directly with us may depend, in part, on our ability to attract and retain skilled scientific and research personnel, develop technologically superior products, develop competitively priced products, obtain patent or other required regulatory approvals for our products, be an early entrant to the market and manufacture, market, and sell our products, independently or through collaborations. We currently rely ~~in part~~ upon external resources for ~~many~~ engineering and product development services. If we are unable to secure ~~an~~ engineering or product development ~~partner~~**partners** or establish satisfactory engineering and product development capabilities, we may not be able to successfully commercialize our technology. Our success depends upon our ability to develop products that are accurate and provide solutions for our customers. Achieving the desired results for our customers requires solving engineering issues in concert with them. Any failure of our technology or related products to meet customer expectations could result in customers choosing to retain their existing methods or to adopt systems other than ours. Historically, we have not had sufficient internal resources to work on all necessary engineering and product development matters. We have used third parties in the past and will continue to do so. These resources are not always readily available, and the absence of their availability could inhibit our research and development efforts and our responsiveness to our customers. Our inability to secure those resources could impact our ability to provide engineering and product development services and could have an impact on our customers' willingness to use our technology. Moreover, third parties have their own internal demands on time and resources which may not always align with ours. Hence, our own expectations for development and product timelines may not be shared by third parties upon whom we rely. We are in the early stages of commercialization and our technology and related products may never achieve significant commercial market acceptance. Our success depends on our ability to develop and market devices that are recognized as accurate, safe and cost- effective. They must be safe and deliver the required level of accuracy under any condition, regardless of the user, as determined by their intended use. This will be achieved through ~~contin~~**continued** refinement of our technology. Before presenting it to the FDA, additional development is needed to increase its generalizability. Many of our potential customers may be reluctant to use our new technology. Market acceptance will depend on many factors, including our ability to convince potential customers that our technology and related products are an attractive alternative to existing technologies. We will need to demonstrate that our products provide accurate and cost- effective alternatives to existing technologies. Compared to most competing technologies, our technology is new, and most potential customers will have limited knowledge of, or experience with, our products. Prior to implementing our technology and related products, some potential customers may be required to devote significant time and effort to testing and validating our products. Any failure of our technology or related products to meet customer expectations could result in customers choosing to retain their existing methods or to adopt systems other than ours. ~~25~~**Many** ~~Many~~ factors influence the perception of a new technology including its use by leaders in the industry. If we are unable to induce industry leaders in our target markets to implement and use our technology and related products, acceptance and adoption of our products could be slowed. In addition, if our products fail to gain significant acceptance in the marketplace and we are unable to expand our customer base, we may never generate sufficient revenue to achieve or sustain profitability. ~~Additionally~~**26Additionally**, we may not be able to penetrate or successfully operate in international markets or encounter difficulty expanding into international markets because

of limited brand recognition in certain parts of the world, which may lead to delayed acceptance of our products by consumers in these international markets. If we are unable to expand internationally and manage the complexity of international operations successfully, then it could have a material adverse effect on our business, financial condition, and results of operations. If our efforts to introduce our products into foreign markets are not successful, then we may have expended significant resources without realizing the expected benefit. Ultimately, the investment required for expansion into foreign markets could exceed the results of operations generated from this expansion. We are dependent on key personnel. Our success depends to a significant degree upon the continued contributions of key management and other personnel, some of whom could be difficult to replace. While our continued operation and ultimate success is not dependent upon one individual, our success does depend on the performance of our officers, our ability to retain and motivate our officers, our ability to integrate new officers into our operations, and the ability of all personnel to work together effectively as a team. Our failure to retain and recruit officers and other key personnel could have a material adverse effect on our business, financial condition and results of operations. Our success also depends on our continued ability to identify, attract, hire, train, retain and motivate highly skilled technical, managerial, manufacturing, administrative and sales and marketing personnel. Competition for these individuals is intense, and we may not be able to successfully recruit, assimilate or retain sufficiently qualified personnel. In particular, we may encounter difficulties in recruiting and retaining a sufficient number of qualified technical personnel, which could harm our ability to develop new products and adversely impact our relationships with existing and future customers. The inability to attract and retain necessary technical, managerial, manufacturing, administrative and sales and marketing personnel could harm our ability to obtain new customers and develop new products and could adversely affect our business and operating results. We rely on the timely supply of components and parts and could suffer if suppliers fail to meet their delivery obligations, raise prices or cease to supply us with components or parts. The manufacture of our products is complex and requires the integration of a number of components from several sources of supply. We rely on numerous critical suppliers for various key components that are used in the manufacturing of our products. We can make no assurance that we will be able to maintain such supply arrangements. If we are unable to maintain supply arrangements, our access to key components could be reduced, which could harm our business. Additionally, if demand for our products decreases, we may have excess inventory and inventory that may expire, which could result in inventory write-offs that would have a material adverse effect on our business, financial condition, and results of operations. We may also encounter defects in materials and / or workmanship, which could lead to a failure to adhere to regulatory requirements. Any defects could delay operations at our contract manufacturers' facilities, lead to regulatory fines, or halt or discontinue manufacturing indefinitely. Any of these outcomes could have a material adverse effect on our business, financial condition, and results of operations. This reliance also adds additional risks to the manufacturing process that are beyond our control. For example, the occurrence of epidemics or pandemics may cause one or more of our suppliers to close or reduce the scope of their operations either temporarily or permanently. In addition, these suppliers may provide components and products to our competitors. The medical device industry's reliance on a limited number of key components and product suppliers subjects us to the risk that in the event of an increase in demand, our suppliers may fail to provide supplies to us in a timely manner while they continue to supply our competitors, many of which have greater purchasing power than us, or seek to supply components to us at a higher cost. The failure of our suppliers to deliver components or products in a timely fashion could have disruptive effects on our ability to produce our products in a timely manner, or we may be required to find new suppliers at an increased cost. ~~26~~Moreover-- **Moreover**, our reputation and the quality of our products are in part dependent on the quality of the components that we source from third-party suppliers. If we are unable to control the quality of the components supplied to us or to address known quality problems in a timely manner, then our reputation in the market may be damaged and sales of our products may suffer. As a result, we may experience a material adverse effect on our business, financial condition, and results of operations. We have limited insurance which may not cover claims by third parties against us or our officers and directors. We have directors' and officers' liability insurance and commercial liability insurance policies. Claims, however, by third parties against us may exceed policy amounts and we may not have amounts to cover these claims. Any significant claims would have a material adverse effect on our business, financial condition and results of operations. In addition, our limited directors' and officers' liability insurance may affect our ability to attract and retain directors and officers. ~~Our~~**27****Our** inability to effectively protect our intellectual property would adversely affect our ability to compete effectively, our revenue, our financial condition and our results of operations. We rely on a combination of patent, trademark, and trade secret laws, and confidentiality procedures to protect our intellectual property rights. Creating and maintaining a strong patent portfolio is important to our business. Patent law relating to the scope of claims in the technology fields in which we operate is complex and uncertain, so we cannot be assured that we will be able to obtain or maintain patent rights, or that the patent rights we may obtain will be valuable, provide an effective barrier to competitors or otherwise provide competitive advantages. Others have filed, and in the future are likely to file, patent applications that are similar or identical to ours or those of our licensors. To determine the priority of inventions or demonstrate that we did not derive our invention from another, we may have to participate in interference or derivation proceedings in the United States Patent and Trademark Office or in court that could result in substantial costs in legal fees and could substantially affect the scope of our patent protection. We cannot be assured our patent applications will prevail over those filed by others. Also, our intellectual property rights may be subject to other challenges by third parties. Patents we obtain could be challenged in litigation or in administrative proceedings such as ex parte reexam, inter parties review, or post grant review in the United States or opposition proceedings in Europe or other jurisdictions. There can be no assurance that: · any of our existing patents will continue to be held valid, if challenged; · patents will be issued for any of our pending applications; · any claims allowed from existing or pending patents will have sufficient scope or strength to protect us; · our patents will be issued in the primary countries where our products are sold in order to protect our rights **·** and potential commercial advantage; or · any of our products or technologies will not infringe on the patents of other companies. If we are prevented from selling our products, or if we are required to develop new technologies or pay significant monetary

damages or are required to make substantial royalty payments, our business and results of operations would be harmed. Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and / or applications due in several stages over the lifetime of patents and / or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may or may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer. ~~27~~Legal-- Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or interferences against those that have infringed on our patents, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could have a material adverse effect on our results of operations and business. ~~Claims~~28Claims by others that our products infringe their patents or other intellectual property rights could prevent us from manufacturing and selling some of our products or require us to pay royalties or incur substantial costs from litigation or development of non- infringing technology. In recent years, there has been significant litigation in the United States involving patents and other intellectual property rights. We may receive notices that claim we have infringed upon the intellectual property of others. Even if these claims are not valid, they could subject us to significant costs. Any such claims, with or without merit, could be time- consuming to defend, result in costly litigation, divert our attention and resources, cause product shipment delays or require us to enter into royalty or licensing agreements. Such royalty or licensing agreements, if required, may not be available on terms acceptable to us or at all. We have not been engaged in litigation but litigation may be necessary in the future to enforce our intellectual property rights or to determine the validity and scope of the proprietary rights of others. Litigation may also be necessary to defend against claims of infringement or invalidity by others. A successful claim of intellectual property infringement against us and our failure or inability to license the infringed technology or develop or license technology with comparable functionality could have a material adverse effect on our business, financial condition and operating results. The analysis of our patent portfolio by PatSnap Research and ipCapital Group is not a legal analysis and does not predict the outcome of any legal challenges we or others might make in regard to patents, nor does it constitute a view on the overall legal strength of our patents. If we are unable to secure a sales and marketing partner or establish satisfactory sales and marketing capabilities at our company, we may not be able to successfully commercialize our technology. If we are not successful entering into appropriate collaboration arrangements or recruiting sales and marketing personnel or in building a sales and marketing infrastructure, we will have difficulty successfully commercializing our technology, which would adversely affect our business, operating results and financial condition. We may not be able to enter into collaboration agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties. If we elect to establish a sales and marketing infrastructure, we may not realize a positive return on this investment. In addition, we must compete with established and well- funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize technology without strategic partners or licensees include: · our inability to recruit and retain adequate numbers of effective sales and marketing personnel; · the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and · unforeseen costs and expenses associated with creating an independent sales and marketing organization. We may engage in acquisitions, mergers, strategic alliances, joint ventures and divestitures that could result in final results that are different than expected. In the normal course of business, we engage in discussions relating to possible acquisitions, equity investments, mergers, strategic alliances, joint ventures and divestitures. Such transactions are accompanied by a number of risks, including the use of significant amounts of cash, potentially dilutive issuances of equity securities, incurrence of debt on potentially unfavorable terms as well as impairment expenses related to goodwill and amortization expenses related to other intangible assets, the possibility that we may pay too much cash or issue too many of our shares as the purchase price for an acquisition relative to the economic benefits that we ultimately derive from such acquisition, and various potential difficulties involved in integrating acquired businesses into our operations. ~~28~~From-- From time to time, we have also engaged in discussions with candidates regarding the potential acquisitions of our product lines, technologies and businesses. If a divestiture such as this does occur, we cannot be certain that our business, operating results and financial condition will not be materially and adversely affected. A successful divestiture depends on various factors, including our ability to effectively transfer liabilities, contracts, facilities and employees to any purchaser; identify and separate the intellectual property to be divested from the intellectual property that we wish to retain; reduce fixed costs previously associated with the divested assets or business; and collect the proceeds from any divestitures. If we do not realize the expected benefits of any acquisition or divestiture transaction, our financial position, results of operations, cash flows and stock price could be negatively impacted. ~~We~~29We may make strategic acquisitions in the future, and if the acquired companies do not perform as expected, this could adversely affect our operating results, financial condition and existing business. We may continue to expand our business through strategic acquisitions. The success of any acquisition will depend on, among other things: · the availability of suitable candidates; · higher than anticipated acquisition costs and expenses; · competition from other companies for the purchase of available candidates; · our ability to value those candidates accurately and negotiate favorable terms for those acquisitions; · the availability of funds to finance acquisitions and obtaining any consents necessary under our credit facility; · the ability to establish new informational, operational and financial systems to

meet the needs of our business; · the ability to achieve anticipated synergies, including with respect to complementary products or services; and · the availability of management resources to oversee the integration and operation of the acquired businesses. We may not be successful in effectively integrating acquired businesses and completing acquisitions in the future. We also may incur substantial expenses and devote significant management time and resources in seeking to complete acquisitions. Acquired businesses may fail to meet our performance expectations. If we do not achieve the anticipated benefits of an acquisition as rapidly as expected, or at all, investors or analysts may not perceive the same benefits of the acquisition as we do. If these risks materialize, our stock price could be materially adversely affected. Government regulatory approval may be necessary before some of our products can be sold and there is no assurance such approval will be granted. Our technology will have a number of potential applications in fields of use that will require prior governmental regulatory approval before the technology can be introduced to the marketplace. For example, we are exploring the use of our technology for certain medical diagnostic applications, with an initial focus on the monitoring of blood glucose. There is no assurance that we will be successful in developing glucose monitoring medical applications for our technology. If we were to be successful in developing glucose monitoring medical applications of our technology, prior clearance by FDA and other governmental regulatory bodies will be required before the technology could be introduced into the marketplace. Our devices leverage **Machine machine Learning learning (ML)** and **Artificial artificial Intelligence intelligence (AI)** to process the massive data collected through the Bio-RFID sensor. **ML/AI-Our intelligence and machine learning** also controls the sensor operation, enabling the device to emit and capture data, and, ultimately, to identify and measure blood glucose levels. Machine learning -enabled device software functions (ML- DSF) continue to be evaluated by FDA, which recently released new guidance proposing a science- based approach for **AI/ML- machine learning and artificial intelligence** enabled medical devices to be modified and improved more quickly. There is no assurance that such regulatory approval would be obtained for a glucose monitoring medical diagnostic device or other applications requiring such approval. FDA can refuse to grant, delay, and limit or deny approval of an application for clearance of marketing a glucose monitoring device for many reasons. We may not obtain the necessary regulatory approvals or clearances to market these glucose monitoring systems in the United States or outside of the United States. Any delay in, or failure to receive or maintain, approval or clearance for our products could prevent us from generating revenue from these products or achieving profitability. **29We-30We** or our manufacturers may be unable to obtain or maintain international regulatory clearances or approvals for our current or future products, or our distributors may be unable to obtain necessary qualifications, which could harm our business thus limited sales to the U. S. Sales of our products internationally are subject to foreign regulatory requirements that vary widely from country to country. In addition, FDA regulates exports of medical devices from the U. S. Complying with international regulatory requirements can be an expensive and time- consuming process, and marketing approval or clearance is not certain. The time required to obtain clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approvals, and requirements for such clearances or approvals may significantly differ from FDA requirements. We may rely on third- party distributors to obtain regulatory clearances and approvals required in other countries, and these distributors may be unable to obtain or maintain such clearances or approvals. Our distributors may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or clearances, which could increase the difficulty of attracting and retaining qualified distributors. If our distributors experience delays in receiving necessary qualifications, clearances or approvals to market our products outside the U. S., or if they fail to receive those qualifications, clearances or approvals, then we may be unable to market our products or enhancements in international markets effectively, or at all. Foreign governmental authorities that regulate the manufacture and sale of medical devices have become increasingly stringent and, to the extent we market and sell our products outside of the U. S., we may be subject to rigorous international regulation in the future. In these circumstances, we would be required to rely on our foreign independent distributors to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our product in foreign countries. Cybersecurity risks and cyber incidents could result in the compromise of confidential data or critical data systems and give rise to potential harm to customers, remediation and other expenses, expose us to liability under consumer protection laws, or other common law theories, subject us to litigation and federal and state governmental inquiries, damage our reputation, and otherwise be disruptive to our business and operations. Cyber incidents can result from deliberate attacks or unintentional events. We collect and store on our networks sensitive information, including intellectual property, proprietary business information and personally identifiable information of our customers. The secure maintenance of this information and technology is critical to our business operations. We have implemented multiple layers of security measures to protect the confidentiality, integrity and availability of this data and the systems and devices that store and transmit such data. We utilize current security technologies, and our defenses are monitored and routinely tested internally and by external parties. Despite these efforts, threats from malicious persons and groups, new vulnerabilities and advanced new attacks against information systems create risk of cybersecurity incidents. These incidents can include, but are not limited to, gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, corrupting data, or causing operational disruption. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and may not immediately produce signs of intrusion, we may be unable to anticipate these incidents or techniques, timely discover them, or implement adequate preventative measures. These threats can come from a variety of sources, ranging in sophistication from an individual hacker to malfeasance by employees, consultants or other service providers to state- sponsored attacks. Cyber threats may be generic, or they may be custom crafted against our information systems. Over the past several years, cyber- attacks have become more prevalent and much harder to detect and defend against. Our network and storage applications may be vulnerable to cyber- attack, malicious intrusion, malfeasance, loss of data privacy or other significant disruption and may be subject to unauthorized access by hackers, employees, consultants or other service providers. In addition, hardware, software or applications we develop or procure from third parties may contain defects in design or manufacture or other problems that could unexpectedly compromise information security. Unauthorized parties may also

attempt to gain access to our systems or facilities through fraud, trickery or other forms of deceiving our employees, contractors and temporary staff. ~~30 There~~ **There** can be no assurance that we will not be subject to cybersecurity incidents that bypass our security measures, impact the integrity, availability or privacy of personal health information or other data subject to privacy laws or disrupt our information systems, devices or business, including our ability to deliver services to our customers. As a result, cybersecurity, physical security and the continued development and enhancement of our controls, processes and practices designed to protect our enterprise, information systems and data from attack, damage or unauthorized access remain a priority for us. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any cybersecurity vulnerabilities. ~~Additionally~~ **31 Additionally**, the U. S. may institute additional cybersecurity requirements especially for medical devices. For example, the data security requirements in the Food and Drug Omnibus Reform Act (“ FDORA ”), enacted in December 2022, that among other provisions, requires developers of certain “ cyber devices ” to design and implement plans to monitor, identify and address cybersecurity vulnerabilities of those devices and to submit those plans to FDA as part of every new 510 (k) or PMA for a cyber device. “ Cyber devices ” are defined as devices that include software, connect to the internet, and contain any technological features that could be vulnerable to cybersecurity threats. This provision entered into effect on March 29, 2023, and FDA has indicated that it expects sponsors of cyber devices to begin to comply with these requirements as of October 1, 2023. FDA has stated that failure to comply with these requirements will result in FDA denying approval of the cyber device application. We are subject to corporate governance and internal control requirements, and our costs related to compliance with, or our failure to comply with existing and future requirements could adversely affect our business. We must comply with corporate governance requirements under the Sarbanes- Oxley Act of 2002 and the Dodd – Frank Wall Street Reform and Consumer Protection Act of 2010, as well as additional rules and regulations currently in place and that may be subsequently adopted by the Securities and Exchange Commission, or the SEC, and the Public Company Accounting Oversight Board. These laws, rules, and regulations continue to evolve and may become increasingly stringent in the future. The financial cost of compliance with these laws, rules, and regulations is expected to remain substantial. We cannot assure you that we will be able to fully comply with these laws, rules, and regulations that address corporate governance, internal control reporting, and similar matters in the future. Failure to comply with these laws, rules and regulations could materially adversely affect our reputation, financial condition, and the value of our securities. 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 stock is currently listed on the 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 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. 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. ~~We have been informally advised by~~ **On September 27, 2024, we received a notification from the staff of NYSE American LLC (the “ NYSE American ”) stating that, given our current company is not in compliance with the minimum stockholders’ equity requirements and history of net losses, we may be subject to the equity standards set forth in Section Sections 1003 (a) (i), 1003 (a) (ii) and 1003 (a) (iii) of the NYSE American Company Guide (the “ Company Guide ”) requiring stockholders’ equity of \$ 2. 0 million or more if our company has reported losses from continuing operations and that/ or net losses in two of its three most recent fiscal years, \$ 4. 0 million or more if our company has reported losses from continuing operations and / or net losses in three of the four most recent fiscal years and \$ 6. 0 million or more if our company has reported losses from continuing operations and / or net losses in its five most recent fiscal years, respectively. As of June 30, 2024, we may had stockholders’ deficit of \$ 4. 6 million and we have had losses in the most recent five fiscal years ended September 30, 2023. We are now subject to the procedures and requirements of Section 1009 of the Company Guide. On October 27, 2024, we submitted a plan (the “ Plan ”) of actions it has taken or will take to regain compliance with the continued listing standards by March 27, 2026. If the NYSE American accepts the Plan, we will be able to continue its listing during the Plan period and will be subject to periodic reviews including quarterly monitoring for compliance with the Plan until it has regained compliance. If the Plan is not satisfy accepted by these-- the standards or the exemption criteria for NYSE American, delisting proceedings will commence. We may appeal a staff delisting determination in accordance with Section 1010 and Part 12 of these-- the standards Company Guide .** There is no assurance that we will be able to maintain compliance with the NYSE American continued listing rules and / or continue its listing on the NYSE American in the future. ~~If~~ **32 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; ~~31~~ · 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. The price of our common stock is volatile, which may cause investment losses for our stockholders. The market price of our common stock has been and is likely in the future to be volatile. Our common stock price may fluctuate in response to factors such as: · Announcements by us regarding liquidity, significant acquisitions, equity investments and divestitures, strategic relationships, addition or loss of significant customers and contracts, capital expenditure commitments and litigation; · Issuance of convertible or equity securities and related warrants for general or merger and acquisition purposes; · Issuance or repayment of debt, accounts payable or convertible debt for general or merger and acquisition purposes; · Sale of a significant number of shares of our common stock by stockholders; · General market and economic conditions; · Quarterly variations in our operating results; · Investor and public relation activities; · Announcements of technological innovations; · New product introductions by us or our competitors; · Competitive activities; · Low liquidity; and · Additions or departures of key personnel. ~~These 33~~ **These** broad market and industry factors may have a material adverse effect on the market price of our common stock, regardless of our actual operating performance. These factors could have a material adverse effect on our business, financial condition, and results of operations. ~~32~~ ~~The~~ ~~---~~ ~~The~~ sale of a significant number of our shares of common stock could depress the price of our common stock. As of September 30, ~~2023~~ **2024**, we had ~~80~~ **108**, ~~358~~ **097**, ~~463~~ **936** shares of common stock issued and outstanding. As of September 30, ~~2023~~ **2024**, there were options outstanding for the purchase of ~~14~~ **27**, ~~506~~, ~~158~~ **731** shares of our common stock (including unearned stock option grants totaling 3, 869, 825 shares related to performance targets), warrants for the purchase of ~~20~~ **49**, ~~866~~ **341**, ~~313~~ **861** shares of our common stock, ~~8~~, ~~108~~, ~~356~~ shares of our common stock issuable, collectively, upon the conversion of our Series C ~~and D~~ **Convertible Preferred Stock**, ~~and approximately 480, 436 shares of our common stock, collectively, reserved to pay accrued dividends on our Series C and Series D Convertible Preferred Stock~~, ~~In addition~~, ~~and approximately 3~~ ~~we currently have 9~~, ~~040~~ ~~020~~, ~~219~~ **264** shares of our common stock ~~are issuable upon conversion of convertible debentures of \$ 2~~, collectively ~~761~~, reserved to pay ~~accrued dividends on~~ ~~931~~ ~~and 3, 840, 000 shares of our common stock are issuable upon conversion of convertible debentures of \$ 1, 961, 575. Further, under the current terms of~~ our Series C ~~Convertible Preferred Stock~~ and Series D ~~Convertible Preferred Stock~~. ~~In addition, we currently have 9, 020, 264 shares of our common stock at the current price of \$ 0. 25 per share reserved and are issuable upon conversion of convertible debentures. Further, under the current terms of our Series C Convertible Preferred Stock and Series D Convertible Preferred Stock~~, and assuming no changes in the ownership thereof, going forward on a quarterly basis ~~we the Company~~ will accrete as a preferred dividend the value of approximately 160, 000 shares of common stock ~~Future accreted, which are issuable if such dividends become payable as will be settled by issuing additional shares of preferred stock which can, and such preferred stock is then be converted to into common stock~~. ~~We have the option to repay Lind in cash or common stock. Should we make our monthly payments in common stock, there may be a price adjustment~~. All of the foregoing shares could potentially dilute future earnings per share ~~but and~~ are excluded from the September 30, ~~2023~~ **2024**, calculation of **diluted** net loss per share because their impact is antidilutive. Significant shares of common stock are held by our principal stockholders, other company insiders and other large stockholders. As “ affiliates,” as defined under Rule 144 under the Securities Act, our principal stockholders, other of our insiders and other large stockholders may only sell their shares of common stock in the public market pursuant to an effective registration statement or in compliance with Rule 144. These options, warrants, convertible notes payable and convertible preferred stock could result in further dilution to common stockholders and may affect the market price of the common stock. Future capital raises or other issuances of equity or debt securities may dilute our existing stockholders’ ownership and / or have other adverse effects on our operations. Pursuant to our articles of incorporation, we are authorized to issue ~~200~~ **300**, 000, 000 shares of common stock. To the extent that common stock is available for issuance, subject to compliance with applicable stock exchange listing rules, our board of directors has the ability to issue additional shares of common stock in the future for such consideration as the board of directors may consider sufficient. The issuance of any additional shares could, among other things, result in substantial dilution of the percentage ownership of our stockholders at the time of issuance, result in substantial dilution of our earnings per share and adversely affect the prevailing market price for our common stock. Pursuant to our articles of incorporation, we are also authorized to issue 5, 000, 000 shares of blank check preferred stock of which 30, 000 shares have been designated as our Series C Convertible Preferred Stock and 20, 000 shares have been designated as our Series D Convertible Preferred Stock. Such preferred stock is senior to our common stock in terms of dividend priority and liquidation preference. Any preferred stock that we issue in the future may rank ahead of our common stock in terms of dividend priority or liquidation preference and may have greater voting rights than our common stock. In addition, such preferred stock may contain provisions allowing those shares to be converted into shares of common stock, which could dilute the value of our common stock to current stockholders and could adversely affect the market price, if any, of our common stock. In addition, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. Although we have no present intention to designate or issue any shares of our authorized blank check preferred stock, there can be no assurance that we will not do so in the future. As a result of the modifications of our Series C ~~Convertible Preferred Stock~~ and Series D ~~Convertible Preferred Stock~~ (see Description of Securities — Preferred Stock), assuming no changes in the amount of outstanding ~~Preferred~~ Series C **Convertible Preferred Stock** or Series D **Convertible Preferred Stock** ownership, going forward on a quarterly basis ~~we the Company~~ will accrete as a preferred dividend the value of approximately 160, 000 shares of common stock. Future accreted dividends will be settled by issuing additional shares of preferred stock which can then be converted to common stock. ~~In 34~~ **In** the future, we may also attempt to increase our capital resources by offering debt securities. These debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. Because our decision to issue securities or incur debt in our future offerings will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings and debt financing. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future. Thus, you will bear the risk of our future offerings reducing

the value of your shares and diluting your interest in us. ~~33The~~ **The** exercise prices of certain warrants, and the conversion prices of our outstanding convertible notes payable and our preferred stock may require further adjustment. If in the future, **if** we sell our common stock at a price below \$ 0. 25 per share, the conversion price of our **(i) the** outstanding shares of Series C Convertible Preferred Stock and Series-D Convertible Preferred Stock ; **(ii)** would adjust below \$ 0. 25 per share pursuant to their respective certificates of designation. In addition, the conversion price of the convertible promissory notes referred to above and the exercise price **convertible into 9, 020, 264 shares** of certain outstanding **our common stock; and (iii)** warrants to purchase 7, 684 ~~634~~, 381 shares of common stock would adjust below \$ 0. 25 per share pursuant to the documents governing such instruments. **We have the option to repay Lind** Warrants totaling 4, 439, 707 would adjust below \$ 1. 20 per share and warrants totaling 4, 484, 725 would adjust below \$ 2. 40 per share, in each case ~~cash~~ pursuant to **or common stock. Should we make our monthly payments in common stock, the there** documents governing such instruments **may be a price adjustment** . If our company were to dissolve or wind ~~up~~ **down** operations, holders of our common stock would not receive a liquidation preference **distribution** . If we were to wind ~~up~~ or dissolve our company and liquidate and distribute our assets, our common stockholders would share in our assets only after we satisfy any amounts we owe to our creditors and preferred equity holders. If our liquidation or dissolution were attributable to our inability to profitably operate our business, then it is likely that we would have material liabilities at the time of liquidation or dissolution. Accordingly, it is very unlikely that sufficient assets will remain available after the payment of our creditors and preferred equity holders to enable common stockholders to receive any liquidation distribution with respect to any common stock. **Provisions of the warrants could discourage an acquisition of us by a third party. Certain provisions of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting “ fundamental transactions ” unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of our outstanding warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.** We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business, and we do not anticipate paying any cash dividends on our capital stock in the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.