Risk Factors Comparison 2024-03-08 to 2023-03-13 Form: 10-K

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The following important factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward- looking statements made in this Form 10- K or presented elsewhere by management from time to time. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are not material may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment. Risks Associated with Our Business Risks Related to Our Operating and Financial Results ~~and additional capital may be required~~ .Our strategy to maximize revenues by focusing our efforts on patients whose insurance has reimbursed for the MyoPro in the past has resulted in a concentration of revenues with patients covered by a single insurer.Adverse changes in that insurer' s reimbursement policy regarding the MyoPro could have an adverse effect on our business.In order to maximize revenues and minimize cash used for operations,we focus our lead generation efforts in geographical areas of the country where insurers who have previously reimbursed for the MyoPro operate their businesses.Beginning in September 2021,a large insurer that has historically reimbursed for the MyoPro began denying claims after having granted a pre- authorization and after we delivered the devices to patients,and these post- service denials currently continue.Revenues from patients insured by this payer represented ~~38~~ **30** % of total ~~product~~ revenues during the year ended December 31, ~~2023~~ **2022** .With a small number of exceptions,appeals filed with the payer **requesting payment** have been successful and these claims have ultimately been paid.This payer also continues to provide us with pre- authorizations to serve new patients.If this payer were to start regularly denying appeals on filed claims,reduce the number of MyoPro' s that it will authorize for its insured patients,or delays payments pending resolution of the denial and appeals process,our revenues and cash flows would be negatively impacted,which would have an adverse effect on our business.We may experience significant fluctuations in our quarterly and annual results.Fluctuations in our quarterly and annual financial results have resulted and will continue to result from numerous factors,including:• timing,number and dollar value of reimbursements of our products by insurance payers;• changes in the mix of products we sell;• strategic actions by us,such as acquisitions of businesses,products,or technologies;• effects of domestic and foreign economic conditions and exchange rates on our industry and / or customers;• the divestiture or discontinuation of a product line or other revenue generating activity;• the relocation and integration of manufacturing operations and other strategic restructuring;• regulatory actions which may necessitate recalls of our products or warning letters that negatively affect the markets for our products;• costs incurred by us in connection with the termination of contractual and other relationships,including distributorships;• our ability to collect outstanding accounts receivable;• the expiration or exhaustion of deferred tax assets such as net operating loss **carry-** ~~carryforwards~~ ----- **forwards** ;• increased product and price competition,due to the regulatory landscape,market conditions or other factors;• technology changes to enhance individual data privacy that could negatively impact our ability to market our products to prospective candidates and could result in increased advertising costs;• market reception of our new or improved product offerings;and • the loss of any significant customer.These factors,some of which are not within our control,may cause the price of our common stock to fluctuate substantially.If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors,our stock price could drop suddenly and significantly.We believe quarterly comparisons of our financial results are not always meaningful and should not be relied upon as an indication of **our future performance** If CMS ~~does not allow~~ **amends or retracts** coverage **requirements** ~~for the MyoPro~~ , insurers offering Medicare Advantage insurance plans may no longer reimburse for the MyoPro, which would have an adverse effect on our business. Revenues from patients who are covered by Medicare Advantage insurance plans **have become a** ~~are becoming an increasingly~~ significant portion of our overall revenues. For the year ended December 31, ~~2022~~ **2023** , approximately ~~60~~ **57** % of our product revenues were derived from patients with Medicare Advantage insurance plans. If CMS **amends** ~~does not allow coverage for~~ **or** ~~the~~ **retracts its November 2023 rule classifying** MyoPro ~~,~~ **as a brace** or **amends or** ~~if such coverage is obtained and is subsequently retracted~~ **retracts any published fees** , insurers offering Medicare Advantage insurance plans may no longer **cover or adequately** reimburse for the MyoPro. As a result, our revenues and cash flows would be negatively impacted, which could have an adverse effect on our business. See "- Risks Related to our Reliance on Third Parties — We may not be able to obtain third- party payer reimbursement, including reimbursement by Medicare, for our products " for additional information about CMS coverage decisions . Our strategy to maximize revenues by..... as an indication of our future performance . We currently rely, and in the future will rely, on sales of our MyoPro products for our revenue, and we may not be able to achieve or maintain market acceptance. We currently rely, and in the future will rely, on sales of our MyoPro products for our revenue. MyoPro products are relatively new products, and market acceptance and adoption depend on educating people with limited upper extremity mobility and healthcare providers as to the distinct features, ease- of- use, improved quality of life and other benefits of MyoPro systems compared to alternative technologies and treatments. MyoPro products may not be perceived to have sufficient potential benefits compared with these alternatives, which include rehabilitation therapy or amputation with a prosthetic replacement. Also, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third- party reimbursement. Accordingly, healthcare providers may not recommend the MyoPro until there is sufficient evidence to convince them to alter the treatment methods they typically recommend. This evidence may include prominent healthcare providers or other key opinion leaders in the upper extremity paralysis community recommending the MyoPro as effective in providing

identifiable immediate and long- term health benefits, and the publication of additional peer- reviewed clinical studies demonstrating its value. Additionally, because the MyoPro is a prescription device, patients require the prescription of a healthcare provider to access our products and to have the device reimbursed by insurance. Achieving and maintaining market acceptance of MyoPro products could be negatively impacted by many other factors, including, but not limited to: • lack of sufficient evidence supporting the benefits of MyoPro over competitive products or other available treatment, or lifestyle management to accommodate the disability; • patient resistance to wearing an external device or making required insurance co-payments; • limitations on the ability of patients to complete evaluations and fittings, including adverse changes in their health, or other environmental, social and economic barriers to patient access; • results of clinical studies relating to MyoPro or similar products; • claims that MyoPro, or any component thereof, infringes on patent or other intellectual property rights of third parties; • perceived risks associated with the use of MyoPro or similar products or technologies; • the introduction of new competitive products or greater acceptance of competitive products; • adverse regulatory or legal actions relating to MyoPro or similar products or technologies; and • problems arising from the insourcing of our manufacturing capabilities, or our existing manufacturing and supply relationships with third parties. Any factors that negatively impact sales of MyoPro would adversely affect our business, financial condition and operating results. We may not be able to obtain third- party payer reimbursement, including reimbursement by Medicare, for our products. Sales of our device depend, in part, on the extent to which our products will be covered by third- party payers, such as government health programs, commercial insurance and managed healthcare organizations. See section titled " Business Section – Government Regulation – Health Insurance Reimbursement. " Third- party payers are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost- effectiveness of medical products and services and imposing controls to manage costs. Third- party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. 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 payer separately, with no assurance that coverage and adequate reimbursement will be obtained. Currently, we are almost entirely dependent on third parties to cover the cost of our products to patients and rely on our distributors' ability to obtain reimbursement for the cost of our products. If the U. S. Department of Veterans Affairs, or the VA, health insurance companies and other third- party payers do not provide adequate coverage or reimbursement for our products, then our sales will be limited to clinical facilities and individuals who can pay for our devices without reimbursement. To our knowledge, through the year ended December 31, ~~2022~~ **2023** , fewer than ~~30~~ **50** units have been self- paid or funded by non- profit foundations. Some commercial health insurance plans have published statements that they will not cover the cost of the MyoPro for their members. Starting in 2023, we no longer pursue sales to patients whose insurance payers have not previously reimbursed for the MyoPro. In the event we are unsuccessful in obtaining coverage and adequate reimbursement for our products from third- party payers, our sales will be significantly constrained. Currently, reimbursement for the cost of our products is obtained primarily on a case- by- case basis until such time, if any, we obtain broad coverage policies with Medicare and third- party payers. There can be no assurance that we will be able to obtain these broad coverage policies. See section ~~title~~ **titled** " Business Section – Government Regulation – Health Insurance Reimbursement. " ~~In connection with Medicare reimbursement, the Centers for Medicare and Medicaid Services, or CMS, had published two new codes pursuant to our application for HCPCS codes, which became effective on January 1, 2019. CMS placed the Myopro device in a DME rental benefit category instead of lump sum, which is standard practice for other custom-fabricated orthotics and prosthetics.~~ We **began** ~~submitted an appeal to change our benefit category to an orthotic, or brace, which was presented at a public meeting in June 2022. In September 2022, CMS announced that it elected not to make a determination on our application at this time. In January 2023, CMS provided notice that it intends to publish a proposed rule covering the scope of the Medicare Part B benefit for leg, arm, back and neck braces as well as newer technology devices. We cannot give any assurance that CMS will change our benefit category determination, that the DME MAC' s will cover the device on a case by case basis, or at all, or that the amount of reimbursement, if any, to be approved will be sufficient to provide a reasonable profit to us, that the receipt of these codes would result in appropriate coverage and payment terms or otherwise lead to any greater access to our products or reimbursement for such products. While we announced that we became accredited as a Medicare provider in July 2021, enabling us to bill Medicare directly when we deliver our MyoPro powered orthosis to patients in 39 states and the District of Columbia, since we continue to await a decision by CMS on our benefit category change request, coverage policy and allowable fee for the MyoPro, we are currently not serving Medicare Part B patients, though we intend to start~~ submitting claims **to the DME MACs** on behalf of Medicare Part B beneficiaries in ~~early~~ **March** 2023. **A total of 40 claims have been submitted** ~~There is no specific timetable or guarantee that CMS will in fact issue such coverage~~ and ~~payment~~ **payments** ~~guidelines,~~ **have been received** ~~or~~ **for** ~~agree to change~~ **21 patients either as rentals or as purchases as of the filing date of this Annual Report on Form 10- K, covering all** ~~our~~ **four** ~~benefit category~~ **of the DME MAC billing regions. The other claims remain under review** . There is no guarantee that we will receive **payment** ~~those terms in a timely manner or~~ **for** ~~at all~~ **any unapproved claims** . In addition, decisions by CMS or other governmental payers on whether and to what extent they would cover our products, as well as decisions on what basis they would cover our products, ~~whether as outright purchases by patients or on a rental basis,~~ may impact similar coverage decisions by private payers that may follow the decisions by governmental payers. **In connection with Medicare** ~~Reimbursement~~ **reimbursement** ~~amounts~~ , ~~whether~~ **in November 2023 CMS reclassified the MyoPro from the durable medical equipment benefit to the brace benefit category effective January 1, 2024, thereby allowing for lump sum reimbursement. If CMS' s Medicare administrative contractors, referred to as the DME MAC' s, agree to reimburse for submitted claims, such reimbursements are expected to be on a lump sum basis for claims submitted after January 1, 2024. In addition, on February 29, 2024, CMS published final average payment determinations for the MyoPro Motion W (L8701) of approximately $ 33, 500 and the MyoPro Motion G (L8702) of approximately $ 65, 900, effective April 1, 2024. We believe that despite the publication of a final fee, our**

claims are expected to be evaluated on a case- by- case basis **during most of 2024. There can** ~~or pursuant to broader coverage policies, which may~~ be ~~established in~~ **no assurance that** the ~~future, may~~ **final fees will** be ~~insufficient~~ -- **sufficient** to permit us to generate ~~sufficient~~ gross ~~margins~~ -- **margin required** to allow us to operate on a profitable basis. Third- party payers also may **continue to** deny coverage, limit reimbursement or reduce their levels of payment, or our costs of production may increase faster than increases in reimbursement levels. In addition, we may not obtain coverage and reimbursement approvals in a timely manner. Our failure to **operate profitably** ~~receive such approvals would~~ **could** negatively impact market acceptance of MyoPro ~~. Further, due to the COVID- 19 pandemic, millions of individuals have lost employer- based coverage, which may adversely affect our sales to our patients relying on such coverage~~ . We depend on a single third- party to manufacture key subassemblies for the MyoPro and a limited number of third- party suppliers for certain components of the MyoPro. While we are the manufacturer of record with the U. S. Food and Drug Administration, or the FDA, for the MyoPro device we sell, we have contracted with Cogmedix, Inc., or Cogmedix, a contract manufacturer with expertise in the medical device industry, for the contract manufacture of all of our products and the sourcing of all of our components and raw materials. Pursuant to this contract, Cogmedix manufactures the MyoPro pursuant to our specifications at its facility in West Boylston, Massachusetts. As the manufacturer of the MyoPro, we ultimately remain responsible to the FDA for overseeing Cogmedix' s manufacturing activities to ensure that they conform with product specifications and applicable laws and regulations, including FDA' s good manufacturing practice requirements for medical devices. Any failure to effectively oversee the regulatory compliance of the product and contract manufacturing activities by Cogmedix can lead to potential enforcement actions, including civil or criminal liabilities, as well as recalls with the FDA. We may terminate our relationship with Cogmedix at any time upon sixty (60) days' written notice. For our business strategy to be successful, Cogmedix must be able to manufacture our products in sufficient quantities, and to source raw materials and components, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Increases in our product sales, whether forecasted or unanticipated, or supply chain constraints that may arise for any number of reasons, could strain the ability of Cogmedix to manufacture an increasingly large supply of our current or future products in a manner that meets these various requirements. In addition, although we are not restricted from engaging an alternative manufacturer, the process of moving our manufacturing activities would be time consuming and costly, and may limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Further, any new contract manufacturer would need to be compliant with FDA regulations and International Organization for Standardization, or ISO, standard 13485. We also rely on third- party suppliers, **including AB Corp, for 3D printed orthotic components.** ~~some~~ **Some** ~~of which~~ **third- party suppliers** contract directly with Cogmedix, to supply certain components of the MyoPro products. Cogmedix does not have long- term supply agreements with most of their suppliers and, in many cases, makes purchases on a purchase order basis. We do not have any long- term supply ~~agreement~~ **agreements** directly with Cogmedix' s suppliers. Our ability and Cogmedix' s ability to secure adequate quantities of such products may be limited. Suppliers may encounter problems that limit their ability to manufacture components for our products, including financial difficulties or damage to their manufacturing equipment or facilities. If we, or Cogmedix, fail to obtain sufficient quantities of high- quality components to meet demand on a timely basis, or fail to effectively oversee the regulatory compliance of the supply chain, we could face regulatory enforcement, have to conduct recalls, lose customer orders, our reputation may be harmed, and our business could suffer. Cogmedix generally uses a small number of suppliers for the MyoPro products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our suppliers ceases to provide sufficient quantities of components in a timely manner or on acceptable terms, Cogmedix would have to seek alternative sources of supply. It may be difficult to engage additional or replacement suppliers in a timely manner. Failure of these suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Cogmedix also may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of Cogmedix' s suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require Cogmedix to cease using the components, seek alternative components or technologies and we could be forced to modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results. We also rely on a limited number of suppliers for the batteries used by the MyoPro and do not maintain any long- term supply agreement with respect to batteries. If we fail to obtain sufficient quantities of batteries in a timely manner, our reputation may be harmed and our business could suffer. While we currently believe we have sufficient inventory in our supply chain in the near term, if we, or any third parties in our supply chain for materials which are used in either the manufacture of our products are adversely impacted by infections or restrictions ~~resulting~~ from **public heath crises, such as** the ~~coronavirus outbreak~~ **Covid- 19 pandemic** , or other factors, our supply chain may be disrupted and our ability to manufacture and ship our products may be limited. While many companies ~~are~~ **continue to** ~~experiencing~~ **experience** shortages of certain electronic components, so far we and our contract manufacturing partners have been able to procure the electronic components necessary for the manufacture of our products, but we are dealing with longer lead times and delivery delays for certain critical components. There can be no assurance that such supplies will become less constrained in the future. ~~In addition, as a result of shelter- in- place orders, workplace capacity restrictions, or other mandated travel restrictions, our on- site staff conducting sales and marketing and engineering activities may not be able to access our office or laboratory space, and these restrictions may adversely impact our contract manufacturing partners as well. Further, these core activities may be significantly limited or curtailed, possibly for an extended period of time.~~ Risks Related to Limited Operating History and Capital Requirements ~~We have a history of operating losses and our financial statements for the year ended December 31, 2022~~

include disclosures regarding there being substantial doubt about our ability to continue as a going concern. We have a history of losses since inception. For the years ended December 31, 2022 and 2021, we incurred net losses of $ 10. 7 million and $ 10. 4 million, respectively. At December 31, 2022, we had an accumulated deficit of approximately $ 88. 8 million. We expect to continue to incur operating and net losses for the foreseeable future, though we have implemented measures to reduce our operating expenses through eliminating costs associated with activities to broaden the number of payers reimbursing for MyoPro. However, there can be no assurance that our cost reduction measures will be effective in reducing our operating expenses, or that these measures would not adversely affect our revenue- generating activities. Our cash and cash equivalents at December 31, 2022 was approximately $ 5. 3 million. In January 2023, we completed a follow- on offering of our common stock and pre- funded warrants, raising net proceeds of approximately $ 5. 7 million. In addition, we entered into a Common Stock Purchase Agreement (the" Purchase Agreement") with Keystone Capital Partners (" Keystone") on August 2, 2022 to establish an equity line facility permitting the sale of up to $ 5. 0 million of shares of common stock, subject to an exchange cap that limits the number of shares that we may sell to 1, 349, 334, unless stockholder approval were obtained to remove such cap. We also have an at- the- market facility with Alliance Global Partners (the " ATM Facility "), that permits us to sell up to $ 0. 3 million of shares of common stock from time to time. Because the shares of common stock to be sold under the Purchase Agreement and the ATM Facility are registered under our registration statement on Form S- 3, we are subject to the limitations imposed by General Instruction I. B. 6 of Form S- 3, which limits the amount of securities that we may issue under our registration statement on Form S- 3 to one- third of our public float in any 12- month period. We have also agreed with the purchasers in our January 2023 financing not to sell shares under our Purchase Agreement and ATM Facility for a period of one year. We believe that there is substantial doubt that our cash and cash equivalents at December 31, 2022, together with the net proceeds from our January 2023 financing will be sufficient to fund our operations for the twelve months from the date of this report. Disclosure of this substantial doubt about our ability to continue operations in the future as a going concern, is disclosed in the notes to the audited financial statements for the year ended December 31, 2022. Because our financial statements raise substantial doubt about our ability to continue as a going concern, they do not reflect any adjustments that might result if we are unable to continue our business. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in our company. Our limited operating history makes it difficult for us to evaluate our future business prospects and make decisions based on those estimates of our future performance. Since inception through December 31, 2022 **2023**, we have delivered nearly **more than** 2, 000 **400** units for use by patients at home and at clinical facilities. Our latest product line, the MyoPro, was introduced to the market in fiscal year 2012 and we have delivered more than 1 **2**, 600 **000** units since such time. As a result, we have a limited operating history. It is difficult to forecast our future results based upon our historical data. Because of the uncertainties related to our limited historical operations, we may be hindered in our ability to anticipate and timely adapt to increases or decreases in revenues or expenses. We may not have sufficient funds to meet our future capital requirements. Our cash and **,** cash equivalents **, and short term investments** at December 31, 2022 **2023** was approximately $ 5 **8**. 3 **9** million. In **On** January **19,** 2023 **2024**, we completed a **registered direct** follow- on offering of our common stock and pre- funded warrants, raising **generating** net proceeds of approximately $ 5. 7 **4** million . In addition, we entered into a Purchase Agreement with Keystone to establish an equity line facility permitting the sale of up to $ 5. 0 million of shares of common stock, subject to an exchange cap that limits the number of shares that we may sell to 1, 349, 334, unless stockholder approval were obtained to remove such cap. We also have an ATM Facility, that permits us to sell up to $ 0. 3 million of shares of common stock from time to time. Because the shares of common stock to be sold under the Purchase Agreement and the ATM Facility are registered under our registration statement on Form S- 3, we are subject to the limitations imposed by General Instruction I. B. 6 of Form S- 3, which limits the amount of securities that we may issue under our registration statement on Form S- 3 to one- third of our public float in any 12- month period. We have also agreed with the purchasers in our January 2023 financing not to sell shares under our ATM Facility for a period of one year. However, there can be no assurance that we will be able to sell any or all of the shares under the Purchase Agreement or the ATM Facility, or raise significant amounts of capital even if we do. If we cannot use these facilities to raise sufficient capital to operate our business, we may be required to utilize more costly and time- consuming means of accessing the capital markets. Our financial statements for the year ended December 31, 2022 contain a qualification regarding substantial doubt about our ability to continue as a going concern . Our ability to **grow our business** continue as a going concern is dependent on our ability to generate sufficient cash flows from operations or to raise additional capital to meet our obligations . Based on our historical cash burn , we do not anticipate **if necessary. We believe** that our existing cash and cash equivalents **proceeds from our registered direct offering in January 2024** will be sufficient to enable us to maintain our currently **achieve cash flow breakeven on a quarterly basis, which we believe is achievable by the fourth quarter of 2024, assuming that we are able to hire at least 50 additional employees during the first half of 2024 as we have** planned operations for the next twelve months from the date of this report **to increase our clinical, reimbursement and manufacturing capacity, and our supply chain is able to meet our volume requirements without disruption** . We **If additional capital is required to achieve cash flow breakeven, we** may be unable to obtain additional funds on reasonable terms, or at all. Our ability to secure financing and the cost of raising such capital are dependent on numerous factors, including general economic and capital markets conditions, credit availability from lenders, investor confidence and the existence of regulatory and tax incentives that are conducive to raising capital. Uncertainty in the financial markets has caused banks and financial institutions to decrease the amount of capital available for lending and has significantly increased the risk premium of such borrowings. In addition, such turmoil and uncertainty has significantly limited the ability of companies to raise funds through the sale of equity or debt securities. If we are unable to raise additional funds, we may need to delay, modify or abandon some or all of our business plans or cease operations. If we raise funds through the issuance of debt, the amount of any indebtedness that we may raise in the future may be substantial, and we may be required to secure such indebtedness with our assets and may have substantial interest expenses. If we default on any future indebtedness, our lenders

could declare all outstanding principal and interest to be due and payable and our secured lenders may foreclose on the facilities securing such indebtedness. The incurrence of indebtedness could require us to meet financial and operating covenants, which could place limits on our operations and ability to raise additional capital, decrease our liquidity and increase the amount of cash flow required to service our debt. If we raise funds through the issuance of equity securities, such issuance could result in dilution to our stockholders and the newly issued securities may have rights senior to those of the holders of our common stock. ~~Rising~~ **Persistent** inflation may materially impact our financial operations or results of operations. Inflation has ~~increased~~ **remained persistent** during the period covered by this Annual Report on Form 10- K, and is expected to remain elevated for the near future. Inflationary factors, such as increases in the cost of our raw materials, manufacturing, interest rates and overhead costs may adversely affect our operating results. The price and availability of key components used to manufacture our products has been increasing and may continue to fluctuate significantly. In addition, the cost of labor internally or at our third-party manufacturers could increase significantly due to regulation or inflationary pressures. Additionally, the cost of logistics and transportation fluctuates in large part due to the price of oil, and availability can be limited due to political and economic issues. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future, especially if inflation rates continue to rise. Risks Related to ~~COVID- 19~~ ~~The outbreak of the novel strain of coronavirus, SARS- CoV- 2, which causes COVID- 19, could adversely impact our business. The outbreak of the novel coronavirus, SARS- CoV- 2, which causes coronavirus disease 2019 (" COVID- 19 "), has evolved into a global pandemic. The coronavirus has spread to many regions of the world, including the United States and Europe. As a result of the coronavirus pandemic, we have experienced and may continue to experience disruptions that could materially impact our business. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions taken to contain the coronavirus or treat its impact, among others. As a result of COVID- 19, various aspects of our business operations have been, and could continue to be, disrupted. For example, because we provide a custom- fabricated device to each patient, the in- person contact required as part of the fabrication and delivery process has been impacted and likely will continue to be impacted if COVID- 19- related public health restrictions on travel and personal interaction are broadly reinstated. Similarly, the impairment in the ability for patient consultation and fittings has caused us to delay and re- prioritize in our launch of MyoPal, our product for pediatric patients. While we continued in- person interactions with, and deliveries to, patients during the fourth quarter of 2022, incidences of the virus and its variants remain prevalent in the United States and the world. The spread of the current variants has resulted in more incidences of infection involving employees of the Company and its vendors and subcontractors as compared to earlier in the pandemic, which has impacted the Company in terms of lost productivity and temporary reductions in capacity. While current variants do not appear to be as virulent as previous variants, it is possible that future variants will be more transmissible and virulent. As a result, public health restrictions may be reinstated in various areas in the future. While insurance reimbursement practices of government and third- party payers were largely unaffected by the pandemic, we can provide no assurance that will continue in the future. While we currently believe we have sufficient inventory in our supply chain and currently expect to have sufficient fabrication capacity available to manufacture and deliver devices to patients, there can be no assurance that we will be able to continue to do so. If we, or any third parties in our supply chain for materials which are used in the manufacture of our products are adversely impacted by infections or restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted and our ability to manufacture and ship our products may be limited. Further, these core activities may be significantly limited or curtailed, possibly for an extended period of time. In addition, the company through which we have a joint venture in China for our MyoPro product has advised us that effects of COVID lockdowns in China are delaying the banking and government approvals necessary to pay the remaining amounts owed to us under our technology license for the joint venture. We cannot be certain as to if or when the remaining license fee will be paid. If uncured, failure to pay us the required fees contemplated by the Agreements may entitle us to terminate such our agreements related to the joint venture and withdraw from the joint venture. In response to COVID- 19, we have implemented a work from home policy, with many of our employees continuing their work outside of our offices. The increase in working remotely could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators and manufacturing sites. In addition, the trading prices for our common stock and other companies in the life sciences industry have been highly volatile as a result of the COVID- 19 pandemic. As a result, if we needed to raise additional capital, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID- 19 could materially and adversely affect our business and the value of our common stock. The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our commercialization, sales and marketing, research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely~~ Risks Related to ~~~~Competitors and Our Market The industries in which we operate are highly competitive and subject to rapid technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies. Industrial and medical robotics is characterized by intense competition and rapid technological change, and we will face competition on the basis of product features, clinical outcomes, price, services and other factors. Competitors may include large medical device and other companies, some of which

have significantly greater financial and marketing resources than we do, and firms that are more specialized than we are with respect to particular markets. Our competition may respond more quickly to new or emerging technologies, undertake more extensive marketing campaigns, and have greater financial, marketing and other resources than we do or may be more successful in attracting potential customers, employees and strategic partners. Our competitive position will depend on multiple complex factors, including our ability to achieve market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory clearances or approvals, if necessary, for products under development and protect our intellectual property. In some instances, competitors may also offer, or may attempt to develop, alternative therapies for disease states that may be delivered without a medical device. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive. The entry into the market of manufacturers located in low- cost manufacturing locations may also create pricing pressure, particularly in developing markets. Our future success depends, among other things, upon our ability to compete effectively against current technology, as well as to respond effectively to technological advances, and upon our ability to successfully implement our marketing strategies and execute our research and development plans. We sell to O & P providers and distributors who are free to market products that compete with the MyoPro, and we rely on these parties to market and promote our products in accordance with their FDA listings, select appropriate patients and provide adequate follow- on care. We rely on our relationships with qualified O & P providers and our distribution arrangements to market and sell our products. We believe that a meaningful percentage of our sales will continue to be generated through these channels in the future. However, none of these partners are required to sell or provide our products exclusively. If a key independent O & P provider were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent providers or increase our reliance on our other independent providers or our direct field representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our profit margins to be lower than if we directly marketed and sold our products. If these independent O & P providers or distributors do not follow our inclusion / exclusion criteria for patient selection or do not provide adequate follow- on care, then our reputation may be harmed by patient dissatisfaction. This could also lead to product returns and adversely affect our financial condition. When issues with distributors have arisen in the past, we have supplied additional training and documentation and / or ended the distributor relationship. The sales and marketing of medical devices is under increased scrutiny by the FDA and other enforcement bodies. If our sales and marketing activities fail to comply with FDA regulations, such as regulations for the labeling and advertising of our products, or other applicable laws, we may be subject to warnings or enforcement actions from the FDA or other enforcement bodies. For example, we are restricted from promoting our products for any use that is beyond the scope of their applicable FDA classification regulation. Such promotion could result in enforcement action by the FDA, which may include, but is not limited to untitled letters or warning letters, injunctions, recall or seizure of our products, and imposition of FDA' s premarket clearance or approval requirements. The market for myoelectric braces is new and the rate of adoption is uncertain, and important assumptions about the potential market for our products may be inaccurate. The market for myoelectric braces, or orthotics, is new and the rate of adoption is uncertain. Our estimates of market size are derived from statistics regarding the number of individuals with paralysis, but not necessarily limited to their upper extremities. Accordingly, it is difficult to predict the future size and rate of growth of the market. We cannot be certain whether the market will continue to develop or if orthotics will achieve and sustain a level of market acceptance and demand sufficient for us to continue to generate revenue and achieve profitability. Limited sources exist to obtain reliable market data with respect to the number of mobility-impaired individuals and the occurrence of upper extremity paralysis in our target markets. In addition, there are no third- party reports or studies regarding what percentage of those with upper extremity paralysis would be able to use orthotics in general, or our current or planned future products in particular. In order to use our current products marketed to those with upper extremity paralysis, users must meet a set of inclusion criteria and not have a medical condition which disqualifies them from being an appropriate candidate. Future products for those with upper extremity paralysis may have the same or other restrictions. Our business strategy is based, in part, on our estimates of the number of upper extremity impaired individuals and the incidence of upper extremity injuries in our target markets and the percentage of those groups that would be able to use our current and future products. Our assumptions and estimates may be inaccurate and may change. If the upper extremity orthotics market fails to develop or develops more slowly than we expect, or if we have relied on sources or made assumptions or estimates that are not accurate, our business could be adversely affected. In addition, because we operate in a new market, the actions of our competitors could adversely affect our business. Adverse events such as product defects or legal claims with respect to competing or similar products could cause reputational harm to the market on the whole. Further, adverse regulatory findings or reimbursement- related decisions with respect to other products could negatively impact the entire market and, accordingly, our business. Risks Related to Our Products We may receive a significant number of warranty claims or our MyoPro may require significant amounts of service after sale. Sales of MyoPro products generally include a three- year warranty for parts and labor, other than for normal wear and tear. As the number and complexity of the features and functionalities of our products increase, we may experience a higher level of warranty claims. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated expenditures for parts and services, which could have a material adverse effect on our operating results. Defects in our products or the software that drives them could adversely affect the results of our operations. The design, manufacture and marketing of the MyoPro products involve certain inherent risks. Manufacturing or design defects, unanticipated use of the MyoPro, or inadequate disclosure of risks relating to the use of MyoPro products can lead to injury or other adverse events. In addition, because the manufacturing of our products is outsourced to Cogmedix, we may not always be aware of manufacturing defects that could occur and corrective or preventive actions implemented by Cogmedix may not be effective at resolving such defects. Such adverse events could lead to recalls or safety alerts relating to

MyoPro products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of MyoPro products from the market. A recall could result in significant costs. To the extent any manufacturing defect occurs, our agreement with Cogmedix contains a limitation on Cogmedix' s liability, and therefore we could be required to incur the majority of related costs. **A** ~~Our agreement with GRE does not contain a similar limitation of liability; however, a~~ defect in connection with the fabrication of our products may result in significant costs in connection with lawsuits or refunds. Product defects or recalls could also result in negative publicity, damage to our reputation or, in some circumstances, delays in new product approvals. MyoPro users may not use MyoPro products in accordance with safety protocols and training, which could enhance the risk of injury. Any such occurrence could cause delay in market acceptance of MyoPro products, damage to our reputation, additional regulatory filings, product recalls, increased service and warranty costs, product liability claims and loss of revenue relating to such hardware or software defects. The medical device industry has historically been subject to extensive litigation over product liability claims. We have not been subject to such claims to date, but we may become subject to product liability claims alleging defects in the design, manufacture or labeling of our products in the future. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and high punitive damage payments. Although we maintain product liability insurance, the coverage is subject to deductibles and limitations, and may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts. While there is long- term clinical data supporting the safety of our existing MyoPro products, updates to our products inherently have uncertain safety risks as they enter the market. While clinical data have established the safety of MyoPro products, our products undergo periodic updates for various reasons, including performance and reliability improvements and cost reductions. For example, in January 2022, we announced the availability of MyoPro2 . Because MyoPro users generally do not have feeling in their upper extremities, they may not immediately notice adverse effects from updates to the MyoPro, which could exacerbate their impact. If MyoPro products are shown to present new risks or to be unsafe or cause such unforeseen effects in the future, our business and reputation could be harmed, including through field corrections, withdrawals, removals, mandatory product recalls, suspension or withdrawal of FDA registration, significant legal liability or harm to our business reputation. Risks Related to Collaborations and Licensing Agreements We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues. In the ordinary course of our business, in the future we may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships to develop the MyoPro and to pursue new markets. We are selling the MyoPro in several European countries, as well as Australia. In January 2021, we announced that we had entered into a joint venture (the " JV") with Beijing Ryzur Medical Investment Co., Ltd. (" Ryzur Medical "), to manufacture and sell the products containing our technology in China, Hong Kong, Taiwan and Macau. The company is named Jiangxi Myomo Medical Assistive Appliance Co., Ltd. (the " JV Company "). In December 2021, we entered into a technology license agreement and a trademark license agreement with the JV Company, under which we **were** ~~will be~~ entitled to receive a license fee of $ 2. 7 million and the JV Company will commit to purchase a minimum of $ 10. 75 million of MyoPro control units over the next ten years. As of December 31, ~~2022~~ **2023** , we received **full payment of the** $ ~~1~~ **2** . ~~0~~ **7** million ~~partial payment of the~~ license fee ~~. The joint venture has advised us that effects of COVID- 19 lockdowns in China are delaying the banking~~ and **have received payment** ~~government approvals necessary to pay the remaining amounts owed to us under our technology license. We cannot be certain as to if or~~ **for MyoPro control units of $ 50** ~~when the remaining license fee will be paid. If uncured~~ , **000** ~~failure to pay us the required fees contemplated by the Agreements may entitle us to terminate such our agreements related to the joint venture and withdraw from the joint venture~~ . This and any other of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a ~~competitive~~ lengthy and complex process. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. Any delays in entering into new strategic partnership agreements related to our products could delay the development and commercialization of our products in certain geographies, which would harm our business prospects, financial condition and results of operations. If we pursue collaborations, additional licensing arrangements and joint ventures, strategic alliances or partnerships, we may not be able to consummate them, or we may not be in a position to exercise sole decision decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators. Our collaborators may act in their self- interest, which may be adverse to our best interest, and they may breach their obligations to us. Any such disputes could result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements. Risks Related to Our Business Operations and Management If we fail to properly manage our anticipated growth, including in international markets, our business could suffer. As we expand the number of locations which provide the MyoPro products, including future planned international distribution, we expect that it will place significant strain on our management team and on our financial resources. Failure to manage our growth effectively could cause us to misallocate management or financial resources and result in losses or weaknesses in our infrastructure, systems, processes and controls, which could materially adversely affect our business. Additionally, our anticipated growth will increase the

demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Moreover, there are significant costs and risks inherent in selling our products in international markets, including: (a) time and difficulty in building a widespread network of distribution partners; (b) increased shipping and distribution costs, which could increase our expenses and reduce our margins; (c) potentially lower margins in some regions; (d) longer collection cycles in some regions; (e) compliance with foreign laws and regulations; (f) compliance with anti- bribery, anti- corruption, and anti- money laundering laws, such as the Foreign Corrupt Practices Act and the Office of Foreign Assets Control regulations, by us, our employees, and our business partners; (g) currency exchange rate fluctuations and related effects on our results of operations; (h) economic weakness, including inflation, or political instability in foreign economies and markets; (i) compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; (j) workforce uncertainty in countries where labor unrest is more common than in the United States; (k) business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires; and (l) other costs and risks of doing business internationally, such as new tariffs which may be imposed. For example, ~~in January 2021, we had~~ **have** ~~announced that we had~~ entered into a joint venture with Beijing Ryzur Medical Investment Co., Ltd., to manufacture and sell the products containing the Company' s technology in China, Hong Kong, Taiwan and Macau. In connection with this joint venture, we may encounter challenges in working with our joint venture partners, including with respect to compliance with local laws and domestic laws related to foreign operations. These and other factors could harm our ability to implement planned international operations and, consequently, harm our business, results of operations, and financial condition. Further, we may incur significant operating expenses as a result of our planned international expansion, and it may not be successful. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. We may also encounter difficulty expanding into international markets because of limited brand recognition, leading to delayed or limited acceptance of our products by patients in these markets. Accordingly, if we are unable to expand internationally or manage our international operations successfully, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be harmed. We depend on the knowledge and skills of our senior management. We have benefited substantially from the leadership and performance of our senior management and other key employees. We do not carry key person insurance. Our success will depend on our ability to retain our current management and key employees. Competition for these key persons in our industry is intense and we cannot guarantee that we will be able to retain our personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives or divert management' s attention to seeking qualified replacements. We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results. From time to time, we may consider opportunities to acquire other products or technologies that may enhance our products or technology or advance our business strategies. Potential acquisitions involve numerous risks, including: • problems assimilating the acquired products or technologies; • issues maintaining uniform standards, procedures, controls and policies; • unanticipated costs associated with acquisitions; • diversion of management' s attention from our existing business; • risks associated with entering new markets in which we have limited or no experience; and • increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters. We have no current commitments with respect to any acquisition and no current plans to seek acquisitions; however, depending on industry and market conditions, we may consider acquisitions in the future. If we do proceed with acquisitions, we do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition. ~~Our recent organizational changes and cost cutting measures may not be successful. In January 2023, we implemented reduction- in- force affecting approximately 12 % of our workforce. The objective of this workforce reduction was to realign our workforce to meet our needs and to improve operating efficiency in our direct billing channel and reduce our cash burn. However, these restructuring and cost cutting activities may yield unintended consequences and costs, such as attrition beyond our intended reduction- in- force, a reduction in morale among our remaining employees, and the risk we may not achieve the anticipated benefits of such reduction- in- force measure, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated, certain functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover the reductions in workforce and cost cutting measures will make it difficult for us to resume development activities we have suspended or pursue new initiatives, requiring us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. As a result of the loss of services of substantially all of our personnel, including several of our executive officers, we may be unable to continue our operations and meet our ongoing obligations. Any of these unintended consequences may have a material adverse impact on our business, financial condition, and results of operations.~~ Risks Related to Government Regulation Risks Related to Healthcare Industry We are subject to extensive governmental regulations relating to the design, development, manufacturing, labeling and marketing **, delivery and billing** of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market. Our products are regulated as medical devices in the United States under the ~~Federal Food, Drug, and Cosmetic Act, or~~ FFDCA, as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with the medical device, what is known about the type of device, and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA pre- market review. This determination is

required prior to marketing the device. See **section titled** " Business — Government Regulation **.** " ~~in our Annual Report on Form 10- K.~~ In 2012, we listed the MyoPro device as a Class I, 510 (k)- exempt, limb orthosis with the FDA. From time to time, the FDA may disagree with the classification regulation under which a registrant lists their device. For example, the FDA may disagree with a registrant' s determination to classify their device as a Class I medical device. Instead, the FDA may determine the device to be a Class II or Class III device requiring the submission of a premarket notification, or 510 (k), or a premarket approval, or PMA, application for premarket clearance or approval. As the FDA is now giving more attention to the differentiated performance of myoelectric controlled orthotics, we elected to change our device listing to be under a Class II classification regulation for biofeedback devices. Under the classification regulation, we believe our device remains 510 (k)- exempt as a prescription battery powered external limb orthosis that is indicated for functional improvement, a device which is generally 510 (k)- exempt under the classification regulation. In the event that the FDA determines that our devices, whether by functionality or marketing claims, exceed the limitations on 510 (k)- exemption such that premarket clearance or approval is required (i. e., that our device is intended for a use different from the intended use of a legally marketed device in the generic type of device under the applicable classification regulation or that our modified device operates using a different fundamental scientific technology than such a legally marketed device), should be classified as Class II devices or Class III devices requiring premarket clearance or approval, or should FDA decide to reclassify our device as a Class II or Class III device requiring premarket clearance or approval, we could be precluded from marketing our devices for clinical use within the **United States** ~~U. S.~~ for months or longer depending on the requirements of the classification. Obtaining premarket clearance or approval could significantly increase our regulatory costs, including expense associated with required pre- clinical (animal) and clinical (human) trials, more extensive mechanical and electrical testing and other costs. We are registered with the FDA as a manufacturer for medical devices. We are also subject to regulation by foreign governmental agencies in connection with international sales. The agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of our medical device products. Following the introduction of a product, the governmental agencies will periodically review our product development methodology, quality management systems, and product performance. We are under a continuing obligation to ensure that all applicable regulatory requirements, such as the FDA' s medical device good manufacturing practice / Quality System Regulation, or QSR, requirements and the FDA' s medical device reporting requirements for certain device- related adverse events and malfunction, continue to be met. Our facilities are subject to periodic and unannounced inspection by U. S. and foreign regulatory agencies to audit compliance with the QSR, and comparable foreign regulations. The process of complying with the applicable QSR, medical device reporting, and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of the MyoPro. If the FDA determines that we fail to comply with applicable regulatory requirements, they may issue an inquiry or an untitled or warning letter with one or more citations of non- compliance. These inquiries or letters, if not closed promptly, can result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Similarly, if we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing. In addition, governmental agencies of the United States or other countries may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re- register the MyoPro once it is already on the market or otherwise impact our ability to market the MyoPro in the ~~US~~ **United States** or other countries **. For example, on February 2, 2024, the FDA published a final rule to amend its QSR requirements to align more closely with the international consensus standards for medical devices by converging with quality management system, or QMS, requirements used by other regulatory authorities from other countries. Specifically, the final rule does so primarily by incorporating by reference the 2016 edition of the ISO 13485 standard. The amended regulation is referred to as the Quality Management System Regulation, or QMSR, and is effective February 2, 2026. 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 may have obtained, which could have a material adverse effect on our business, prospects, results of operations, financial condition and our ability to achieve or sustain profitability** . The process of complying with these governmental regulations can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of the MyoPro. For instance, the FDA may issue mandates, known as 522 orders, requiring us to conduct post- market surveillance studies of our devices. Failure to comply could result in enforcement of the FFDCA against us or our products including an agency request that we recall our MyoPro products. Our relationships with healthcare providers and physicians and third- party payers will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. We are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e. g. **,** healthcare providers, physicians and third- party payers), 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 commission (s), certain customer incentive programs and other business arrangements generally. We are also subject to patient information and privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct business. See section ~~entitled~~ -- **titled** " Business – Government Regulation – Healthcare Privacy Laws and Regulations. " **.** The scope and

enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business. The failure to comply with any of these laws or regulatory requirements subject entities to possible legal or regulatory action. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, could, despite efforts to comply, be subject to challenge under one or more of such laws. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages, reputational harm and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management' s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. In addition, the commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. If we or our third- party manufacturers or key suppliers fail to comply with the FDA' s Quality System Regulation, our manufacturing operations could be interrupted. We and our third- party manufacturers and key suppliers are also required to comply with the FDA' s QSR which covers the methods and documentation of the production, control, quality assurance, labeling, packaging, storage and shipping of our products. We, Cogmedix, our electromechanical kit manufacturer, and other key suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process with respect to the market for our products abroad. We continue to monitor our quality management, as well as that of our third- party manufacturers and suppliers to improve our overall level of compliance. Our facilities and those of our third- party manufacturers and key suppliers are subject to periodic and unannounced inspection by U. S. and foreign regulatory agencies to audit compliance with the QSR and comparable foreign regulations. If our facilities or the facilities of our third- party manufacturers and suppliers are found to be in violation of applicable laws and regulations, or if we or our third- party manufacturers and suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions: • untitled letters, warning letters, Form 483 findings (results from quality system inspections), fines, injunctions, consent decrees and civil penalties; • customer notifications or repair, replacement or refunds; • detention, recalls or seizure of our products; • operating restrictions or partial suspension or total shutdown of production; • withdrawing our FDA registration; • refusing to provide certificates to foreign governments with respect to exports; **and** • pursuing criminal prosecution. Any of these sanctions could impair our ability to produce the MyoPro in a cost- effective and timely manner in order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits. Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 comply with these 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations. We face risks in connection with the Affordable Care Act or its possible replacement or modifications and other ongoing healthcare legislative and regulatory reform measures. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could affect our ability to profitably sell our products. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In the United States, there have been and continue to be a number of legislative and regulatory initiatives and judicial challenges to contain healthcare costs. See section titled " Business ~~Section~~ – Government Regulations – Current and Future Legislation. " ~~.~~ We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for our products. Any denial in coverage or reduction in reimbursement from Medicare or other

government- funded programs may result in a similar denial or reduction in payments from private payers, including Medicare Advantage plans, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our products. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results. It is not clear how these developments, or other future potential changes to the ACA, will change the reimbursement model and market outlook for O & P devices such as the MyoPro. We intend to monitor industry trends relative to the ACA to assist in our determination of how the MyoPro can fit into patient care protocols with providers such as rehabilitation hospitals and surgery centers. If reimbursement policies change significantly, the demand for MyoPro products may be impacted. Risks Related to Cybersecurity and Data Protection Our internal computer systems **and infrastructure** , or those of our customers, collaborators **, contractors,** or other ~~contractors~~ **third parties** , may be subject to cyber- attacks or security **compromises or** breaches, which could result in a material disruption of our product development programs **, damage to our reputation or financial condition** . Despite the implementation of security measures, our internal computer systems and **infrastructures and** those of our customers, collaborators ~~and~~ **, contractors, or** other ~~contractors~~ **third parties** are vulnerable to damage **, compromise or interruption** from computer viruses ~~and~~ **,** unauthorized access **, misuse, or other security compromises or breaches** . Cyber- attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber- attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, **wrongful conduct by employees, vendors, or other third parties, hostile foreign governments, industrial espionage,** social engineering **and business email compromises,** and other means to affect service reliability and threaten **or compromise** the **security,** confidentiality, integrity and availability of **systems and** information. Cyber- attacks also could include phishing attempts or e- mail fraud to cause payments or information to be transmitted to an unintended recipient. A ~~material~~ cyber- attack or security **compromise or** breach could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation or a loss of revenues. In the ordinary course of our business, we collect and store **confidential and / or proprietary information or other** sensitive ~~data~~ **information** , including, among other things, ~~personally~~ -- **personal** ~~identifiable~~ information about our employees and patients, intellectual property, and proprietary business information. Any cyber- attack or security **compromise or** breach that leads to unauthorized access, use ~~or~~ **,** disclosure **, loss, corruption or other compromise** of ~~personal~~ **confidential and /** or proprietary **information or other sensitive** information could harm our reputation, cause us not to comply with federal and / or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations **, including those** that protect the privacy and security of personal information. In addition, we could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information **technology** systems **, infrastructure,** and networks of our company and our vendors, including personal information of our employees, and **patients, and** company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems **and infrastructure** or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and / or systems. If a ~~material~~ breach **or compromise** of our information technology systems **or infrastructure** or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to **detect, mitigate and** respond to these threats **, compromises,** or breaches and to repair or replace information **technology** systems **infrastructure** or networks and could suffer financial loss or the loss of valuable confidential **and / or proprietary** information. In addition, we could be subject to regulatory actions **, inquiries, investigations, orders, penalties, fines,** and / or claims made by individuals and groups in private litigation **, including those** involving privacy **and security** issues related to data collection and use practices and other data privacy **and security** laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process **designed** to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent **or adequately address** cyber- attacks or security **compromises or** breaches that could adversely affect our business. **We, our collaborators and our service providers may be subject to a variety of privacy and data protection laws, regulations and contractual obligations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with them could expose us to fines or other penalties and otherwise harm our business and operations.** In the United States, **several layers of federal and** ~~states~~ - **state** ~~have recently become~~ **data protection laws and regulations may apply** to ~~be rather active in~~ **our business, including HIPAA, the Federal Trade Commission (FTC) Act and state consumer** privacy **and health data privacy laws** . **For example,** ~~Leading efforts has been California which has recently enacted~~ the California Consumer Privacy Act, or CCPA, **is** a comprehensive ~~measure~~ **law** that creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt- out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020 and the California State Attorney General became empowered to commence enforcement actions against violators as of July 1, 2020. Further, ~~also in California,~~ as of January 1, 2023, the California Privacy Rights Act (CPRA), ~~will create~~ **created** additional obligations with respect to processing and storing personal information ~~that are scheduled to take effect on January 1, 2023~~ . ~~We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. While the CCPA and CPRA contain an exception for certain activities involving PHI under HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws,~~

~~regulations and standards may have on our business. Certain other state laws impose similar~~ **Similar** ~~privacy obligations and we also anticipate that more states will increasingly enact legislation similar to the CCPA and the CPRA. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act, or CDPA. The CDPA became effective January 1, 2023. The CDPA regulates how businesses (which the CDPA refers to as " controllers ") collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Also, on July 8, 2021, Colorado' s governor signed the Colorado Privacy Act, or CPA, into law. The CPA is rather similar to Virginia' s CDPA, but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to residents of the state that either: (1) control or process the personal data of at least 100, 000 consumers during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25, 000 consumers. With the CPA, Colorado became the third state to enact a comprehensive privacy law. A number of additional other states have proposed bills for comprehensive~~ consumer privacy laws **have passed or come into force in more than a dozen U. S. states. Like the CPRA, these laws grant consumers rights in relation to their personal information** and **impose new obligations on regulated businesses, including, in some instances, broader data security requirements. In addition, federal and state legislators and regulators have signaled their intention to further regulate health and other sensitive information, and new and strengthened requirements relating to this information could impact our business. At the state level, some states have passed or proposed laws to specifically regulate health information. For example, Washington' s My Health My Data Act, which comes into force in March 2024, requires regulated entities to obtain consent to collect health information, grants consumers certain rights, including to request deletion, and provides for robust enforcement mechanisms, including enforcement by the Washington state attorney-general and a private right of action for consumer claims. At the federal level, the FTC has used** ~~it~~ **its authority over " unfair or deceptive acts or practices " to impose stringent requirements on the collection and disclosure of sensitive categories of personal information, including health information. Moreover, the FTC' s expanded interpretation of a " breach " under** ~~is~~ **its** ~~quite possible~~ **Health Breach Notification Rule could impose new disclosure obligations** that ~~certain of~~ **would apply in** ~~these~~ -- **the event** ~~bills will pass. The existence~~ of **a qualifying breach** ~~comprehensive privacy laws in different states in the country, if enacted, will add additional complexity, variation in requirements, restrictions and potential legal risk, may require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data, and has resulted in and may result in further increased compliance costs and / or changes in business practices and policies~~ . European data collection is governed by restrictive regulations governing the use, processing, and cross- border transfer of personal information. The collection and use of personal **data, including personal** health data in the European ~~Union~~ **Economic Area, or the EEA and the UK** is governed by the provisions of the **EU** General Data Protection Regulation, or **EU** GDPR **(with regards to the EEA)** and **the UK General Data Protection Regulation, or UK GDPR, or UK GDPR (with regards to the UK), as well as** applicable data protection laws in effect in the member states of the ~~European Union~~ **EEA and in the UK (including the UK Data Protection Act 2018). In this Annual Report on Form 10- K, " GDPR " refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR applies to the processing of personal data by any company established in the EEA / UK and to companies established outside the EEA / UK to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA / UK or the monitoring of the behavior of data subjects in the EEA / UK** . The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the ~~European Economic Area, or~~ EEA **/ UK** , including to the U. S., providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record- keeping. **In** ~~The GDPR substantially increases the penalties to which we could be subject in~~ the event of any non- compliance **with the GDPR and any supplemental EEA Member State or UK national data protection laws, we could be subject to warning letters, mandatory audits, orders to cease / change the use of data, and financial penalties** , including fines of up to € 20, 000, 000 **(£ 17. 5 million for the UK GDPR)** or 4 % of total annual global revenue, whichever is greater. ~~In addition, further~~ **The GDPR also confers a private right of action on data subjects and consumer associations** to **lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. The GDPR imposes strict rules on the transfer of personal data outside of the EEA or** the UK ~~' s exit from~~ **to countries that do not ensure an adequate level of protection, like** the ~~EU~~ **United States in certain circumstances unless adequate safeguards (such as the European Commission approved standard contractual clauses, or SCCs, or the UK International Data Transfer Agreement / Addendum or IDTA and transfer impact assessments carried out when relying** on ~~January 31, 2020,~~ the **SCCs and** ~~GDPR ceased to apply in the~~ UK **IDTA** ~~at the end of the transition period on December 31, 2020~~ . **The international transfer obligations under** ~~However, as of January 1, 2021,~~ the ~~UK' s~~ European ~~Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK' s~~ data protection ~~regime,~~ **laws will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data**

is transferred and which ~~is independent~~ **service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data** from ~~but aligned to~~ the ~~EU' s~~ **EEA and UK to the United States in compliance with** data protection **laws** ~~regime. Non- compliance with the UK GDPR~~ may **impede** ~~result in monetary penalties of up to £ 17. 5 million or~~ **our** ~~4 % of worldwide revenue, whichever is higher~~ **ability to conduct trials and may adversely affect our business and financial position** . Although the UK is regarded as a third country under the EU' s GDPR, the European Commission (" EC ") has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the ~~EU~~ **EEA** to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. **The UK' s** ~~To enable the transfer of personal~~ data ~~outside of~~ **protection regime is independent from but aligned to** the ~~EEA or~~ **EU' s data protection regime. However following** the UK **' s exit from the EU** , ~~adequate safeguards must~~ **or Brexit, there will** be ~~implemented~~ **increasing scope for divergence** in ~~compliance with European~~ **application, interpretation** and ~~UK~~ **enforcement of the** data protection laws **between** ~~. On June 4, 2021, the~~ **these territories.** ~~EC issued new forms of standard contractual clauses for data transfers from controllers or~~ **For** ~~processors in~~ **example,** the **UK Government has introduced a** ~~EU / EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU / EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU~~ Data Protection ~~Directive. The~~ **and Digital Information Bill, or Data Reform Bill into the** UK **legislative process** ~~is not subject~~ to **reform** the ~~EC~~ **UK** ' s ~~new standard contractual clauses but has published a draft~~ **data protection regime following Brexit. If passed, the final** version of **the Digital Information Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK adequacy decision from the EU Commission, which may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of European personal data and our privacy and data security compliance programs, and could require us to implement different compliance measures for the UK and the EEA. Compliance with the GDPR will be** a **rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European and** UK- **based activities** ~~specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so may require significant effort and additional cost~~ .

Risks Related to Our Intellectual Property ~~We depend on certain patents that are licensed to us. We do not control these patents and any loss of our rights to them could prevent us from manufacturing our products. We rely on licenses to two core patents that are material to our business, including the development of the MyoPro, which expire in November 2023 and December 2023, respectively. We have entered into the MIT License for those certain patents that cover (i) a powered orthotic device worn on a patient' s elbow or other joint, that senses relatively low level signals in the vicinity of the joint generated by a patient having spinal cord or other nerve damage and (ii) a method of providing rehabilitation movement training for a person suffering from nerve damage, stroke, spinal cord injury, neurological trauma or neuromuscular disorder in attempt to move a body part with a powered orthotic device. Our rights to use these patents will be subject to the continuation of and our compliance with the terms of those licenses. We have certain revenue obligations, or Revenue Obligations under the MIT License. Our revenue exceeded $ 750, 000 for the fiscal years ended December 31, 2022 and 2021, which satisfied the Revenue Obligations for each of those fiscal years. The Revenue Obligations are a continuing requirement of the MIT License. While we expect to exceed the required revenue and satisfy the Revenue Obligations in 2023, the final year of the MIT License, we cannot make any assurance that we will continue to comply with these obligations. Additionally, MIT has the right to terminate the MIT License upon any future uncured material breach of the agreement or if we fail to make any payments due under the agreement. If the MIT License is terminated for any reason, our business will be harmed. Specifically, if we were to lose access to these licenses, we would be unable to manufacture the MyoPro or develop new products until we obtained access to a comparable technology. We may not control the prosecution, maintenance or filing of the patents to which we now hold or in the future intend to acquire licenses. Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents may be subject to the control or cooperation of our licensors. We cannot be certain that our licensors will prosecute, maintain, enforce and defend the licensed patent rights in a manner consistent with the best interests of our business. We also cannot be certain that drafting or prosecution of the licensed patents and patent applications by the relevant licensors have been or will be conducted in compliance with applicable law.** Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products. Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products. We seek to protect our intellectual property through a combination of patents, trademarks, confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors **. We licensed two core patents from Massachusetts Institute of Technology, or MIT, which expired in November 2023. While we have enhanced our patent portfolio since we entered into the license agreement with MIT in 2006, including patents which cover the movement of multiple joints, the expiration of the original MIT patents may result in new entrants to the market in the United States** . In addition, we rely on trade secrets law to protect our proprietary software and product candidates or products in development. The patent position of myoelectric orthotic inventions can be highly uncertain and involves many new and evolving complex legal, factual and technical issues. Patent laws and interpretations of those laws are subject to change and any such changes may diminish the value of our patents or narrow the scope of protection. In addition,

we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of technology or processes by third parties. Also, we cannot be sure that any patents will be granted in a timely manner or at all with respect to any of our patent pending applications or that any patents that are granted will be adequate to protect our intellectual property for any significant period of time or at all. Litigation to establish or challenge the validity of patents, or to defend against or assert against others infringement, unauthorized use, enforceability or invalidity claims, can be lengthy and expensive and may result in our patents being invalidated or interpreted narrowly and our not being granted new patents related to our pending patent applications. Even if we prevail, litigation may be time consuming and force us to incur significant costs, and any damages or other remedies awarded to us may not be valuable and management' s attention could be diverted from managing our business. In addition, U. S. patents and patent applications may be subject to interference proceedings, and U. S. patents may be subject to re- examination and review in the U. S. Patent and Trademark Office. Foreign patents may also be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings may be expensive and could result in the loss of a patent or denial of a patent application, or the loss or reduction in the scope of one or more of the claims of a patent or patent application. In addition, we seek to protect our trade secrets, know- how and confidential information that is not patentable by entering into confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third- party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. Enforcing a claim that a third- party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary information, which could lead to the loss or impairment thereof or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. In addition, unauthorized parties may attempt to copy or reverse engineer certain aspects of our products that we consider proprietary or our proprietary information may otherwise become known or may be independently developed by our competitors or other third parties. If other parties are able to use our proprietary technology or information, our ability to compete in the market could be harmed. Further, unauthorized use of our intellectual property may have occurred, or may occur in the future, without our knowledge. If we are unable to obtain or maintain adequate protection for intellectual property, or if any protection is reduced or eliminated, competitors may be able to use our technologies, resulting in harm to our competitive position. We are not able to protect our intellectual property rights in all countries. Filing, prosecuting, maintaining and defending patents on each of our products in all countries throughout the world would be prohibitively expensive, and thus our intellectual property rights outside the United States are currently limited to selected countries in the European Union **, or EU** , China, Hong Kong, and Japan. In addition, the laws of some foreign countries, especially developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Also, it may not be possible to effectively enforce intellectual property rights in some countries at all or to the same extent as in the United States and other countries. Consequently, we are unable to prevent third parties from using our inventions in all countries, or from selling or importing products made using our inventions in the jurisdictions in which we do not have (or are unable to effectively enforce) patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop, market or otherwise commercialize their own products, and we may be unable to prevent those competitors from importing those infringing products into territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents and other intellectual property rights may not be effective or sufficient to prevent them from competing in those jurisdictions. Moreover, competitors or others in the chain of commerce may raise legal challenges against our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Proceedings to enforce our patent rights in the United States or 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 to assert patent infringement or other 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. Accordingly, our efforts to enforce our intellectual property rights in the United States and around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties. We may be subject to patent infringement claims, which could result in substantial costs and liability and prevent us from commercializing our current and future products. The medical device industry is characterized by competing intellectual property and a substantial amount of litigation over patent rights. In particular, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, have been issued patents and filed patent applications with respect to their products and processes and may apply for other patents in the future. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation. Determining whether a product infringes a patent involves complex legal and factual issues and the outcome of patent litigation is often uncertain. Even though we have conducted research of issued patents, no assurance can be given that patents containing claims covering our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, published

applications may issue with claims that potentially cover our products, technology or methods. Infringement actions and other intellectual property claims brought against us, with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management and harm our reputation. We cannot be certain that we will successfully defend against any allegations of infringement. If we are found to infringe another party' s patents, we could be required to pay damages. We could also be prevented from selling our products that infringe, unless we could obtain a license to use the technology covered by such patents or could redesign our products so that they do not infringe. A license may be available on commercially reasonable terms or none at all, and we may not be able to redesign our products to avoid infringement. Further, any modification to our products could require us to conduct clinical trials and revise our filings with the FDA and other regulatory bodies, which would be time consuming and expensive. In these circumstances, we may not be able to sell our products at competitive prices or at all, and our business and operating results could be harmed. We rely on trademark protection to distinguish our products from the products of our competitors. We rely on trademark protection to distinguish our products from the products of our competitors. We have registered the trademarks " MyoPro " (Registration No. 4, 532, 331), " MYOMO " (Registration No. 4, 451, 445), " MyoPal " (Registration No. 6, 086, 533) and " MyoCare " (Registration No. 6, 579, 736) in the United States. The MyoPro mark is registered in Canada and in selected ~~European Union, or~~ EU, countries with pending registration. In jurisdictions where we have not yet registered our trademark and are using it, and as permitted by applicable local law, we seek to rely on common law trademark protection where available. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks, and may be able to use our trademarks in jurisdictions where they are not registered or otherwise protected by law. If our trademarks are successfully challenged or if a third- party is using confusingly similar or identical trademarks in particular jurisdictions before we do, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. If others are able to use our trademarks, our ability to distinguish our products may be impaired, which could adversely affect our business. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks. We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers. Some of our employees were previously employed at other medical device companies, including our competitors or potential competitors, and we may hire employees in the future that are so employed. We could in the future be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. If any of these technologies or features are important to our products, this could prevent us from selling those products and could have a material adverse effect on our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and divert the attention of management. Risks Related to our Securities Risks Related to Ownership of Our Securities Our stockholders will experience significant dilution upon the issuance of common stock if the shares of our common stock underlying our warrants, are exercised or converted. We have a significant number of securities convertible into, or allowing the purchase of, our common stock. Investors could be subject to increased dilution upon the conversion or exercise of these securities. For example, **in conjunction** ~~as of December 31, 2022, we had 680, 363 shares issuable upon the exercise of warrants,~~ with ~~a weighted- average exercise price of $ 8. 30 per share, and 29, 605 shares issuable upon the exercise of stock options under our~~ equity ~~incentive plans~~ **offerings in January 2024** , **August 2023 and** ~~with a weighted- average exercise price of $ 40. 50 per share. In addition, we have 454, 447 restricted stock units outstanding. In~~ January 2023, we issued **224, 730, 1, 920, 000 and** 6, 830, 926 pre- funded warrants **, respectively** ~~in conjunction with our follow- on equity offering~~ . Each pre-funded warrant is exercisable for one share of common stock at the nominal exercise price of $ 0. 0001 per share. **As of December 31, 2023, we had 8, 271, 519 shares issuable upon the exercise of pre- funded warrants with an exercise price of $ 0. 0001 per share, and 668, 250 shares issuable upon the exercise of other warrants, with a weighted- average exercise price of $ 7. 50 per share and 1, 501, 659 unvested restricted stock units outstanding. In addition, we had 24, 529 shares issuable upon the exercise of stock options under our equity incentive plans, with a weighted- average exercise price of $ 41. 13 per share.** We may not be able to maintain a listing of our common stock on the NYSE American. We must meet certain financial and liquidity criteria to maintain such listing. If we fail to meet any of the NYSE American' s listing standards, our common stock may be delisted. In addition, our board may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the NYSE American may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. A delisting of our common stock could significantly impair our ability to raise capital. There is no public market for our warrants or pre- funded warrants to purchase common stock. There is no established public trading market for our warrants or pre- funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of such warrants on any securities exchange. Without an active market, the liquidity of such warrants will be limited. Holders of our warrants and pre- funded warrants have no rights as a common stockholder until such holders exercise their warrants and acquire our common stock. Until holders of our warrants and pre- funded warrants exercise such warrants, they will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of such warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date. The market price of our common stock has been and may continue to be volatile. The stock market in general, and the market price of our common stock in particular will likely be subject to fluctuation, whether due to, or irrespective of, our operating results, financial condition and prospects. For example, from ~~June 9, 2017 to~~ December 31, 2022 **to December 31, 2023** , the high and low sales price of our common stock on the NYSE American has fluctuated from a low of $ 0. 37 to a ~~split adjusted~~ high of $ ~~695~~ **5** . ~~88~~ **58** per share. During

the period from January 1, ~~2023~~ **2024** to the date of the filing of this report, our stock price has ranged from $ ~~0~~ **2** . ~~37~~ **69** to $ ~~0~~ **5** . ~~84~~ **04** . Our financial performance, our industry' s overall performance, changing consumer preferences, technologies, government regulatory action, tax laws and market conditions in general could have a significant impact on the future market price of our common stock. Some of the other factors that could negatively affect our share price or result in fluctuations in our share price include: • actual or anticipated variations in our periodic operating results; • increases in market interest rates that lead purchasers of our common stock to demand a higher investment return; • changes in earnings estimates; • changes in market valuations of similar companies; • actions or announcements by our competitors; • adverse market reaction to any increased indebtedness we may incur in the future; • additions or departures of key personnel; • actions by stockholders; • speculation in the media, online forums, or investment community; and • our intentions and ability to maintain our common stock on the NYSE American. We do not expect to declare or pay dividends in the foreseeable future. We do not expect to declare or pay dividends in the foreseeable future, as we anticipate that we will invest future earnings in the development and growth of our business. Therefore, holders of our common stock will not receive any return on their investment unless they sell their securities, and holders may be unable to sell their securities on favorable terms or at all. If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected. Any trading market for our common stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not have any control over these analysts. We currently have limited research coverage by securities industry analysts and we may be unable to maintain analyst coverage or have analysts initiate coverage on us. If securities industry analysts cease coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage on us, the market price and market trading volume of our common stock could be negatively affected. Future issuances of our common stock or equity- related securities could cause the market price of our common stock to decline and would result in the dilution of your holdings. Future issuances of our common stock or securities convertible into our common stock could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our common stock or securities convertible into our common stock on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your holdings. In addition, the perception that new issuances of our common stock, or other securities convertible into our common stock, could occur, could adversely affect the market price of our common stock. Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect our common stock price. In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred securities in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our common stock must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return they may be able to achieve from an investment in our common stock. If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares. The SEC has adopted rules that regulate broker- dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $ 5. 00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on the NYSE American or another national securities exchange and if the price of our common stock is less than $ 5. 00, our common stock will be deemed a penny stock. The penny stock rules require a broker- dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser' s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock. Provisions in our amended and restated certificate of incorporation and bylaws may have the effect of delaying or preventing a change in control or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that: • authorize our board of directors to issue preferred stock, without further stockholder action and with voting liquidation, dividend and other rights superior to our common stock; • establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for director nominees; • establish that our board of directors is divided into three classes, with directors in each class serving three- year staggered terms; • require the approval of holders of two- thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or amend or repeal the provisions of our certificate of incorporation regarding the election and removal of directors and the ability of stockholders to take action by written consent or call a special meeting; • prohibit cumulative voting in the election of directors; and • provide that vacancies on our board of directors may be filled only

by the vote of a majority of directors then in office, even though less than a quorum or by the holders of at least sixty- six and two- thirds percent (66 2 / 3 %) of the issued and outstanding shares of common stock. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any " interested " stockholder for a period of three years following the date on which the stockholder became an " interested " stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your common stock in an acquisition. ~~As a result of sales of shares of our Common Stock pursuant to our equity line of credit, our existing stockholders will experience immediate dilution and our stock price may decrease. Pursuant to the Purchase Agreement, we may sell up to $ 5, 000, 000 of shares of our common stock at our discretion to Keystone, subject to satisfaction of certain conditions and limitations contained in the equity line facility. Because the purchase price under the facility includes a discount to prevailing market prices, the sale of shares of our common stock pursuant to the Purchase Agreement will have a dilutive impact on our existing stockholders. Keystone may resell some or all of the shares we issue to it under the Purchase Agreement and such sales could cause the market price of our common stock to decline, and such decline could be significant.~~ Risks Related to Internal Controls We are a" smaller reporting company " under the reporting rules set forth under the Exchange Act. For so long as we remain a " smaller reporting company, " we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not " smaller reporting companies . " ~~.~~ We are a " smaller reporting company ~~,~~ . " ~~.~~ For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not " smaller reporting companies, " including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act (so long as we remain a non- accelerated filer) and reduced disclosure obligations regarding executive compensation in the Annual Report on Form 10- K and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We are obligated to develop and maintain a system of effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may harm investor confidence in our company and, as a result, the value of our common stock. We are required, pursuant to Section 404 of the Sarbanes- Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the annual and quarterly reports we file with the SEC. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our auditors are not required to ~~formally~~ attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer a " smaller reporting company " as set forth under the Exchange Act. We will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As we continue to grow as a public company, we may need to add additional finance staff. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. If we are unable to assert that our internal control over financial reporting is effective, or if our auditors are unable to express an opinion on the effectiveness of our internal controls when they are required to issue such opinion, investors could lose confidence in the accuracy and completeness of our financial reports, which could harm our stock price. The preparation of our financial statements involves the use of estimates, judgments and assumptions, and our financial statements may be materially affected if such estimates, judgments or assumptions prove to be inaccurate. Financial statements prepared in accordance with accounting principles generally accepted in the United States typically require the use of estimates, judgments and assumptions that affect the reported amounts. Often, different estimates, judgments and assumptions could reasonably be used that would have a material effect on such financial statements, and changes in these estimates, judgments and assumptions may occur from period to period over time. Significant areas of accounting requiring the application of management' s judgment include, but are not limited to, determining the fair value of assets and the timing and amount of cash flows from assets. These estimates, judgments and assumptions are inherently uncertain and, if our estimates were to prove to be wrong, we would face the risk that charges to income or other financial statement changes or adjustments would be required. Any such charges or changes could harm our business, including our financial condition and results of operations and the price of our securities. See " Management' s Discussion and Analysis of Financial Condition and Results of Operations " for a discussion of the accounting estimates, judgments and assumptions that we believe are the most critical to an understanding of our financial statements and our business. We are incurring increased costs as a public company and our management team is required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we are no longer a " small reporting company, " we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE American and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these

requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. Risks Related to Tax Laws We may be subject to adverse legislative or regulatory changes in tax laws that could negatively impact our financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U. S. Internal Revenue Service, or IRS and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ **2023**, we had U. S. federal and state net operating loss, or NOL, carryforwards of $ **77. 4 million and $** 72. 7 million ~~and $ 64. 7 million~~, respectively, which begin to expire in the year 2028 and ~~2023~~ **2024** through ~~2043~~ **2044**, respectively. Additionally, we had U. S. federal and state research and development tax credits, or tax credits, of $ 0. ~~3~~ **4** million and $ 0. ~~1~~ **2** million, respectively, which begin to expire in the year ~~2027~~ **2026** and ~~2036~~ **2033**, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the ~~code~~ **Code**, and corresponding provisions of state law, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change NOL **carry-** ~~carryforwards~~ ----- **forwards** or tax credits, or NOLs or credits, to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5 % of a corporation' s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have determined that such ownership changes have occurred in prior years **and as recently as January 2023**. The result of these ownership changes is that we have a $ ~~281~~ **64**, 000 annual limitation on our ability to utilize pre- ownership change NOL' s and that approximately $ ~~437, 000~~ **20. 0 million** of our **federal** NOL ~~'~~**' s and $ 48. 0 million of our state NOL'** s will expire unutilized ~~. We believe that we may have experienced an ownership change as a result of our follow- on equity offering in January 2023. As of the date of this report, we have not determined the extent of any further limitations on our ability to utilize our NOL' s~~. We may undergo an ownership change in connection with future changes in our stock ownership (many of which are outside of our control), whereby our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code or under corresponding provisions of state law. Furthermore, our ability to utilize our NOLs or tax credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under " Risk factors — Risks Associated with Our Business, " we have incurred net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U. S. federal or state taxable income necessary to utilize our NOLs or tax credits that are subject to limitation by Sections 382 and 383 of the Code. Under current law, U. S. federal NOL carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration, but the amount of such NOL carryforwards that we are permitted to deduct in a taxable year beginning after December 31, 2020 will be limited to 80 % of our taxable income in each such year to which the NOL carryforwards are applied. CAUTIONARY STATEMENT REGARDING FORWARD- LOOKING STATEMENTS Some of the statements under " Business, " " Risk Factors, " " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " " Business " and elsewhere in this Annual Report on Form 10- K constitute forward- looking statements. Forward- looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar matters that are not historical facts. In some cases, you can identify forward- looking statements by terms such as " anticipate, " " believe, " " could, " " estimate, " " expect, " " intend, " " may, " " plan, " " potential, " " should, " " will " and " would " or the negatives of these terms or other comparable terminology. You should not place undue reliance on forward looking statements. The cautionary statements set forth in this Annual Report on Form 10- K, including in " Risk Factors " and elsewhere, identify important factors which you should consider in evaluating our forward- looking statements. These factors include, among other things: • ~~We have a history of operating losses and our financial statements for the year ended December 31, 2022 include disclosures regarding there being substantial doubt about our ability to continue as a going concern. •~~ our ability to achieve reimbursement from third- party payers for our products ~~, including the establishment of reimbursement codes from third- party payers for our products~~; • our dependence upon external sources for the financing of our operations ~~; • our ability to operate our business during the COVID- 19 pandemic, including manufacturing and delivery, sales, patient consultations, supply chain insurance reimbursement and employees~~; • our ability to obtain and maintain our strategic collaborations and to realize the intended of such collaborations; • our ability to effectively execute our business plan; • our ability to maintain and grow our reputation and to achieve and maintain the market acceptance of our products; • our expectations as to our clinical research program and clinical results; • our ability to improve our products and develop new products; • our ability to manage the growth of our operations over time; • our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others; • our ability to gain and maintain regulatory approvals; • our ability to maintain relationships with existing customers and develop relationships with new customers; • our ability to compete and succeed in a highly competitive and evolving industry; and • other risks and uncertainties, including those listed under the captain " Risk Factors " in this Annual Report on Form 10- K. Although the forward- looking statements in this Annual Report on Form 10- K are based on our beliefs, assumptions and expectations, taking into account all information currently available to us, we cannot guarantee future transactions, results, performance, achievements or outcomes. No assurance can be made to any investor by anyone that the expectations reflected in our forward- looking statements will be attained, or that deviations from them will not be material and adverse. We undertake no obligation, other than as maybe be required by law, to re- issue this Annual Report on

Form 10- K or otherwise make public statements updating our forward- looking statements.