Risk Factors Comparison 2024-03-28 to 2023-03-09 Form: 10-K

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Risks Related to Our Financial Position and Capital Requirements We were formed in August 2011 and are thus subject to the risks associated with new businesses. We were formed in August 2011 as a new business and, commencing from 2015, we entered the commercialization stage of our technology. As such, this limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize the Dario Smart Diabetes Management Solution, achieve market acceptance of the Dario Smart Diabetes Management Solution, develop other products and respond to competition. We commenced a commercial launch of the free Dario Smart Diabetes Management application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario Smart Diabetes Management Solution (including the app and the Dario Blood Glucose Monitoring System) in selected jurisdictions in March 2014 with the goal of collecting customer feedback to refine our longer- term roll- out strategy and continued to scale up launch during 2014 in the United Kingdom, the Netherlands and New Zealand, in 2015 in Australia, Israel and Canada and in 2016 in the United States. These efforts have not generated sufficient revenues, and we will need to generate additional revenues over the next years. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties, inherent in a new business and the development and sale of new medical devices and related software applications. As a result, we may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues in the timeframes we project, if at all, and our inability to do so would materially and adversely impact our viability as a company. In addition, we still must establish many functions necessary to operate a business, including finalizing our managerial and administrative structure, continuing product and technology development, assessing and commencing our marketing activities, implementing financial systems and controls and personnel recruitment. Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their initial revenue generating stages, particularly those in the medical device and mobile health fields. In particular, potential investors should consider that there is a significant risk that we will not be able to: ● implement or execute our current business plan, or that our business plan is sound; ● maintain our management team and the Company' s board of directors (the " Board of Directors "); ● raise sufficient funds in the capital markets or otherwise to effectuate our business plan; ● determine that our technologies that we have developed are commercially viable; and / or ● attract, enter into or maintain contracts with, and retain customers. In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected. Given our limited revenue and lack of positive cash flow, we will need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate. According to our management' s estimates, based on our current cash on hand and further based on our budget and the assumption that initial commercial sales will commence during our anticipated timeframes, we believe that we will have sufficient resources to continue our activities through ~~2023~~ **2025** . Since we might be unable to generate sufficient revenue or cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. We may also need additional funding for developing products and services, increasing our sales and marketing capabilities, and promoting brand identity, as well as for working capital requirements and other operating and general corporate purposes. Moreover, the regulatory compliance arising out of being a publicly registered company has dramatically increased our costs. We currently have a credit facility in place with **Avenue Venture** ~~OrbiMed Royalty and Credit~~ Opportunities **Fund L. P. and Avenue Venture Opportunities Fund** ~~III~~ **II** , ~~LP~~ **L. P.** , of which $ ~~25~~ **30** million was made available in ~~June~~ **May** ~~2022~~ **2023** . However, there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected. If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity raising is the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for stockholders of our company. Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets be provided as a security for such debt. Debt financing would also be required to be repaid regardless of our operating results. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us. Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, we may not be able to achieve or maintain competitiveness, which could lead to the failure of our business and the loss of your investment. We have incurred significant losses since inception. As such, you cannot rely upon our historical operating performance to make an investment decision regarding our company. Since our inception, we have engaged primarily in research and development activities and in 2015 entered the commercialization stage. We have financed our operations primarily through private placements and public offerings of common stock and have incurred losses in each year since inception including net losses of $ **59, 427, 000 and $** 62, 193, 000 ~~and $ 76, 761, 000~~ in **2023 and** 2022 ~~and 2021~~ , respectively. Our accumulated deficit at December 31, ~~2022~~ **2023** was approximately $ ~~285~~ **349** , ~~850~~ **361** , 000. We do not know whether or when we will become profitable. Our ability to generate revenue and achieve profitability depends upon

our ability, alone or with others, to launch Dario in additional European countries, and elsewhere and manufacture, market and sell Dario where approved. We may be unable to achieve any or all of these goals. We may be subject to claims for rescission or damages in connection with certain sales of shares of our securities. In March 2016, the Securities and Exchange Commission declared effective a registration statement that we filed to cover 66, 667 shares 76, 667 warrants to purchase common stock, 76, 667 shares of common stock underlying such warrants, and underwriters' warrants to purchase up to 7, 172 shares of common stock. Sales of approximately 2, 778 shares of common stock, approximately 12, 778 shares of common stock underlying warrants and approximately 1, 278 shares of common stock underlying underwriters' warrants may not have been made in accordance with Section 5 of the Securities Act of 1933, as amended. Accordingly, the purchasers of those securities may have rescission rights or be entitled to damages. The amount of such liability, if any, is uncertain. In the event that we are required to make payments to investors as a result of these unregistered sales of securities, our liquidity could be negatively impacted. ~~33Risks~~ **57Risks** Related to Our BusinessThere is no assurance that our DarioEngage software platform will succeed or be adopted by healthcare providers. Our product offering consists of our DarioEngage software platform, where we digitally engage with Dario users, assist them in monitoring their chronic illnesses and provide them with coaching, support, digital communications, and real- time alerts, trends and pattern analysis. We expect that the DarioEngage software platform may be leveraged by our potential partners, such as clinics, health care service providers, employers, and payers for scalable monitoring of people with diabetes in a cost- effective manner, which we expect will open for us additional revenue streams. While we have begun to execute agreements with employers and health plans in the United States, we have not yet seen wide adoption of our platform. Therefore, the success of our DarioEngage software platform will depend entirely on our potential partners' adoption of the platform and we cannot assure you that our potential partners will do so, or, if adopted, that they will continue to use the platform continually and for an extended period of time. If we cannot encourage potential partners to utilize our DarioEngage software platform we may not succeed in marketing the product to our potential partners, the failure of which may materially and adversely affect our business and operating results. We only recently began commercializing Dario, and our success will depend on the acceptance of Dario in the healthcare market. Dario has been CE marked since 2013, enabling us to commercialize in 32 countries across Europe as well as in certain other countries worldwide. It was also approved by the regulatory authorities in Australia, New Zealand, Canada, Israel and South Africa, and most recently in December 2015, we received FDA clearance. As a result, we have a limited history of commercializing Dario and commenced selling Dario in the United States in 2016. We have limited experience engaging in commercial activities and limited established relationships with physicians and hospitals as well as third- party suppliers on whom we depend for the manufacture of our product. We are faced with the risk that the marketplace will not be receptive to Dario over competing products and that we will be unable to compete effectively. Factors that could affect our ability to establish Dario or any potential future product include: ● the development of products or devices which could result in a shift of customer preferences away from our device and services and significantly decrease revenue; ● the increased use of improved diabetes drugs that could encourage certain diabetics to test less often, resulting in less usage of a self- monitoring test device for certain types of diabetics; ● the challenges of developing (or acquiring externally- developed) technology solutions that are adequate and competitive in meeting the requirements of next-generation design challenges, including interoperability with various electronic health records; ● the significant number of current competitors in the BGMS market who have significantly greater brand recognition and more recognizable trademarks and who have established relationships with healthcare providers and payors; and ● intense competition to attract acquisition targets, which may make it more difficult for us to acquire companies or technologies at an acceptable price or at all. We cannot assure you that Dario or any future product will gain broad market acceptance. If the market for Dario or any future product fails to develop or develops more slowly than expected, or if any of the technology and standards supported by us do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected. ~~A pandemic, epidemic or outbreak of an infectious disease in the United States, Israel or elsewhere may adversely affect our business. A regional or global health pandemic, including COVID- 19, could severely affect our business, results of operations and financial condition. A regional or global health pandemic, depending upon its duration and severity, could have a material adverse effect on our business. For example, the COVID- 19 pandemic has had numerous effects on the 34global economy and governmental authorities around the world have implemented measures to reduce the spread of COVID- 19. In addition, the COVID- 19 pandemic has negatively impacted the global economy, disrupted consumer spending and global supply chains, and created significant volatility of financial markets. The COVID- 19 pandemic may also impact our supply chain partners, including third- party manufacturers, logistics providers and other vendors. Current vessel, container and other transportation shortages, labor shortages and port congestion globally have delayed and may continue to delay inventory orders and, in turn, it may delay the delivery of our products to customers. In addition, the impact of COVID- 19 on macroeconomic conditions may impact the proper functioning of financial and capital markets, foreign currency exchange rates, commodity prices, and interest rates. Even after the COVID- 19 global pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession that has occurred or may occur in the future. Following the COVID- 19 pandemic, many of our personnel continue to work remotely, it is possible that this could have a negative impact on the execution of our business plans and operations. If a natural disaster, power outage, connectivity issue, or other event occurred that impacted our employees' ability to work remotely, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The increase in remote working may also result in consumer privacy, IT security and fraud concerns as well as increase our exposure to potential wage and hour issues. We are unable to accurately predict the impact that COVID- 19 will have on our operations going forward due to uncertainties that will be dictated by the length of time that the pandemic and related disruptions continue, the impact of governmental regulations that might be imposed in response to the pandemic and overall changes in consumer behavior. The extent to which COVID- 19 will impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning~~

~~the severity of the coronavirus, including the actions to contain COVID- 19 or treat its impact, the efficacy and scale of the various vaccines currently deployed across the world, among others. Moreover, COVID- 19 has had indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID- 19 or any other epidemic continues to harm the global economy generally. To the extent the COVID- 19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this " Risk factors " section.~~ We cannot accurately predict the volume or timing of any future sales, making the timing of any revenues difficult to predict. We may be faced with lengthy customer evaluation and approval processes associated with Dario. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of Dario which may not result in revenue generation. We must also obtain regulatory approvals of Dario in certain ~~jurisdictions~~ **58jurisdictions** as well as approval for insurance reimbursement in order to initiate sales of Dario, each of which is subject to risk and potential delays, and neither of which may actually occur. As such, we cannot accurately predict the volume or timing of any future sales. If Dario fails to satisfy current or future customer requirements, we may be required to make significant expenditures to redesign the product, and we may have insufficient resources to do so. Dario is being designed to address an evolving marketplace and must comply with current and evolving customer requirements in order to gain market acceptance. There is a risk that Dario will not meet anticipated customer requirements or desires. If we are required to redesign our products to address customer demands or otherwise modify our business model, we may incur significant unanticipated expenses and losses, and we may be left with insufficient resources to engage in such activities. If we are unable to redesign our products, develop new products or modify our business model to meet customer desires or any other customer requirements that may emerge, our operating results would be materially adversely affected, and our business might fail. ~~35We~~ **We** expect to derive substantially all of our revenues from our principal technology, which leaves us subject to the risk of reliance on such technology. We expect to derive substantially all of our revenues from sales of products derived from our principal technology. Our initial product utilizing this technology is Dario. As such, any factor adversely affecting sales of Dario, including the product release cycles, regulatory issues, market acceptance, product competition, performance and reliability, reputation, price competition and economic and market conditions, would likely harm our operating results. We may be unable to develop other products utilizing our technology, which would likely lead to the failure of our business. Moreover, in spite of our efforts related to the registration of our technology, if patent protection is not available for our principal technology, the viability of Dario and any other products that may be derived from such technology would likely be adversely impacted to a significant degree, which would materially impair our prospects. We are dependent upon third- party manufacturers and suppliers making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business. We do not own or operate manufacturing facilities for clinical or commercial production of the Dario Blood Glucose Monitoring System, and we lack the resources and the capability to manufacture the Dario Blood Glucose Monitoring System on a commercial scale. Therefore, we rely on a limited number of suppliers who manufacture and assemble certain components of the Dario Blood Glucose Monitoring System. Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third- party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third- party suppliers also subjects us to other risks that could harm our business, including: ● we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours; ● third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us; ● we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms; ● our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the Dario Blood Glucose Monitoring System or cause delays in shipment; ● we may have difficulty locating and qualifying alternative suppliers; **59** ● switching components or suppliers may require product redesign and possibly submission to FDA, European Economic Area Notified Bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities; ● one or more of our sole- or single- source suppliers may be unwilling or unable to supply components of the Dario Blood Glucose Monitoring System; ● other customers may use fair or unfair negotiation tactics and / or pressures to impede our use of the supplier; ● the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and ● our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements. We may not be able to quickly establish additional or alternative suppliers if necessary, in part because we may need to undertake additional activities to establish such suppliers as required by the regulatory approval process. Any ~~36interruption~~ -- **interruption** or delay in obtaining products from our third- party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain single- source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available. We rely in part on a small group of third- party distributors to effectively distribute our products. We depend in part on medical device distributors for the marketing and selling of our products in certain territories in which we have launched product sales. We depend on these distributors' efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non- competing products that may limit the resources they dedicate to selling Dario. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell Dario, in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third- party distributors and training them in our technology and product offering requires

significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed. Failure in our online and digital marketing efforts could significantly impact our ability to generate sales. In several of our principal target markets, we utilize online and digital marketing in order to create awareness to Dario. Our management believes that using online advertisement through affiliate networks and a variety of other pay- for- performance methods will be superior for marketing and generating sales of Dario rather than utilizing traditional, expensive retail channels. However, there is a risk that our marketing strategy could fail. Because we plan to use non- traditional retail sales tools and to rely on healthcare providers to educate our customers about Dario, we cannot predict the level of success, if any, that we may achieve by marketing Dario via the internet. The failure of our online marketing efforts would significantly and negatively impact our ability to generate sales. ~~Our~~ **60Our** Dario ~~Smart Diabetes Management~~ application, which is a key to our business model, is available via Apple' s App Store and via Google' s Android platforms and maybe in the future via additional platforms. If we are unable to achieve or maintain a good relationship with each of Apple and Google or similar platforms, or if the Apple App Store or the Google Play Store or any other applicable platform were unavailable for any prolonged period of time, our business will suffer. A key component of the Dario ~~Smart Diabetes Management~~ Solution is an iPhone or Android application which includes tools to help diabetic patients manage their disease. This application is compatible with Apple' s iOS and with Google' s Android platforms and may in the future become compatible via additional platforms. If we are unable to make our Dario Smart Diabetes Management application compatible with these platforms, or if there is any deterioration in our relationship with either Apple or Google or others after our application is available, our business would be materially harmed. We are subject to each of Apple' s and Google' s standard terms and conditions for application developers, which govern the promotion, distribution, and operation of games and other applications on their respective storefronts. Each of Apple and Google has broad discretion to change its standard terms and conditions, including changes which could require us to pay to have our Dario ~~Smart Diabetes Management~~ application available for downloading. In addition, these standard terms and conditions can be vague and subject to changing interpretations by Apple or Google. We may not receive any advance warning of such changes. In addition, each of Apple and Google has the right to prohibit a developer from distributing its applications on its storefront if the developer violates its standard terms and conditions. In the event that either Apple or Google ever determines that we are in violation of its standard terms and conditions, including by a new interpretation, and prohibits us from distributing our Dario ~~Smart Diabetes~~ Management application on its storefront, it would materially harm our business. ~~37Additionally~~ **Additionally** , we will rely on the continued function of the Apple App Store and the Google Play Store as digital storefronts where our Dario ~~Smart Diabetes Management~~ application may be obtained. There have been occasions in the past when these digital storefronts were unavailable for short periods of time or where there have been issues with the in- app purchasing functionality within the storefront. In the event that either the Apple App Store or the Google Play Store is unavailable or if in- app purchasing functionality within the storefront is non- operational for a prolonged period of time, it would have a material adverse effect on the ability of our customers to secure the Dario Smart Diabetes Management application, which would materially harm our business. We rely upon Software- as- a- Services, or SAAS, technologies from third parties to operate our business, and interruptions or performance problems with these technologies may adversely affect our business, financial condition and results of operations. We rely on hosted SaaS applications from third parties in order to operate critical functions of our business, including platform delivery, enterprise resource planning, customer relationship management, billing, project management and accounting and financial reporting. If these services become unavailable due to extended outages, interruptions or because they are no longer available on commercially reasonable terms, our expenses could increase, our ability to manage finances could be interrupted and our processes for managing sales of our platform and products and supporting our customers could be impaired until equivalent services, if available, are identified, obtained and implemented, all of which could adversely affect our business, financial condition and results of operations. The SaaS pricing model is evolving and our failure to manage its evolution and demand could lead to lower than expected revenue and profit. We derive most of our revenue growth from subscription offerings and, specifically, SaaS offerings. This business model depends heavily on achieving economies of scale because the initial upfront investment is costly and the associated revenue is recognized on a ratable basis. If we fail to achieve appropriate economies of scale or if we fail to manage or anticipate the evolution and demand of the SaaS pricing model, then our business and operating results could be adversely affected. Our results of operations may fluctuate significantly due to the timing of our recognition of SaaS revenues. We may experience volatility in our reported revenues and operating results due to the differences in timing of revenue recognition between our SaaS offerings and our traditional on- premise software and hardware sales. SaaS revenues are generally recognized ratably over the life of the subscriptions. In contrast, revenue from our on- premise ~~software~~ **61software** and hardware sales is generally recognized in full at the time of delivery. Accordingly, the SaaS delivery model creates risks related to the timing of revenue recognition not associated with our traditional on- premise software delivery model and hardware sales. A portion of our SaaS revenue results from the recognition of deferred revenue relating to subscription agreements entered into during prior reporting periods. A decline in new or renewed subscriptions in any period may not be immediately reflected in our reported financial results for that period, but may result in a decline in our revenue in future reporting periods. If any of our assumptions about revenue from our SaaS delivery model prove incorrect, our actual results may vary materially from those anticipated, estimated, or projected. Any damage, failure or disruption of our SaaS network infrastructure or data centers could impair our ability to effectively provide our solution, harm our reputation and adversely affect our business. Our SaaS network infrastructure is a critical part of our business operations. Our clients access our

solution through standard web browsers, smart phones, tablets and other web- enabled devices and depend on us for fast and reliable access to our solution. We serve all of our clients from our data centers located in the United- States. Our SaaS network infrastructure and data centers are vulnerable to damage, failure and disruption. In the future, we may experience issues with our computing and communications infrastructure, or data centers caused by the following factors: • human error; • telecommunications failures or outages from third- party providers; ~~38~~ • computer viruses or cyber- attacks; • break- ins or other security breaches; • acts of terrorism, sabotage, intentional acts of vandalism or other misconduct; • tornadoes, fires, earthquakes, hurricanes, floods and other natural disasters; • power loss; and • other unforeseen interruptions or damages. If our SaaS network infrastructure or our clients' ability to access our solution is interrupted, client and employee data from recent transactions may be permanently lost, and we could be exposed to significant claims by clients, particularly if the access interruption is associated with problems in the timely delivery of funds payable to employees or tax authorities. Further, any adverse changes in service levels at our data centers resulting from damage to or failure of our data centers could result in disruptions in our services. Any significant instances of system downtime or performance problems at our data centers could negatively affect our reputation and ability to attract new clients, prevent us from gaining new or additional business from our current clients, or cause our current clients to terminate their use of our solution, any of which would adversely impact our revenues. In addition, if our network infrastructure and data centers fail to support increased capacity due to growth in our business, our clients may experience interruptions in the availability of our solution. Such interruptions may reduce our revenues, cause us to issue refunds to clients or adversely affect our retention of existing clients, any of which could have a negative impact on our business, operating results or financial condition. Our products are subject to technological changes which may impact their use. Our Dario Blood Glucose Monitoring System is currently designed to be plugged into the Lighting jack for Apple devices or the USB- C jack for other mobile devices. As a result, our products are subject to future technological changes to mobile devices that may occur in the future. If we are unable to modify our products to keep pace with such technological changes, it would have a material adverse effect the ability of our customers to use our products, which would materially harm our business. ~~As~~ **62As** we conduct business internationally, we are susceptible to risks associated with international relationships. Outside of the United States, we operate our business internationally, presently in Europe, Australia and Canada. The international operation of our business requires significant management attention, which could negatively affect our business if it diverts their attention from their other responsibilities. In the event that we are unable to manage the complications associated with international operations, our business prospects could be materially and adversely affected. In addition, as a result of the crisis in Ukraine, both the United States and the EU have implemented sanctions against certain Russian individuals and entities, as well with respect to Belarus, and may impact the economic and political stability in the EU. If the EU experiences economic and political instability as a result of these current tensions, our business, including revenue, profitability and cash flows, and operations could be adversely affected. In addition, doing business with foreign customers subjects us to additional risks that we do not generally face in the United States. These risks and uncertainties include: ● management, communication and integration problems resulting from cultural differences and geographic dispersion; ● localization of products and services, including translation of foreign languages; ● delivery, logistics and storage costs; ● longer accounts receivable payment cycles and difficulties in collecting accounts receivable; ● difficulties supporting international operations; ~~39~~ ● difficulties supporting customer services; ● changes in economic and political conditions; ● impact of trade protection measures; ● complying with import or export licensing requirements; ● exchange rate fluctuations; ● competition from companies with international operations, including large international competitors and entrenched local companies; ● potentially adverse tax consequences, including foreign tax systems and restrictions on the repatriation of earnings; ● maintaining and servicing computer hardware in distant locations; ● keeping current and complying with a wide variety of foreign laws and legal standards, including local labor laws; ● securing or maintaining protection for our intellectual property; and ● reduced or varied protection for intellectual property rights, including the ability to transfer such rights to third parties, in some countries. The occurrence of any or all of these risks could adversely affect our international business and, consequently, our results of operations and financial condition. ~~We~~ **63We** expect to be exposed to fluctuations in currency exchange rates, which could adversely affect our results of operations. Because we expect to conduct a material portion of our business outside of the United States but report our financial results in U. S. Dollars, we face exposure to adverse movements in currency exchange rates. Our foreign operations will be exposed to foreign exchange rate fluctuations as the financial results are translated from the local currency into U. S. Dollars upon consolidation. Specifically, the U. S. Dollar cost of our operations in Israel is influenced by any movements in the currency exchange rate of the New Israeli Shekel (NIS). Such movements in the currency exchange rate may have a negative effect on our financial results. If the U. S. Dollar weakens against foreign currencies, the translation of these foreign currencies denominated transactions will result in increased revenue, operating expenses and net income. Similarly, if the U. S. Dollar strengthens against foreign currencies, the translation of these foreign currencies denominated transactions will result in decreased revenue, operating expenses and net income. As exchange rates vary, sales and other operating results, when translated, may differ materially from our or the capital market' s expectations. Non- U. S. governments often impose strict price controls, which may adversely affect our future profitability. We intend to seek approval to market Dario and any future product in both the U. S. and in non- U. S. jurisdictions. If we obtain approval in one or more non- U. S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our products. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing may be subject to governmental control under certain circumstances. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of our product to other available products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

~~40Our~~ -- **Our** Dario ~~Smart Diabetes Management~~ Solution and associated business processes may contain undetected errors, which could limit our ability to provide our services and diminish the attractiveness of our service offerings. The Dario ~~Smart Diabetes~~ Management Solution may contain undetected errors, defects or bugs. As a result, our customers or end users may discover errors or defects in our products, software or the systems we design, or the products or systems incorporating our designs and intellectual property may not operate as expected. We may discover significant errors or defects in the future that we may not be able to fix. Our inability to fix any of those errors could limit our ability to provide our products, impair the reputation of our brand and diminish the attractiveness of our product offerings to our customers. In addition, we may utilize third- party technology or components in our products, and we rely on those third parties to provide support services to us. Failure of those third parties to provide necessary support services could materially adversely impact our business. Our future performance will depend on the continued engagement of key members of our management team. Our future performance depends to a large extent on the continued services of members of our current management including, in particular, Erez Raphael, our Chief Executive Officer and a member of our Board of Directors and Zvi Ben David, our Chief Financial Officer, Treasurer and Secretary, and Richard Anderson, our President and General Manager for North America. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations, and prospects. If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully. We believe that our management team must be able to act decisively to apply and adapt our business model in the rapidly changing markets in which we will compete. In addition, we will rely upon technical and scientific employees or third- party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we ~~currently~~ **64currently** expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high- quality personnel is intense and we cannot assure that we will be able to recruit and retain such personnel. We may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively. We may not generate the expected benefits of our acquisition of **Twill** ~~Upright and PsyInnovations~~, and the integration of ~~these~~ **this** ~~businesses~~ -- **business** could disrupt our ongoing business, distract our management and increase our expenses. Through our acquisitions of **Twill** ~~Upright and PsyInnovations~~, we expanded our product offering to include **digital- first** solutions ~~for MSK as well as behavioral conditions~~ **with a mission to improve users mental and physical health**. We believe that the successful integration of ~~Upright and PsyInnovations~~ **Twill' s** ~~businesses~~ -- **business** into our operations is important for our future financial performance. This will require that we integrate more closely the companies' product offerings and research and development capabilities, retain key employees, assimilate diverse corporate cultures, further integrate management information systems and consolidate the acquired operations, each of which could pose significant challenges. The difficulty of combining **Twill** ~~Upright and PsyInnovations~~ with our company may be increased by the need to integrate personnel, and changes effected in the combination may cause key employees to leave. It is possible that the integration process could take longer than anticipated and could result in the loss of valuable employees, additional and unforeseen expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisitions. The diversion of the attention of management created by the integration process, any disruptions or other difficulties encountered in the integration process, and unforeseen liabilities or unanticipated problems with the acquired businesses could have a material adverse effect on our business, operating results and financial condition. There can be no assurance that these acquisitions will provide the ~~41benefits~~ -- **benefits** we expect or that we will be able to integrate and develop the operations of **Twill** ~~Upright and PsyInnovations~~ successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition. Risks Related to Product Development and Regulatory ApprovalThe regulatory clearance process which we must navigate is expensive, time- consuming, and uncertain and may prevent us from obtaining clearance for the commercialization of Dario or our any future product. We are not permitted to market Dario **in any jurisdiction** until we receive **marketing authorization from the applicable** regulatory ~~clearance~~ **authority**. To date, we have received regulatory ~~clearance~~ **authorization** in Australia, Canada, Israel, Italy, the Netherlands, New Zealand, the United Kingdom, and the United States. The research, design, testing, manufacturing, labeling, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and non- U. S. regulatory authorities, which regulations differ from country to country **. In particular, marketing authorization requirements vary between countries and can involve additional product testing and additional administrative review periods. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA clearance or other marketing authorization. Obtaining authorization for a device in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory authorization in one country may negatively impact the regulatory process in others**. There can be no assurance that even after such time and expenditures, we will be able to obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. In addition, during the regulatory process, other companies may develop other technologies with the same intended use as our products. **Significant delays in receiving, or the failure to receive, marketing authorization for our new products would have an adverse effect on our ability to expand our business.** We are also subject to numerous post- marketing regulatory requirements, which include **quality management system regulations,** labeling regulations and medical device reporting regulations **. Specifically** , ~~which may~~ **the medical device reporting regulations** require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that

adversely affects us **, or various regulatory authorities may take other actions that could prevent or delay authorization of our products under development or impact our ability to gain authorization for modifications to our currently approved or cleared products in a timely manner** . If we fail to comply ~~with~~ **65with** present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by regulatory agencies, which may include, among others, any of the following sanctions: ● 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; ● imposing operating restrictions, suspension or shutdown of production; ● refusing our requests for ~~510 (k) clearance or pre- market~~ **marketing** ~~approval~~ **authorization** of new products, new intended uses or modifications to Dario or future products; ● ~~rescinding 510 (k) clearance or~~ suspending or withdrawing ~~pre- market~~ **marketing** ~~approvals~~ **authorizations** that have already been granted; and ● criminal prosecution. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations. ~~In addition, on September 23, 2013, the FDA issued final guidance (which we refer to herein as the Guidance) for developers of mobile medical applications, or apps, which are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. The Guidance outlines the FDA' s tailored approach to mobile apps. The FDA plans to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Food, Drug and Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. The FDA plans to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended.~~ We ~~anticipate that the Dario Smart Diabetes Management application will be subject to FDA regulation as a " mobile medical app. " 42We~~ have conducted limited clinical ~~studies~~ **trials** of Dario. Clinical and ~~pre- clinical~~ **nonclinical** data is susceptible to varying interpretations, which could delay, limit or prevent additional regulatory clearances. To date, we have conducted limited clinical ~~studies~~ **trials** on Dario. There can be no assurance that we will successfully complete additional clinical ~~studies~~ **trials** necessary to receive additional regulatory approvals in certain jurisdictions. While studies conducted by us have produced results we believe to be encouraging and indicative of the potential efficacy of Dario, data already obtained, or in the future obtained, from ~~pre-~~ **nonclinical studies and** clinical **trials** ~~studies and clinical studies~~ do not necessarily predict the results that will be obtained from later ~~pre-~~ **nonclinical studies or** clinical **trials** ~~studies and clinical studies~~ . Moreover, ~~pre- clinical~~ **nonclinical** and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical ~~studies~~ **trials** , even after promising results in earlier studies. ~~The failure~~ **If we fail** to adequately demonstrate the safety and effectiveness of **a** ~~an intended~~ product **candidate** under development **, it** could delay or prevent regulatory ~~clearance~~ **authorization** of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received CE mark and FDA clearance of Dario, there can be no assurance that we will be able to receive ~~approval~~ **authorization** for other potential applications of our principal technology, or that we will receive regulatory ~~clearances~~ **authorizations** from other targeted regions or countries. We may be unable to complete required clinical trials, or we may experience significant delays in completing such clinical trials, which could significantly delay our targeted product launch timeframe and impair our viability and business plan. The completion of any future clinical trials for Dario or other trials that we may be required to undertake in the future could be delayed, suspended or terminated for several reasons, including: ● **delay** ~~our~~ **or failure in reaching agreement with regulatory authorities on a trial design that we are able to execute; ● delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a product candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial; ● delay in reaching, or failure to reach, agreement on acceptable terms with prospective contract research organizations and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ●** failure or inability to conduct the clinical trial in accordance with regulatory requirements; **66** ● sites participating in the trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial; ● **failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by a regulatory authority due to observed safety findings or other reasons; ●** delays that we may experience in **patient** enrollment ~~,~~ or completion of certain trials ~~, as a result of COVID- 19~~ ; ● patients may not enroll in, remain in or complete, the clinical trial at the rates we expect; and ● clinical investigators may not perform our clinical trial on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices. ~~If our~~ **In addition, the U. S. Congress recently amended the FDCA to require sponsors of any pivotal study to support marketing authorization of a medical device to design and submit a diversity action plan for such** clinical trial **. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. For any future pivotal studies involving our device products or product candidates, we must submit a diversity action plan to the FDA by the time a pivotal study protocol** is **submitted to the agency for review, as applicable, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future pivotal study for our products or product candidates or what specific information FDA will expect in such plan. However, initiation of such studies may be delayed if the FDA objects to a proposed diversity action plans for any future pivotal study of our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan. If our ongoing or future clinical trials are** delayed it will take us longer to further commercialize Dario and generate additional revenues. Moreover, our development costs will increase if we have material delays in our clinical trial or if we need to perform more or larger clinical trials than planned. We may be faced with similar risks in connection with future trials we conduct. See " Business- Clinical Trials " for a description of our clinical trials performed to date. If we or our manufacturers fail to comply with the FDA' s Quality System

Regulation or any applicable state equivalent, our operations could be interrupted, and our operating results could suffer. We, our manufacturers and suppliers must, unless specifically exempt by regulation, follow the FDA' s ~~Quality System Regulation (“~~ QSR **, as well as similar** ~~”) and are also subject to the~~ regulations of foreign jurisdictions regarding the manufacturing process. **In addition, we and certain of our manufacturers and suppliers are subject to inspection by regulatory authorities to assess regulatory compliance from time to time and may not be able to demonstrate adequate compliance with applicable regulations.** If **we,** our affiliates, our manufacturers or suppliers are found to be in significant non- compliance or fail to take satisfactory corrective action in response to adverse ~~QSR~~ inspectional findings, the FDA **or other applicable regulatory authority** could take enforcement actions against us and our manufacturers which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. Accordingly, our operating results could suffer. We are subject to the risk of reliance on third parties to conduct our clinical trial work. We depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the number of resources, including the time that they devote to products that we develop. **Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators or contract research organizations does not relieve us of our regulatory responsibilities.** If **the** independent investigators **or contract research organizations** fail to devote sufficient resources to our clinical ~~43~~**trials** ~~--~~ **trials** , or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA and other regulatory bodies around the world require that we comply with **GCP** standards ~~, commonly referred to as good clinical practice,~~ for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research ~~organizations~~ **67organizations** fail to comply with **GCP** ~~good clinical practice~~ , the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations could adversely affect the clinical development of our product candidates and harm our business. Moreover, we intend to ~~have~~ **conduct** several clinical trials in order to support our marketing efforts and business development purposes. Such clinical trials will be conducted by third parties as well. Failure of such clinical trials to meet their primary endpoints could adversely affect our marketing efforts. ~~Legislative~~ **If any of our relationships with the investigators or contract research organizations conducting our ongoing or future trials terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Entering into arrangements with alternative contract research organizations, trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new contract research organization, trial investigator or other third party begins work. If third parties 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 are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing authorization for or successfully commercialize our product candidates. Because we have relied on third parties to conduct our clinical trials, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third- party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. To the extent we are unable to identify and successfully manage the performance of third- party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our contract research organizations and investigators, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Recent initiatives by the FDA to enhance and modernize various regulatory pathways for device products and its overall approach to safety and innovation in the medical technology industry creates the possibility of changing product development costs, requirements, and other factors and additional uncertainty for our future products and business. Regulatory requirements may change in the future in a way that adversely affects us. Any change in the laws or regulations that govern the clearance and approval processes or the post- market compliance requirements relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. 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, we may lose any marketing authorization that we otherwise may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. In recent years, the U. S. government, including the FDA and other government agencies, have been focusing on the cybersecurity risks associated with certain medical devices and encouraging device manufacturers to take a more proactive approach to assessing the cybersecurity risks of their devices both during development and on a periodic basis after the devices are in commercial distribution. For example, in December 2022, the Congress enacted the Consolidated Appropriations Act for 2023, an omnibus appropriations bill, which included amendments to the FDCA under the Food and Drug Omnibus Reform Act of 2022 (“ FDORA ”). In addition to the requirement that sponsors of pivotal trials submit diversity action plans for pivotal trials (see “ Government Regulation — Clinical Trials ”), FDORA included new requirements for cyber devices, defined as any medical device that is or includes software that is validated, installed, or authorized by the manufacturer;**

can connect to the internet; and may be vulnerable to cybersecurity threats. Under the FDORA amendments to the FDCA, any application for marketing authorization of the cyber device must include a software bill of materials and a cybersecurity plan describing the methods by which the manufacturer will monitor, identify and address cybersecurity vulnerabilities. Any failure by a cyber device manufacturer to comply with applicable cybersecurity requirements is considered a violation of the FDCA and will subject the manufacturer to enforcement actions and possibly legal sanctions. Further regulatory efforts by the FDA or other federal or state regulatory authorities could 68lead to new, onerous cybersecurity requirements in the future as well as additional product liability or other litigation risks if any of our products is considered to be susceptible to third- party tampering. In addition, Congress passed the 21st Century Cures Act in December 2016, which made multiple changes to the FDA' s rules for medical devices as well as for clinical trials, and the Medical Device User Fee reauthorization package in September 2022, which affects medical device regulation both pre- and post- approval and could have certain impacts on our business. In recent years, the FDA has also considered a series of efforts to modernize and streamline the 510 (k) notification and regulatory review process and monitoring post- market safety. For example, as of October 2023, all 510 (k) applications (unless specifically exempted) must be submitted to the FDA electronically using the electronic submission template and resource, or eSTAR, and the Center for Devices and Radiological Health (CDRH) Portal. Further changes in the FDA 510 (k) process could make clearance more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on our ability to obtain and maintain clearance for our products. Furthermore, the FDA issued a Final Rule on February 2, 2024 describing amendments to harmonize the QSR with ISO 13485: 2016, which will become effective on February 2, 2026. The harmonization process is not expected to have a significant impact on the quality system compliance operations of device manufacturers because most requirements described in the QSR correspond to requirements set forth in ISO 13485: 2016. However, device manufacturers will likely need to revise certain quality system procedures to ensure compliance with the harmonized regulations and any failure by us or our third- party manufacturers to make such revisions or adapt to the harmonized regulations, once they become effective, may result in observations of noncompliance during facility inspections by the FDA or comparable regulatory authorities. Broad- based domestic and international government initiatives to reduce spending, particularly those related to healthcare costs, may reduce reimbursement rates for medical procedures, or make it more difficult for customers to purchase our products and services, all of which could adversely affect our business. Healthcare reforms **, changes in healthcare policies and changes** to **third- party coverage and reimbursements, including legislation enacted reforming** the ~~United States~~ **U. S.** healthcare system **and both domestic and foreign healthcare cost containment legislation, and any future changes to such legislation,** may ~~adversely~~ affect **demand** ~~our revenues and business. From time to time, legislative reform measures are proposed or adopted that would impact healthcare expenditures~~ for ~~medical~~ **our products and** services ~~, including the medical devices used to provide those services~~ **and may have a material adverse effect on our financial condition and results of operations**. **Reforms implemented under** ~~For example, in March 2010, U. S. President Barack Obama signed~~ the Patient Protection and Affordable Care Act, as amended by the Health Care and Education **Affordability** Reconciliation Act, ~~collectively referred to (the " ACA ") in the United States,~~ as **well as state- level** ~~the Affordable Care Act. The Affordable Care Act made a number of substantial changes in the way health~~ **healthcare** ~~care is financed by both governmental~~ **reform proposals, could reduce medical procedure volumes** and **impact** ~~private insurers and the way that Medicare providers are reimbursed. Among other~~ **the demand for** ~~things, the Affordable Care Act requires certain~~ medical device ~~manufacturers and importers to pay~~ **products or the prices at which we** ~~an~~ **can sell products** ~~excise tax equal to 2~~. ~~3 %~~ **The impact** of ~~the~~ **healthcare reform legislation, and practices including** price **regulation, competitive pricing, comparative effectiveness of therapies, technology assessments, and managed care arrangements are uncertain. There can be no assurance that current levels of reimbursement will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third parties will not adversely affect the demand** for **our products and services or our ability to sell products and provide services on a profitable basis. The adoption of significant changes to the healthcare system in the United States, the EEA or other jurisdictions in** which **we may market our products and services, could limit the prices we are able to charge for our products and services or the amounts of reimbursement available for our products and services, could limit the acceptance and availability of our products and services, reduce medical procedure volumes and increase operational and other costs. Legislative and regulatory changes under the ACA remain possible, but it is unknown what form any** such **changes or any law would take, and how or whether it may affect the** medical ~~devices~~ **device** ~~are sold, beginning January 1, 2013~~ **industry as a whole or our business in the future**. In addition **to the ACA**, ~~other~~ **there** ~~legislative changes~~ have been ~~proposed~~ and **will likely continue to be** ~~adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among~~ other **federal and state changes that affect** ~~things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, triggering the legislation' s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2. 0 % per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these~~ **the** ~~sequestration provisions~~ **provision** ~~of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2 % Medicare payment reductions went into effect. The Bipartisan Budget Act of 2013, enacted on December 26, 2013, extends these cuts to 2023. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2014, Congress passed an omnibus funding bill (the Consolidated and Further Continuing Appropriations Act, 2015) and a tax**

~~extenders bill, both of which may negatively impact coverage and reimbursement~~ of healthcare ~~items~~ **goods** and services ~~. We expect that additional state and federal healthcare reform measures will be adopted~~ in ~~the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. For example, former U. S. President Donald Trump publicly indicated an intent to lower healthcare costs through various potential initiatives. In addition, former President Trump and other~~ -- **the United States** ~~U. S. lawmakers have made statements about potentially repealing and / or replacing the Affordable Care Act, although specific legislation for such repeal or replacement has not yet been introduced~~ . While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products **and services** are paid for and reimbursed by government and private payers **,** our business could be adversely impacted. **Moreover, complying with any new legislation or reversing changes implemented under the ACA could be time- intensive and expensive, resulting in a material adverse effect on the business. In addition, there has been heightened governmental scrutiny, including increasing legislative and enforcement interest, in recent years over the manner in which manufacturers set prices for their marketed healthcare products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring 69more transparency to healthcare product pricing, review the relationship between pricing and manufacturer patient programs and reform** ~~Government~~ **government program reimbursement methodologies for** ~~and private sector initiatives to limit the growth of health~~ **healthcare** ~~care costs~~ **products. Individual states in the United States have also become increasingly active in implementing regulations designed to control healthcare product pricing** , including price **or patient** ~~regulation, competitive pricing, coverage and payment policies, comparative effectiveness reviews of therapies, technology assessments, and managed- care arrangements, are continuing. Government programs, including Medicare and Medicaid, private health care insurance and managed- care plans have attempted to control costs by limiting the amount of~~ reimbursement **constraints** ~~they will pay for particular procedures or treatments~~ , **discounts** ~~tying reimbursement to outcomes~~ , **restrictions on certain product access** and **marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation of healthcare products from** other **countries** ~~mechanisms designed to constrain utilization and contain costs, including delivery reforms such as expanded bundling of services~~ . **Additionally** ~~Hospitals are also seeking to reduce costs through a variety of mechanisms~~ , ~~which may increase price sensitivity among customers for our products, and adversely affect sales, pricing, and utilization of our products. Some~~ third- party payors ~~must also approve coverage for new or innovative devices or therapies before they will reimburse health~~ **and governmental authorities have become increasingly interested in reference pricing systems and publication of discounts and list prices. We** ~~care~~ - **are** ~~44providers who~~ **subject to federal, state and foreign laws prohibiting " kickbacks " and false or fraudulent claims, and other fraud and abuse laws, transparency laws, and other healthcare laws and regulations, which, if violated, could subject** ~~use~~ - **us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business. Our relationships with customers and third- party payors are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs and certain customer and product support programs, we may have with hospitals, physicians or other purchasers of** medical devices **. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims** ~~or~~ **for** ~~therapies. We cannot predict~~ **payment from Medicare, Medicaid, or** ~~the~~ **other third** ~~potential impact of cost~~ - ~~containment trends on future operating results~~ **party payors that are false or fraudulent, or are for items or services that were not provided as claimed** . ~~We may be subject to~~ **These laws include, among others, the** federal ~~, state and foreign healthcare fraud and abuse laws and regulations. Many federal, state and foreign healthcare laws and regulations apply to the BGMS business and medical devices. We may be subject to certain federal and state regulations, including the federal healthcare programs'~~ Anti- Kickback **Statute, the federal civil False Claims Act, other federal healthcare false statement and fraud statutes, the Open Payments program under the Physician Payments Sunshine Act, the Civil Monetary Penalties** Law, **and analogous fraud and abuse and transparency laws in most states, as described in " Government Regulation — Other U. S. Healthcare Laws and Regulations. " Although** the federal **laws generally apply only to products or services for which payment may be made by a government healthcare program, state laws often apply regardless of whether federal funds may be involved. While we believe and strive to ensure that our business arrangements with third parties and other activities and programs comply with all applicable laws, these laws are complex, and our activities may be found not to be compliant with one or more of these laws, which may result in significant civil, criminal and / or administrative penalties, fines, damages and exclusion from participation in government healthcare programs. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the Office of Inspector General for the U. S. Department of** Health ~~Insurance Portability~~ and ~~Accountability Act of 1996~~ **Human Services (HHS- OIG)** , **CMS,** and ~~other~~ -- **the Department of Justice, or may be subject to whistleblower lawsuits under** federal and state false claims laws ~~. The medical device industry has been under heightened scrutiny as the subject of government investigations and enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of such governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment of our operations. All of these penalties could adversely affect our ability to operate our business and our financial results~~ . Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of Dario or our potential future products. These suits could result in expensive and time-

consuming litigation, payment of substantial damages, and an increase in our insurance rates. If Dario or any of our future products are defectively designed or manufactured **,** contain defective components **,** or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our device or failing to adhere to the operating guidelines or the device producing inaccurate meter readings could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizable damage awards against us. While we maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations. ~~If~~ **70If** we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business. Part of our business plan includes the storage and potential monetization of medical data of users of Dario. There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U. S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (which we refer to as HIPAA). These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We may face difficulties in holding such information in compliance with applicable law. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations. **In addition to data protection laws passed by the U. S. federal government, many U. S. states and foreign countries have implemented their own data protection laws, some of which may apply simultaneously and conflict with U. S. federal law. Many of these laws create consumer rights including the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request that a company delete personal information collected, the right to opt- out of the sale of personal information and the right to non- discrimination in terms of price or service when a consumer exercises a privacy right. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance. In particular, data protection, privacy, and other laws and regulations adopted in jurisdictions outside of the United States can be more restrictive than corresponding U. S. laws and regulations. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and / or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to customers, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the GDPR imposes requirements in the European Economic Area relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third- party processors. The GDPR also imposes restrictions on the transfer of personal data from the European Economic Area to third countries like the United States, although the European Commission recently adopted an adequacy decision for the EU- U. S. Data Privacy Framework. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties and amounts could be significant. Our employees, independent contractors, consultants, manufacturers and suppliers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and suppliers may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. 71Although we have a code of business conduct and ethics, it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other**

sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations. Risks Related to Our Intellectual PropertyThe failure to obtain or maintain patents, licensing agreements and other intellectual property could materially impact our ability to compete effectively. In order for our business to be viable and to compete effectively, we need to develop and maintain, and we will heavily rely on, our proprietary position with respect to our technologies and intellectual property. We filed a Patent Cooperation Treaty (or PCT) application for a " Fluids Testing Apparatus and Methods of Use " in May 2011 which incorporates two U. S. provisional applications submitted in the preceding year. The PCT covers the specific processes ~~45related --~~ **related** to blood glucose level measurement as well as more general methods of rapid tests of body fluids and has subsequently been converted into several national phase patent applications. We have also filed patent applications for other aspects of the Dario Blood Glucose Monitoring Solution. We have also obtained numerous Web domains. However, to date, we have only been issued four patents (three of which were issued in the United States) relating to how the Dario Blood Glucose Monitoring System draws power from and transmits data to a smartphone via the audio jack port. None of our other patents have been granted by a patent office. In addition, there are significant risks associated with our actual or proposed intellectual property. The risks and uncertainties that we face with respect to our pending patent and other proprietary rights principally include the following: ● pending patent applications we have filed or will file may not result in issued patents or may take longer than we expect to result in issued patents; ● we may be subject to interference proceedings; ● we may be subject to opposition proceedings in foreign countries; ● any patents that are issued to us may not provide meaningful protection; ● we may not be able to develop additional proprietary technologies that are patentable; ● other companies may challenge patents licensed or issued to us; ● other companies may have independently developed and / or patented (or may in the future independently develop and patent) similar or alternative technologies, or duplicate our technologies; ● other companies may design their technologies around technologies we have licensed or developed; and ● enforcement of patents is complex, uncertain and very expensive. We cannot be certain that patents will be issued as a result of any of our pending or future applications, or that any of our patents, once issued, will provide us with adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since ~~the~~ **72the** publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions. It is also possible that others may have or may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so. Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others. We may face significant expense and liability as a result of litigation or other proceedings relating to patents and intellectual property rights of others. In the event that another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome was favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology, substantially modify it or to license rights from prevailing third parties. The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial, especially given our early stage of development. Our ability to enforce our patent protection could be limited by our financial resources and may be subject to lengthy delays. A third party may ~~46claim --~~ **claim** that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume significant time and other resources. There is a risk that a court will decide that we are infringing the third party' s patents and will order us to stop the activities claimed by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents. Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our services, technologies or other matters. We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on devices in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in

the United States. Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to medical devices and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third ~~parties~~ **73parties** to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us. Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non- disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to enter into these types of agreements with our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our technology. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know- how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that: ~~47~~ ● these agreements may be breached; ● these agreements may not provide adequate remedies for the applicable type of breach; ● our proprietary know- how will otherwise become known; or ● our competitors will independently develop similar technology or proprietary information. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, the Israeli Supreme Court ruled in 2012 that an employee who receives a patent or contributes to an invention during his employment may be allowed to seek compensation for such contributions from his or her employer, even if the employee' s contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes an employee' s right for royalties and compensation, does not rule out the right of the employee to claim their right for royalties. As a result, it is unclear whether and, if so, to what extent our employees may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of our employees successfully claim for compensation for their work in developing our intellectual property, which in turn could impact our future profitability. ~~Risks~~ **74Risks** Related to Our IndustryWe face intense competition in the digital support solution and the self- monitoring of blood glucose market, and as a result we may be unable to effectively compete in our industry. In recent years, a number of digitally supported solutions have emerged to manage diabetes and other chronic conditions. Competitors are developing new technologies rapidly and, in some cases, are also expanding to manage other chronic conditions. With our first product, Dario, we compete directly and primarily with large pharmaceutical and medical device companies such as Abbott Laboratories, Asensia (formerly Bayer Diabetes Care), Johnson & Johnson LifeScan, Roche Diagnostics and Sanofi. The first four of these companies has a combined majority market share of the BGMS business and strong research and development capacity for next-generation products. Their dominant market position since the late 1990s, and significant control over the market could significantly limit our ability to introduce Dario or effectively market and generate sales of the product. We will also compete with numerous second- tier and third- tier competitors. In addition, we only recently transformed our business to primarily focus on the sale of our digital support solution, which joins a crowded field of competitors such as Amazon, Apple and Google. Our competitors vary by intervention (devices, applications, coaching and analytics), by channel (health plan, pharma, provider, employer) and by condition (including, for example, diabetes, MSK, blood hypertension, and others). Certain of our competitors offer this integrated approach in varying degrees, including, among others, Hinge Health, Inc., Livongo Health Inc. (acquired by Teladoc Health Inc.), Omada Health, Inc., Vida Health, Inc., Virta Health Corp., Informed Data Systems Inc. (OneDrop), Glooko, Inc., and OnDuo LLC. ~~We only recently commenced sales of our products, and most of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is~~

~~a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business and the loss of your investment. 48Competition~~ -- **Competition** in the digitally supported solutions market and BGMS market is extremely intense, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for Dario and potential future devices incorporating our principal technology and offer better strategic concepts, technical solutions, prices and response time, or a combination of these factors, than those of other competitors. If our competitors offer significant discounts on certain products, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad- based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues, if established, to decline. Some of our competitors may bundle certain software products offering competing applications for diabetes management at low prices for promotional purposes or as a long- term pricing strategy. These practices could significantly reduce demand for Dario or potential future products or constrain prices we can charge. Moreover, if our competitors develop and commercialize products that are more effective or desirable than Dario or the other products that we may develop, we may not convince our customers to use our products. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results. If we fail to respond quickly to technological developments our products may become uncompetitive and obsolete. The BGMS market and other markets in which we plan to compete experience rapid technological developments, changes in industry standards, changes in customer requirements and frequent new product introductions and improvements. If we are unable to respond quickly to these developments, we may lose competitive position, and Dario or any other device or technology may become uncompetitive or obsolete, causing revenues and operating results to suffer. In order to compete, we must develop or acquire new devices and improve our existing device on a schedule that keeps pace with technological developments and the requirements for products addressing a broad spectrum and designers and designer expertise in our industries. We must also be able to support a range of changing customer preferences. For instance, as non- invasive technologies become more readily available in the market, we may be required to adopt our platform to accommodate the use of non- invasive or continuous blood glucose sensors. We cannot guarantee that we will be successful in any manner in these efforts. If third- party payors do not provide adequate coverage and reimbursement for the use of our products and services, our revenue will be negatively impacted. In the United States and other jurisdictions such as Germany and England, we expect that our products and services should generally be available for full or partial patient reimbursement by third- party payers. Our success in ~~marketing~~ **75marketing** our services depend and will depend in large part on whether U. S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products and services. In the United States, we expect to derive nearly all our sales from sales directly to consumers as well as retail pharmacy and DME distributors who typically bill various third- party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, health plans and other healthcare- related organizations, to cover all or a portion of the costs and fees associated with our products and services and bill patients for any applicable deductibles or co- payments. Access to adequate coverage and reimbursement for Center for Medicare and Medicaid Services (CMS) procedures using our products and services (and our other products and services in development) by third- party payors is essential to the acceptance of our products by our customers. Third- party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third- party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained. ~~49Reimbursement~~ -- **Reimbursement** systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country- by- country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government- managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government- managed systems. If sufficient coverage and reimbursement are not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected. Risks Related to Our Operations in IsraelPotential political, economic and military instability in the State of Israel, where our management team and our research and development facilities are located, may adversely affect our results of operations. Our operating subsidiary, along with our management team and our research and development facilities, is located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. The hostilities involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Our offices, located in Caesarea, Israel, are within the range of the missiles and rockets that have been fired at Israeli cities and towns from Gaza sporadically since 2006, with escalations in violence (such as the recent escalation in July 2014) during which there were a substantially larger number of rocket and missile attacks aimed at Israel. ~~In addition~~ **On October 7** , **2023** ~~since February 2011~~ , **Hamas** ~~Egypt has experienced political turbulence and an increase in terrorist~~ **terrorists** ~~activity~~ **infiltrated Israel' s southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched**

extensive rocket attacks on Israeli population and industrial centers located along Israel' s border with the Gaza Strip and in ~~the~~ **other** ~~Sinai Peninsula~~ **areas within the State of Israel** . ~~Such political turbulence~~ **Following the attack, Israel' s security cabinet declared war against Hamas** and ~~violence may damage peaceful and diplomatic relations~~ **the Israeli military began to call- up reservists for active duty. Moreover, the clash** between Israel and ~~Egypt~~ **Hezbollah in Lebanon** , ~~and could affect~~ **may escalate in** the **future into a greater** ~~region~~ **regional conflict** ~~as a whole~~ . ~~Similar civil unrest and political turbulence has occurred in~~ **In the months since the initial attack by Hamas, clashes with Hezbollah on Israel' s** ~~other~~ **northern** ~~countries in the region, including Syria which shares a common~~ border with **Lebanon and attacks on** ~~Israel~~ **Israeli** ~~, and~~ **- controlled or owned ships in the Red Sea by members of the Houthi Movement in Yemen have taken place. It** is ~~affecting~~ **possible that** ~~the~~ **other** ~~political stability of~~ **terrorist organizations, including Palestinian military organizations in** ~~those~~ -- **the West Bank, as well as other hostile** countries ~~. This instability and any outside intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for causing additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region~~ , such as ~~Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Additionally, a violent jihadist group named Islamic State of Iraq~~ **Iran , will join the** ~~and Levant (ISIL) is involved in~~ hostilities ~~in Iraq~~ and ~~Syria and have been growing~~ **that such clashes may escalate** in ~~influence. Although ISIL' s activities have not directly affected~~ the ~~political and economic conditions in~~ **future into a greater regional conflict. 76Any hostilities involving** Israel ~~, ISIL' s stated purpose is to take control of the Middle East, including Israel. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts~~ , terrorist activities ~~or ,~~ political instability **or violence** in the region **,** ~~could adversely affect business conditions and could harm our~~ - **or** ~~results~~ **the interruption or curtailment** of ~~operations~~ **trade or transport between Israel** and **its trading partners** could make it more difficult for us to raise capital **and adversely affect our operations and results of operations and the market price of our securities** . ~~Parties with whom we do business may decline~~ **At this time, it is not possible** to ~~travel to~~ **predict the intensity or duration of the war, nor can we predict how this war will ultimately affect** Israel **' s economy** ~~during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary~~ in **general, which may involve** ~~order to meet our business partners face to face. In addition~~ **additional** ~~, the political~~ **credit rating agencies downgrading Israel' s credit rating score after Moody' s downgrading of Israel' s credit rating from A1 to A2** and ~~security~~ **outlook rating from " stable " to " negative ", and we continue to monitor the** situation **closely and examine the potential disruptions** ~~in Israel may result in parties with whom we have agreements involving performance in Israel claiming~~ that **could** ~~they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse~~ **adversely affect** ~~impact on~~ our ~~operating~~ **operations** ~~results, financial condition or the expansion of our business~~ . Our commercial insurance does not cover losses that may occur as a result of **an** ~~events~~ - **event** associated with the security situation in the Middle East. Although the Israeli government **is** currently ~~covers~~ **committed to covering** the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained **or, if maintained, will be sufficient to compensate us fully for damages incurred** . Any losses or damages incurred by us could have a material adverse effect on our business ~~. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations. Further, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results~~ , financial condition **, and results of operations. Further, majority of the members of** ~~or~~ **our management and employees are located and reside in** ~~the expansion of our business. 50Furthermore, the Israeli~~ - **Israel. Shelter- in- place and work- from- home measures,** government ~~is currently pursuing extensive changes~~ **- imposed restrictions on movement and travel and other precautions taken** to ~~Israel~~ **address the ongoing conflict may temporarily disrupt our management and employees** ' s judicial system. In response to....., our results of operations and our ability to **effectively** ~~raise additional funds, if deemed necessary by our management and board of directors. Our operations may be disrupted as a result of the obligation of Israeli citizens to~~ perform ~~military service~~ **their daily tasks** . **Further,** ~~Many~~ **many** Israeli citizens are obligated to perform several days, and in some cases **,** more, of annual military reserve duty each year until they reach the age of 40 (or older ~~'~~ s judicial system.In response to the foregoing developments,individuals,organizations and institutions,both within and outside of Israel,have voiced concerns that the proposed changes may negatively impact the business environment in Israel including **due to** reluctance of foreign investors to invest or ~~transact~~ **conduct** business in Israel **,** as well as **to** increased currency fluctuations,downgrades in credit rating,increased interest rates,increased volatility in securities markets,and other changes in macroeconomic conditions ~~within~~ **.Such proposed changes may also adversely affect the labor market in** Israel **or lead to political instability or civil unrest** . ~~Currently~~ **To the extent that any of these negative developments do occur** , ~~the~~ **they** ~~proposed judicial reforms been put~~ **may have an adverse effect** on **our business** ~~hold due to the ongoing focus on the war~~ , ~~while the Supreme Court~~ -- **our results** of **operations** ~~Israel ruled that the judicial reform passed into legislation relating to reasonability is unconstitutional.If such changes to the judicial system resume~~ and **our** ~~take effect~~ , for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call- ups of military reservists. It is possible that there will be military reserve duty call- ups in the future. Our operations could be disrupted by such call- ups, which may include the call- up of members of our management. Such disruption could materially adversely affect our business, financial condition and results of operations. ~~Investors~~ **77Investors** may have difficulties enforcing a U. S. judgment, including judgments based upon the civil liability provisions of the U. S. federal securities laws, against us, or our executive officers and

directors or asserting U. S. securities laws claims in Israel. Certain of our directors and officers are not residents of the United States and whose assets may be located outside the United States. Service of process upon us or our non- U. S. resident directors and officers and enforcement of judgments obtained in the United States against us or our non- U. S. our directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U. S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U. S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U. S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U. S. law is applicable to the claim. If U. S. law is found to be applicable, the content of applicable U. S. law must be proved as a fact, which can be a time- consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors. Moreover, among other reasons, including but not limited to, fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel. Risks Related to the Ownership of Our Common StockOur officers and directors may exert significant influence over our affairs, including the outcome of matters requiring stockholder approval. As of the date of this Annual Report, our officers and directors collectively have a beneficial ownership interest of approximately ~~9~~ **15** . ~~5~~ **7** % of our Company. As a result, such individuals will have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those individuals. Certain of these individuals also have significant control ~~51over~~ -- **over** our business, policies and affairs as officers or directors of our company. Therefore, you should not invest in reliance on your ability to have any control over our company. If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the price of our common stock and trading volume could decline. The trading market for our common stock may be influenced by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common stock or trading volume to decline. The market price of our common stock may be significantly volatile. The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following: ● actual or anticipated fluctuations in our quarterly or annual operating results; **78** ● changes in financial or operational estimates or projections; ● conditions in markets generally; ● changes in the economic performance or market valuations of companies similar to ours; and ● general economic or political conditions in the United States or elsewhere. In particular, the market prices for securities of mHealth and medical device have historically been particularly volatile. Some of the factors that may cause the market price of our common stock and warrants to fluctuate include: ● any delay in or the results of our clinical trials; ● any delay in manufacturing of our products; ● any delay with the approval for reimbursement for the patients from their insurance companies; ● our failure to comply with regulatory requirements; ● the announcements of clinical trial data, and the investment community' s perception of and reaction to those data; ● the results of clinical trials conducted by others on products that would compete with ours; ● any delay or failure to receive clearance or approval from regulatory agencies or bodies; ● our inability to commercially launch products or market and generate sales of our products, including Dario; ● failure of Dario or any other products, even if approved for marketing, to achieve any level of commercial success; ● our failure to obtain patent protection for any of our technologies and products (including those related to Dario) or the issuance of third- party patents that cover our proposed technologies or products; ● developments or disputes concerning our product' s intellectual property rights; ~~52~~ ● our or our competitors' technological innovations; ● general and industry- specific economic conditions that may affect our expenditures; ● changes in market valuations of similar companies; ● announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents; ● future sales of our common stock or other securities, including shares issuable upon the exercise of outstanding warrants or otherwise issued pursuant to certain contractual rights; ● period- to- period fluctuations in our financial results; and ● low or high trading volume of our common stock due to many factors, including the terms of our financing arrangements. In addition, if we fail to reach important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be a significant impact on the market price of our common stock and warrants. Additionally, as we approach the announcement of anticipated significant information and ~~as~~ **79as** we announce such information, we expect the price of our common stock and warrants to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock and warrants. In some cases, following periods of volatility in the market price of a company' s securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation. Shares eligible for future sale may adversely affect the market for our common stock and warrants. From time to

time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1 % of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non- affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non- affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale report may have a material adverse effect on the market price of our securities. Our compliance with complicated U. S. regulations concerning corporate governance and public disclosure is expensive. Moreover, our ability to comply with all applicable laws, rules and regulations is uncertain given our management' s relative inexperience with operating U. S. public companies. As a publicly reporting company, we are faced with expensive and complicated and evolving disclosure, governance and compliance laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes- Oxley Act and the Dodd- Frank Act, and, to the extent we complete our anticipated public offering, the rules of the Nasdaq Stock Market. New or changing laws, regulations and standards are subject to varying interpretations in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards of a U. S. public company are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue- generating activities to compliance activities. ~~53Moreover~~ -- **Moreover** , our executive officers have little experience in operating a U. S. public company, which makes our ability to comply with applicable laws, rules and regulations uncertain. Our failure to company with all laws, rules and regulations applicable to U. S. public companies could subject us or our management to regulatory scrutiny or sanction, which could harm our reputation and stock price. If we fail to maintain effective internal control over financial reporting, the price of our common stock may be adversely affected. Our internal control over financial reporting may have weaknesses and conditions that could require correction or remediation, the disclosure of which may have an adverse impact on the price of our common stock. We are required to establish and maintain appropriate internal control over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management' s assessment of internal control over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management' s assessment of our internal control over financial reporting may have an adverse impact on the price of our common stock. **80** ~~Anti- takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock and warrants. We are a Delaware corporation and the anti- takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change in control would be beneficial to our existing stockholders. In addition, our certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our certificate of incorporation and bylaws: ● authorize the issuance of " blank- check " preferred stock that could be issued by our Board of Directors to thwart a takeover attempt; ● provide that vacancies on our Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office; ● provide that special meetings of stockholders may only be called by our Chairman, Chief Executive Officer and / or President or other executive officer, our Board of Directors or a super- majority (66 2 / 3 %) of our stockholders; ● place restrictive requirements (including advance notification of stockholder nominations and proposals) on how special meetings of stockholders may be called by our stockholders; ● do not provide stockholders with the ability to cumulate their votes; and ● provide that our Board of Directors or a super- majority of our stockholders (66 2 / 3 %) may amend our bylaws. 54~~