Risk Factors Comparison 2024-03-07 to 2023-03-23 Form: 10-K

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Any investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained in this annual report on Form 10- K before deciding whether to purchase our common stock. Our business, financial condition or results of operations and trading price or value of our securities could be materially adversely affected by these risks if any of them actually occur. This annual report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward- looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this annual report on Form 10- K. Risks Related to Our ~~BusinessIf~~ -- **Business If** we do not successfully implement our business strategy, our business and results of operations will be adversely affected. Our business strategy was formed based on assumptions about the cardiac and vascular diseases market and healthcare reform that might prove wrong. We believe that various demographics and industry- specific trends, including the aging of the general population, growth of capitated payment programs, numbers of undiagnosed patients with cardiac and vascular or other diseases and the importance of codifying vascular disease and potentially other diseases will help drive growth in the cardiac and vascular diseases market and our risk assessment business. However, these demographics and trends, and our assumptions about them, are uncertain. Actual demand for our products and service offerings could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternatives to our products or other risk assessment service providers gain widespread acceptance. Moreover, if our customers do not believe they can benefit from increased capitated payments by identifying sicker patients in their patient pools, they may not see the benefit in screening patients for PAD ~~or heart dysfunction~~ using our products, which would have material and adverse effect on our business, financial condition and results of operations. ~~Recently~~ **For example,** CMS ~~issued an Advance Notice, which proposes to revise~~ **revised** the HCC codes for vascular disease ~~,~~ **and** created uncertainty in the future whether identifying patients with PAD ~~or heart dysfunction~~ will qualify for an increased capitated payment. ~~Although~~ **More specifically, in late March 2023, CMS issued a final 2024 rate announcement with payment changes for** the **Medicare** ~~Advance~~ **Advantage** ~~Notice~~ **and Part D prescription drug programs and under which CMS** is **phasing in a new Medicare Advantage risk adjustment model (2024 model) from the previous model (2020 model) over a three year period. The 2024 model does** not ~~final and~~ **include risk adjusted payments for PAD without complications, which payments many health insurers have previously relied upon for their Medicare Advantage patients under the previous 2020 model. These changes will be phased in as follows: in calendar year 2023, full payment under the 2020 model will continue; in calendar year 2024, 67 % of the 2020 model** is ~~open to public comment~~ **available; in calendar year 2025** , **33 % of** ~~there~~ -- **the** ~~may be uncertainty regarding proper~~ **2020 model is available. Such changes in the regulatory landscape for** HCC codes ~~and reimbursement, which~~ could ~~negatively~~ impact ~~our business~~ **the perceived profitability of using QuantaFlo to aid diagnosis of cardiovascular diseases** . In addition, we may not be able to successfully implement our business strategy. To implement our business strategy, we need to (among other things) find new applications for and improve our products and service offerings and educate healthcare providers and plans about the clinical and cost benefits of our products, all of which we believe could increase acceptance of our products by physicians. ~~Although we recently began distributing licenses to Insulin Insights,~~ **We have ceased marketing of QuantaFlo as an aid in the diagnosis of heart dysfunction and** there is no guarantee that we will ~~be successful~~ **obtain a new FDA 510 (k) clearance** ~~or for the expanded use that our customers will be interested in this software, which we view as complementary to QuantaFlo~~ . **Although we had** ~~We also mutually terminated~~ a distribution agreement for ~~a different~~ **Insulin Insights from Mellitus, we were not able to generate significant revenue and wrote off the entire balance of our $ 2. 5 million investment in December 2023. We will continue our marketing and selling efforts of the** product ~~line in November 2021, and in the fourth quarter of 2021 wrote down $ 1. 2 million of inventory that we had acquired, as our expectations regarding the marketing and distribution of this product line did not prove to be accurate~~ . We may also need to develop or acquire rights to other products and services that would be of interest to our customers given the patient populations they serve. In addition, we are seeking to increase our sales and, in order to do so, might need to continue to expand our direct and distributor sales forces in existing and new territories, ~~all of~~ which could ~~result in our becoming~~ subject **us** to additional or different regulatory requirements ~~,~~ with which we may not be able to comply. Moreover, even if we successfully implement our business strategy, our operating results may not improve or may decline. We may decide to alter or discontinue aspects of our business strategy and may ~~adopt different~~ **adoptdifferent** strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our products obsolete or changes in the regulatory landscape that may undermine the economic rationale for QuantaFlo. Our attempts to alter aspects of our business strategy, such as our ~~recent~~ **prior** entry into an exclusive marketing and distribution agreement and our investments in private companies, may not yield positive effects on our business, results of operations and financial condition. Any delay or failure to implement our business strategy may adversely affect our business, results of operations and financial condition ~~. Our business has been and could continue to be adversely affected by the ongoing COVID- 19 pandemic. Our business has been and could continue to be adversely affected by the global ongoing COVID- 19 pandemic. In the first half of 2020, we experienced decreased test volumes due to" social distancing" and other executive orders mandating" shelter- in- place" or similar restrictions, which limited patient visits by our customers, and restricted participation in trade shows and in- person training, among other items. The testing volume decrease primarily affected 21revenues from our variable- fee licenses, which are based on usage of our QuantaFlo product, often during home visits by our customers. The extent to which COVID- 19 may continue to impact us will depend on~~

~~a variety of factors and future developments, which are highly uncertain and cannot be predicted with confidence, including the duration, scope and severity of the pandemic, business closures or other business disruptions, including supply chain disruptions and labor shortages, and the effectiveness of actions taken in the United States and other countries to contain and treat COVID- 19, including global vaccination efforts. Any recurrence or subsequent " wave " of COVID- 19 cases, including those caused by new variants, could cause other widespread or more severe impacts depending on where infection rates are highest~~ . We predominantly market only one FDA- cleared ~~cardiac and~~ vascular testing product; it may not achieve broad market acceptance or be commercially successful. We may also fail to generate meaningful revenues from our Insulin Insights distribution arrangement, which includes prepaid licenses, or benefit from our recent investments in other companies developing complementary products. We currently actively market only one ~~cardiac and~~ vascular testing product, QuantaFlo ~~, and~~ **. Although we** have an **exclusive marketing and distribution** agreement **for** ~~to exclusively market and distribute~~ Insulin Insights, a ~~new~~ software product line **,** in the United States, including Puerto Rico, for which we ~~have~~ prepaid an aggregate of $ 2. 5 million of software licenses ~~($ 2. 0 million in April 2021~~ **, we did not generate meaningful revenues from distribution of our prepaid licenses,** and ~~$ 0. 5 million~~ **we wrote off our prepaid licenses and a portion of our investment** in December ~~2022~~ **2023** ~~)~~ **. We will continue our marketing and selling efforts of the product** . We also have a minority investment in ~~,~~ NeuroDiagnostics Inc., doing business as SYNAPS Dx, which is developing an additional potentially complementary product offering, Discern, although such product is in early stages and may not ultimately fit with our strategy and customer base. ~~In December 2022, we committed to loan up to $ 5. 0 million through the purchase of a senior convertible promissory note to Monarch, a digital health company whose proprietary product, EndoTool, offers a technology- enabled approach to inpatient glycemic management.~~ We do not have any distribution agreement for Discern ~~or~~ **. In December 2022, we committed to loan up to $ 5. 0 million through the purchase of a senior convertible promissory note to Monarch, a digital health company whose proprietary product,** EndoTool ~~and~~ **, offers a technology- enabled approach to inpatient glycemic management. As of December 31, 2023,** we ~~may never generate meaningful revenues from~~ **loaned $ 4. 5 million out of the $ 5. 0 million loan committed. We do not have any** distribution **agreement** ~~of our prepaid licenses~~ for **EndoTool** ~~Insulin Insights~~ . Moreover, there is a risk that we may never receive repayment of our loans to Mellitus or Monarch, nor receive any benefit from our equity investment in SYNAPS Dx. Accordingly, we expect that revenues from our ~~cardiac and~~ vascular testing product will account for the vast majority of our revenues for at least the next several years. ~~Our cardiac and vascular testing product, including our recent extension of~~ QuantaFlo ~~to aid in diagnosis of heart dysfunction~~ , and any other products we may be offering in the future, may not gain broad market acceptance unless we continue to educate physicians and plans of their benefits. Moreover, even if insurance plans, home health care providers and physicians understand the benefits of cardiovascular and other risk assessment testing, they still may elect not to use our products for a variety of reasons, such as familiarity with other devices and approaches, or the impact of ~~the recent~~ CMS ~~Advance Notice~~ **regulatory revisions** , which **revised** ~~may change~~ the regulatory landscape for HCC codes and could impact the perceived profitability of using QuantaFlo to aid diagnosis of cardiovascular diseases. We may not be successful in gaining market acceptance of a technique measuring comparative blood flows using our proprietary algorithm to indicate flow obstruction as opposed to existing techniques that measure comparative blood pressures using well- accepted criteria to indicate flow obstruction, or imaging techniques that visualize anatomy of the arteries. Providers may also object to renting an examining tool with ongoing monthly payments rather than making a one- time capital purchase or be reluctant to pay monthly fees for tools in the examining room when they have many such tools, such as thermometer and stethoscope that only required one- time minimal purchases. Providers may also not synch their devices as required per their service contracts in the fee- per- test (variable license fees) model, and thus we may not capture all revenue to which we are entitled. If ~~our cardiac and vascular testing product,~~ QuantaFlo ~~, our diabetes software, Insulin Insights,~~ or other products we may offer are not viewed as an attractive alternative to other products, procedures and techniques, we will not achieve significant market penetration or be able to generate significant revenues. To the extent that any products we offer are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted, and our business, operating results and financial condition will be harmed. ~~22Physicians~~ -- **Physicians** and other customers may not widely adopt our products unless they determine, based on experience, long- term clinical data and published peer reviewed journal articles, that the use of our products provides a safe and effective alternative to other existing ABI devices. We believe that physicians and other customers will not widely adopt our vascular testing product or our other products in development or products we distribute unless they determine, based on experience, long- term clinical data ~~and~~ **21and** published peer reviewed journal articles, that the use of such product provides a safe and effective alternative to other existing ABI devices. We cannot provide any assurance that the data collected from our past, current and any future clinical trials will be sufficient to demonstrate that our products are an attractive alternative to other ABI devices or procedures. If we fail to demonstrate safety and efficacy that is at least comparable to other ABI devices that are available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician' s actual experience with our products will vary. We also believe that published peer- reviewed journal articles and recommendations and support by influential physicians regarding our vascular testing product and our other products in development will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published. Accordingly, there is a risk that our products may not be adopted by many physicians, which would negatively impact our business, financial condition and results of operations. Moreover, we acquired exclusive distribution rights to a new product area and may in the future acquire rights to other complementary products. If we are not able to convince potential customers of their benefits, these rights and potential future rights may not generate any meaningful revenues for our company. If healthcare providers are unable to obtain adequate coverage and reimbursement either for procedures performed using our product or patient care incorporating the use of our product, it is unlikely that our product will gain widespread acceptance. Maintaining and growing revenues from our products

and service offerings depends on the availability of coverage and adequate reimbursement from third- party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Healthcare providers that use medical devices such as **QuantaFlo** ~~our cardiac and vascular testing product~~ to test their patients generally rely on third- party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices, or to compensate them for their patient care services. The existence of coverage and adequate reimbursement for the procedures or patient care performed with **QuantaFlo** ~~our cardiac and vascular testing product~~ by third- party payors is central to the acceptance of **QuantaFlo** ~~our cardiac and vascular testing product~~ and any future products. During the past several years, third- party payors have undertaken cost- containment initiatives including different payment methods, monitoring healthcare expenditures, and anti- fraud initiatives. We may not be able to achieve or maintain profitability if third- party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS, which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. **Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures or patient care performed with our vascular testing product.** Future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and / or hospitals or may undermine the economic rationale for using QuantaFlo if there is no increased capitated payment for the vascular diseases it helps diagnose. ~~The recent~~ **For example, the final 2024** CMS **rate announcement for Medicare** ~~Advance~~ **Advantage** ~~Notice has created uncertainty about whether identifying~~ **and Medicare Part D does not include risk- adjustmed** ~~patients~~ **payments** ~~with~~ **for** PAD **without complications** ~~or heart dysfunction will qualify for an increased capitated payment. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures or patient care performed with our vascular testing product~~. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for the procedures or patient care performed with **QuantaFlo** ~~our cardiac and vascular testing product~~ if any payment is made at all. As the portion of the U. S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures or patient care performed with our product will be reimbursed at a cost- effective level. **22QuantaFlo** ~~23Our cardiac and vascular testing product~~ is generally but not specifically approved for reimbursement under any third- party payor codes; if third- party payors refuse to reimburse our customers for their use of our product, it could have a material adverse effect on our business. **QuantaFlo** ~~Our cardiac and vascular testing product~~ is licensed by healthcare providers. They may bill various third- party payors, including governmental healthcare programs, such as Medicare and Medicaid, private insurance plans and managed care programs for procedures in which our testing product is used. Reimbursement is a significant factor considered by healthcare providers in determining whether to license medical devices or systems such as **QuantaFlo** ~~our cardiac and vascular testing product~~. We cannot control whether or not providers who use **QuantaFlo** ~~our cardiac and vascular testing product~~ will seek reimbursement. Therefore, our ability to successfully commercialize our ~~cardiac and~~ vascular testing product could depend on the coverage and adequacy of reimbursement from these third- party payors. Currently, our **QuantaFlo** ~~cardiac and vascular testing product~~ is generally but not specifically approved for any particular reimbursement code. Although most of our customers report being covered and reimbursed by third- party payors consistently for procedures using a variety of different reimbursement codes, there is a risk that third- party payors may disagree with the reimbursement under a particular code. In addition, some potential customers have deferred renting our product given the uncertainty regarding reimbursement. We do not track denial of requests for reimbursement made by the users of our product. It is our belief that such denials have occurred and might occur in the future with more or less frequency. Even if our product and procedures are often currently covered and reimbursed by third- party payors and Medicare, problems for customers to receive reimbursement or adverse changes in payors' coverage and reimbursement policies that affect our product could harm our ability to market our vascular testing product. Obtaining approval for a particular reimbursement code is time consuming and can be costly. Accordingly, at this time, and given the way we intend our **QuantaFlo** ~~cardiac and vascular testing product~~ to be used, we do not intend to pursue formal approval for **QuantaFlo** ~~our cardiac and vascular testing product~~ for any particular code. Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third- party payors. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed, such as those utilized by Medicare and in many privately managed care systems, the cost of our product will be justified and incorporated into the overall cost of the procedure. We rely heavily upon the talents of a small number of key personnel, the loss of whom could severely damage our business. Our performance depends to a large extent on a small number of key scientific, technical, managerial and marketing personnel. We do not maintain key man insurance for any of our personnel. The loss of the services of any of these key personnel could still severely damage our business prospects, which could have a material adverse effect on our financial condition and results of operations. We rely on a small number of employees in our direct sales force and face challenges and risk in managing and maintaining our distribution network and the parties who make up that network. We face significant challenges and risks in managing our distribution network and retaining the parties who make up that network. We had ~~81~~ **56** sales and marketing employees as of December 31, ~~2022~~ **2023** . If any of our sales or marketing force were to resign, our sales could be adversely affected. We may need to seek out alternatives, such as increasing our direct sales and marketing force or contracting with external independent sales representatives or enter another distributor relationship. There is no guarantee that we would be successful in our efforts to find independent sales representatives or a large distributor, or that we would be able to negotiate contract terms favorable to us. Failure to hire or retain qualified direct sales and marketing personnel

or independent distributors would prevent us from expanding our business and generating revenues, which would have a material adverse effect on our ability to achieve or maintain profitability. ~~24To~~ **23To** adequately commercialize our products and any new products we add, we may need to increase our sales and marketing network, which will require us to hire, train, retain and supervise employees and other independent contractors. We are currently exploring other sales models to generate revenues from our products in addition to the leasing model, such as our fee per test model. We also ~~have exclusive distribution rights to a new product area and~~ may in the future acquire rights to other complementary products. As we increase our marketing efforts to pursue these new strategies and expand our efforts to target insurance plans that serve Medicare Advantage members, we may need to increase our sales and marketing network. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives, independent sales representatives or distributors with significant technical knowledge about our product, in addition to coordinating networks of contract medical assistants and other personnel to staff health and wellness fairs and physicians' offices in fee- for- service models. New hires and independent contractors require training, supervision and take time to achieve full productivity. If we fail to train and supervise new hires adequately, or if we experience high turnover in our sales force or trained professionals in the future, we cannot be certain that we will maintain or increase our sales. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize **QuantaFlo** ~~our cardiac and vascular testing product~~ or our other products and service offerings in development, which would adversely affect our business, results of operations and financial condition. We do not require our customers to enter into long- term licenses or maintenance contracts for our products or services and may therefore lose customers on short notice. Our business is primarily based on a leasing model rather than an outright sale of our products although we also generate variable fee revenues, which are based on usage (fee- per- test). Our pricing is based on data collected on use rates and third-party payment rates to physicians and facilities for the use of our product. We require no down payment, long- term commitment or maintenance contract or fees from our customers and replace damaged products free of charge in the service model. If we lose current customers on short notice, we may not be able to find new customers to replace them with in a timely manner and that could adversely affect our business, results of operations and financial condition. In addition, our business model of replacing damaged products free of charge may prove to be costly and affect the profitability of our service model. In our fee- per- test model, we rely on our customers to comply with the terms of service that require them to synchronize devices on a regular and routine basis such that we are able to invoice them for the tests done using our device. There is a risk that customers use our device without synching as agreed, which could lead to inadequate billing and failing to capture revenue based on actual usage. Although we have procedures in place to limit usage of our device if it has not synchronized for a period of time, there is no guarantee that our customers will act in compliance with their terms of service and we may not appropriately capture all per- test fees to which we are entitled. We are exposed to risk as a significant portion of our revenues and accounts receivables are with a limited number of customers. A limited number of customers account for a significant portion of our revenues and accounts receivable. For the year ended December 31, ~~2022~~ **2023** , two customers accounted for **36** ~~40. 4 %, and 29~~ . 0 % **, and 34. 9 %** of our revenues, and as of December 31, ~~2022~~ **2023** , three customers accounted for ~~26~~ **27** . ~~8~~ **5** %, ~~25~~ **27** . ~~9~~ **5** % and ~~16~~ **23** . ~~8~~ **6** % of our accounts receivable. If our largest customers were to cease using or stop payment for our vascular testing devices, it would have a material adverse effect on our revenues and / or our accounts receivable. Our efforts to diversify and potentially expand our product offering such as by distributing licenses to Insulin Insights, are preliminary in nature. This concentration of revenues and accounts receivable among a limited number of customers represents a significant risk. We rely on a small number of independent suppliers and facilities for the manufacturing of **QuantaFlo** ~~our cardiac and vascular testing product~~ . Any delay or disruption in the supply of the product or facility may negatively impact our operations. We manufacture **QuantaFlo** ~~our cardiac and vascular testing product~~ through a small number of independent contractors based in the United States. We also purchase inventory under our exclusive marketing and distribution agreement with Mellitus. The loss or disruption of our relationships with outside vendors and suppliers could subject us to substantial delays in the delivery to customers. Our current contractor manufacturers source some supplies from China and should these outside vendors encounter ~~issues~~ **24issues** due to supply chain disruptions as a result of the ~~ongoing~~ **global health emergency such as** COVID- 19 pandemic or ~~25otherwise~~ -- **otherwise** , we believe alternative suppliers should be available. However, significant delays in the delivery of our product or inventory to us could result in possible cancellation of orders and the loss of customers. Although we expect our vendors and suppliers to comply with our contract terms, we do not have control over such parties. Our inability to provide a product that meets delivery schedules could have a material adverse effect on our reputation in the industry, which could have a material adverse effect on our financial condition and results of operations. Further, **QuantaFlo** ~~our cardiac and vascular testing product~~ is manufactured in the United States in a limited number of facilities. If an event occurred that resulted in material damage to these manufacturing facilities or our manufacturing contractors lacked sufficient labor to fully operate their facilities, we may be unable to transfer the manufacture of **QuantaFlo** ~~our cardiac and vascular testing product~~ to another facility or location in a cost- effective or timely manner, if at all. This potential inability to transfer production could occur for a number of reasons, including but not limited to a lack of necessary relevant manufacturing capability at another facility, or the regulatory requirements of the FDA or other governmental regulatory bodies. Even if there are many qualified contract manufacturers available around the country and our product is relatively easy to manufacture, such an event could have a material adverse effect on our financial condition and results of operations. We will need to generate significant revenues to remain profitable. We will need to generate significant sales to maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our financial performance will likely be adversely affected. Our future financial performance will depend in part on the successful improvements and software updates to **QuantaFlo** ~~our cardiac and vascular testing product~~ on a cost- effective basis. Our future financial performance will depend in part on our ability to influence, anticipate, identify and respond to changing user

preferences and needs and the technologies relating to the care and treatment of vascular problems. We can provide no assurances that **QuantaFlo** ~~our cardiac and vascular testing product~~ will achieve significant commercial success and that it will gain meaningful market share. We may not correctly anticipate or identify trends in user preferences or needs or may identify them later than competitors do. In addition, difficulties in manufacturing or in obtaining regulatory approvals may delay or prohibit improvements to **QuantaFlo** ~~our cardiac and vascular testing product~~ or our other products in development. Further, we may not be able to develop improvements and software updates to **QuantaFlo** ~~our cardiac and vascular testing product~~ at a cost that allows us to meet our goals for profitability. Service costs relating to our product may be greater than anticipated, rentals may be returned prior to the end of the license term, and we may be required to devote significant resources to address any quality issues associated with **QuantaFlo** ~~our cardiac and vascular testing product~~. Failure to successfully introduce, improve or update our products on a cost- effective basis, or delays in customer decisions related to the evaluation of our products could cause us to lose market acceptance and could materially adversely affect our business, financial condition and results of operations. One of our business strategies is developing additional products and service offerings that allow healthcare providers to deliver cost- effective wellness programs and receive increased compensation for their services. The development of new products and service offerings involves time and expense and we may never realize the benefits of this investment. As part of our business strategy, we intend to develop additional products and service offerings that allow healthcare providers to deliver cost- effective wellness programs and receive increased compensation for their services. Such product and service offering development may require substantial investments and we may commit significant resources and time before knowing whether our efforts will translate into profits for our company. We may continue to choose to invest some of our cash resources in other entities that may have complementary technologies or product offerings and may not realize the benefit of such investments. For example, in ~~November~~ **December** ~~2021~~ **2023 ,** we ~~mutually terminated a distribution agreement for a product line and~~ wrote ~~down~~ **off the** $ ~~1.~~2 **. 5** million ~~of inventory~~ **prepayment for Insulin Insights software licenses as we were not able to generate meaningful revenues, and also took at $ 0. 6 million impairment charge on our investment in Mellitus** . It is possible that our development efforts will not be ~~successful~~ **25successful** and that we will not be able to develop new products or service offerings, either alone or in partnership ~~26with~~ -- **with** others, or if developed that we will obtain the necessary regulatory approvals for commercialization. Even if we receive necessary regulatory approvals, there is no guarantee that such approved products or any new service offerings will achieve market acceptance and we may never realize the benefits of any investment in this strategy. We have used our cash resources to invest in other companies, and there is no guarantee that we will be repaid on maturity nor realize any other expected benefits from such investments, which could harm our business. From time to time, we have invested, and may in the future invest, in other companies with potentially complementary products or technologies. For example, in September and October 2020, we made investments in Mellitus and SYNAPS Dx, two private companies working in other product areas, ~~Discern and~~ Insulin Insights (for which we have an exclusive distribution agreement) and **Discern, and** in December 2022, we extended a loan to Monarch, maker of **the software product** EndoTool. There can be no assurance that the businesses we invest in will become profitable or remain so or that we will realize any financial benefit from our investments, including whether or not we will distribute Discern and EndoTool or ~~realize any benefits from our efforts to distribute Insulin Insights, or~~ that we will be repaid upon maturity of our loans **. Notably, we recently wrote- off our $ 2. 5 million prepayment for Insulin Insights software licenses as we were not able to generate meaningful revenues, and also took at $ 0. 6 million impairment charge on our investment in Mellitus** . Additionally, investments in privately held companies are inherently risky, in some instances because the markets for the technologies or products these companies have under development may never materialize or achieve expectations. If these companies do not succeed, we may be forced to record **additional** impairment charges and could lose some or all of our investment in these companies. Further, we may need to divest our investments or increase our investment to become a controlling interest sooner than we may like in order to comply with regulations regarding the amount of our assets represented by minority investments. These regulatory requirements may not always coincide with our business objectives and could adversely affect our investments and strategy. Risks Related to Our Legal and Regulatory EnvironmentOur business is subject to many laws and government regulations governing the manufacture and sale of medical devices, including the FDA' s 510 (k) clearance process, and laws and regulations governing patient data and information, among others. Our ~~cardiac and~~ vascular testing product and any future medical devices that we may develop or services that we may offer are subject to extensive regulation in the United States by the federal government, including by the FDA. For example, our operations are subject to regulations governing packaging and labeling requirements, adverse event reporting, quality system and manufacturing requirements, clinical testing and recalls. For a discussion of the relevant regulatory regime, see " Business — Government Regulation. " We cannot assure that any new medical devices or new uses or modifications for **QuantaFlo** ~~our cardiac and vascular testing product~~ that we develop **, including our planned 510 (k) for the use of QuantaFlo to enable expanded labeling as an aid in the diagnosis of other cardiovascular diseases in addition to PAD,** will be cleared or approved in a timely or cost- effective manner, if cleared or approved at all. Even if such clearances or approvals are received, they may not be for all indications. Because medical devices may only be marketed for cleared or approved indications, this could significantly limit the market for that product and may adversely affect our results of operations. Furthermore, although QuantaFlo has received FDA clearance, we must make our own determination regarding whether a modification to the device requires a new clearance **. For example, in January 2024, we announced that we are seeking a new 510 (k) clearance from the FDA for the expanded use of QuantaFlo intended to enable expanded labeling as an aid in the diagnosis of other cardiovascular diseases in addition to PAD** . We cannot guarantee that the FDA will agree with our decisions not to seek clearances for particular device modifications or that we will be successful in obtaining 510 (k) clearances for modifications. Any such additional clearance processes with the FDA could delay our ability to market a modified product and may adversely affect our results of operations. We also may need to undertake a recall of any modified product that has been distributed. ~~The~~ **26The** FDA may change its policies, adopt additional regulations, or revise existing

regulations, in particular relating to the 510 (k) clearance process. The FDA may change its policies, adopt additional regulations, or revise existing regulations, each of which could prevent or delay ~~pre- market~~ **premarket** approval or 510 (k) clearance of a device, or could impact our ability to market our currently cleared device. **For example, in February 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, 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 International Organization of Standardization, or ISO, ISO 13485 standard. The amended regulation is referred to as the Quality Management System Regulation, and is effective February 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. Further,** ~~Future~~ **future** reforms could require us to file new 510 (k) ~~clearances~~ **s** and could increase the total number of 510 (k) ~~clearances~~ **s** to be filed. We cannot predict what effect these reforms will have on our ability to obtain 510 (k) clearances in a timely manner. We also cannot predict the nature of other regulatory reforms and their resulting effects on our business. ~~27Our~~ -- **Our** business is subject to unannounced inspections by FDA to determine our compliance with FDA requirements. FDA inspections can result in inspectional observations on FDA' s Form- 483, warning letters, untitled letters or other forms of more significant enforcement action. More specifically, if FDA concludes that we are not in compliance with applicable laws or regulations, or that our vascular testing product or any future medical device we develop is ineffective or poses an unreasonable health risk, the FDA could: ● require us to notify health professionals and others that our devices present unreasonable risk of substantial harm to public health; ● order us to recall, repair, replace or refund the cost of any medical device that we manufactured or distributed; ● detain, seize or ban adulterated or misbranded medical devices; ● refuse to provide us with documents necessary to export our product; ● refuse requests for 510 (k) clearance or ~~pre- market~~ **premarket** approval of new products or new intended uses; ● withdraw 510 (k) ~~clearances that are already granted~~ **premarket approvals we may receive** or reclassify our device; ● impose operating restrictions, including requiring a partial or total shutdown of production; ● enjoin or restrain conduct resulting in violations of applicable law pertaining to medical devices; and / or ● assess criminal or civil penalties against our officers, employees or us **. Following correspondence from FDA questioning our reliance on letters- to- file for the expansion into heart dysfunction, we are now seeking a new 510 (k) clearance from the FDA for the expanded use of QuantaFlo to enable expanded labeling** . If the FDA concludes that we failed to comply with any regulatory requirement during an inspection **or otherwise** , it could have a material adverse effect on our business and financial condition. We could incur substantial expense and harm to our reputation, and our ability to introduce new or enhanced products in a timely manner could be adversely affected. ~~We~~ **27We** may rely on third parties to support certain aspects of our clinical trials **and regulatory processes** . If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory clearance or approval or commercialize our products, and our business could be substantially harmed. We ~~have~~ **may** ~~retained~~ -- **retain** the services of knowledgeable external service providers, including consultants and clinical research organizations, to develop and supervise our clinical trials and regulatory processes. ~~We will remain dependent upon these~~ **These** third- party contract research organizations and consultants ~~to~~ **may** carry out portions of our clinical and preclinical research studies and regulatory filing assistance **and as** ~~for the foreseeable future. As~~ a result, **if retained,** we ~~have had and~~ will have less control over the conduct of the clinical trials, the timing and completion of the trials, the required reporting of adverse events, and the management of data developed through the trials than would be the case if we were relying entirely on our own staff. Outside parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials. Failure by these third parties to comply with regulatory requirements or to meet timing expectations may require us to repeat clinical trials or preclinical studies, which would delay the regulatory clearance or approval process, or require substantial unexpected expenditures. If we are found to have improperly promoted our products for off- label uses, we may become subject to significant fines and other liability. FDA and other regulatory agencies strictly regulate the promotional claims that may be made about medical devices. For example, devices cleared under section 510 (k) cannot be marketed for any intended use that is outside of FDA' s substantial equivalence determination for such devices. Physicians nevertheless may use our products on their patients in a manner that is inconsistent with the intended use cleared by FDA. If we are found to have promoted such ~~28~~ " off- label " uses, we may become subject to significant government fines and other related liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. Although part of our business strategy is based on payment provisions enacted under government healthcare reform, we also face significant uncertainty in the industry regarding the implementation, transformation or repeal and replacement of the Health Care Reform Law. Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. For example, the Health Care Reform Law brought a new way of doing business for providers and health insurance plans, shifting the focus from fee for service programs to capitated programs that pay a monthly fee per patient. The Health Care Reform law also provided for higher risk factor adjustment payments for sicker patients who have conditions that are codified, as well as economic benefits for achieving certain quality of care measurements. For a discussion of healthcare reform activity, see " Business — Government Regulation — Healthcare Reform. " We believe that the Health Care Reform Law measures are mainly positive for our business given the ability of **QuantaFlo** ~~our cardiac and vascular testing product~~ to measure blood flow in an in- office setting, which can assist doctors and other providers to suspect PAD and other vascular diseases. However, we cannot predict what changes will now be made, and if these features will be repealed. If changes are made to the Health Care Reform Law, or it is repealed altogether

without a comparable replacement, such that there are no incentives for identifying sicker patients, it would negatively affect our business prospects and strategy, and could materially adversely affect our business, financial condition and results of operations. Further, the Health Care Reform Law encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device acquisitions and the consolidation of medical device suppliers used by hospitals. Changes to or repeal of the Health Care Reform Law could adversely affect our financial results and business. ~~The~~ **28The** applicable healthcare fraud and abuse laws and regulations, along with the increased enforcement environment, may lead to an enforcement action targeting us, which could adversely affect our business. We are subject to various healthcare fraud and abuse laws and regulations, as described " Business — Government Regulation — Healthcare Fraud and Abuse. " We may be subject to liability under such laws and may also be subject to liability for any future conduct that is deemed by the government or the courts to violate these laws, including significant administrative, criminal and civil penalties, damages, fines, disgorgement, imprisonment, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid, additional reporting obligations and oversight if subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of operations. Additionally, the government has continued to pursue an increasing number of enforcement actions. This increased enforcement environment may increase scrutiny of us, directly or indirectly, and could increase the likelihood of an enforcement action targeting us. These customers include parties that bill Federal healthcare programs for use of our product, all of whom may be subject to government scrutiny. Finally, to the extent that any of the agreements are breached or terminated, our business may experience a decrease in revenues. In addition, to the extent that our customers, many of whom are providers, may be affected by this increased enforcement environment, our business could correspondingly be affected. It is possible that a review of our business practices or those of our customers by courts or government authorities could result in a determination with an adverse effect on our business. We cannot predict the effect of possible future enforcement actions on our business. ~~29Our~~ -- **Our** ability to use NOL, carryforwards to offset future taxable income may be subject to limitations. As of December 31, ~~2022~~ **2023** , we had no federal NOL carryforwards. Federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. In addition, under Section 382 of the Code, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " which is generally defined as a greater than 50 % change, by value, in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards and other pre- change tax attributes to offset its post- change income or taxes may be limited. We have completed a formal Code Section 382 study for the period January 1, 2012 through June 30, 2019 and we believe an ownership change has occurred. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. We have had material weaknesses in our internal control over financial reporting. Although we have ~~remedied~~ **remediated** our prior material weaknesses, if we identify additional material weaknesses in the future, or if our former material weaknesses recur, it could have an adverse effect on our company. In prior years, we have identified certain material weaknesses in connection with management' s evaluation of our internal control over financial reporting that we have ~~remedied~~ **remediated** . These weaknesses have included issues arising from our size and inability to segregate duties; ineffective design of certain of our information technology and change management controls; insufficient controls to validate the completeness and accuracy of underlying data; insufficient protocols and procedures to retain adequate documentary evidence related to the timely review and approval of manual journal entries and those supporting the design and operating effectiveness of certain important management review controls; a lack of controls to identify and analyze related party transactions; a lack of technical accounting competence; and inadequate procedures and controls to appropriately comply with, and account for, certain payroll tax withholdings and related expenses. Although we have ~~remedied~~ **remediated** our prior material weaknesses, we cannot assure you that we have identified all material weaknesses or that we will not in the future have additional, or recurrence of our prior, material weaknesses in our internal control over financial reporting. If we have additional material weaknesses in our internal control over ~~financial~~ **29financial** reporting in the future, or if our former material weaknesses recur, it could have an adverse effect on our company. Risks Related to Our Intellectual PropertyOur success largely depends on our ability to obtain and protect the proprietary information on which we base our product. Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others' patents and patent applications necessary to develop our product. If our patent or any future patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our product was to be limited, our ability to continue to manufacture and market our product could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know- how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors. ~~30As~~ **As** of December 31, ~~2022~~ **2023** , we have been issued, or have rights to, one U. S. patent. The patent we hold may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on this patent. These risks are also present for the process we use for manufacturing our product. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our product, either in the United States or in international markets. The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. We may institute, become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product and technology, including interference or derivation

proceedings before the U. S. Patent and Trademark Office, or USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our product and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. The defense and prosecution of intellectual property suits, USPTO proceedings and related legal and administrative proceedings are both costly and time consuming. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights that are important or necessary to the development of our vascular testing product or any future products. It may be necessary for us to use the patented or proprietary technology of a third party to commercialize our own technology or products, in which case we would be required to obtain a license from such third party. A license to such intellectual property may not be available or may not be available on commercially reasonable terms, which could have a material adverse effect on our business and financial condition. ~~We~~ **30We** may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Although we try to ensure that we and our employees and independent contractors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or that these employees or independent contractors have used or disclosed intellectual property in violation of the rights of others. These claims may cover a range of matters, such as challenges to our trademarks, as well as claims that our employees or independent contractors are using trade secrets or other proprietary information of any such employee' s former employer or independent contractors. Although we do not expect the resolution of the proceeding to have a material adverse effect on our business or financial condition, litigation to defend ourselves against claims can be both costly and time consuming, and divert management' s attention away from growing our business. In addition, while it is our policy to require our employees and independent contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. ~~31If~~ **If** we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also generally enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party infringed a patent or illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed. Risks Related to Our Common StockOur executive officers, directors and significant stockholders, if they choose to act together, have the ability to substantially influence the outcome of all matters submitted to stockholders for approval. Our executive officers, directors and significant stockholders beneficially own in the aggregate shares representing approximately ~~47~~ **32** . 0 % of our common stock as of March ~~16~~ **1** , ~~2023~~ **2024** . If these stockholders choose to act together, they are able to substantially influence the outcome of all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, can impact the election of directors ~~and~~ **31and** approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership control may: ● delay, defer or prevent a change in control; ● entrench our management and the board of directors; or ● impede a merger, consolidation, takeover or other business combination involving us that other stockholders may desire. Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of

directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by ~~32making --~~ **making** it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: ● allow the authorized number of our directors to be changed only by resolution of our board of directors; ● allow for a classified board of directors; ● establish advance notice requirements for stockholders proposal that can be acted on at stockholder meeting and nominations to our board of directors; and ● limit who may call stockholder meetings. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. Our amended and restated bylaws designate exclusive forums for the adjudication of certain disputes, which could limit our stockholders' ability to bring claims in a judicial forum it finds favorable for disputes with us or our directors, officers, or employees. Our amended and restated bylaws provide that a state or federal court located within the State of Delaware is the sole and exclusive forum for: ● any derivative action or proceeding brought on our behalf; ● any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee or stockholder of our company to us or our stockholders; **32** ● any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our charter or our bylaws, as to which the General Corporation Law of the State of Delaware confers jurisdiction on the Court of Chancery of the State of Delaware; and ● any action asserting a claim governed by the internal affairs doctrine. Our amended and restated bylaws further provide that a federal district court of the United State is the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These provisions further provide that any person or entity that acquires any interest in shares of our capital stock will be deemed to have notice of and consented to these provisions. These provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find any of these provisions to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Our stock price has been and is likely to continue to be volatile. The stock market in general and the market for smaller medical device companies in particular have experienced extreme volatility that has often been unrelated to the ~~33operating --~~ **operating** performance of particular companies. As a result of this volatility, you may not be able to sell your common stock. The market price for our common stock may be influenced by many factors, including: ● the success of competitive products, services or technologies; ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems; ● market conditions in the medical device sector; ● general economic, industry and market conditions; and ● the other factors described in this " Risk Factors " section. In the past, following periods of volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Due to the potential volatility of our stock price, we may be the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. ~~Because~~ **33Because** we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain. We have never declared or paid cash dividends on our capital stock. We anticipate that we will retain our earnings, if any, for future growth and therefore do not anticipate paying cash dividends in the future. As a result, only appreciation of the price of our common stock will provide a return to stockholders. ~~34General --~~ **General** Risk FactorsBecause we operate in an industry with significant product liability risk, and we may not be sufficiently insured against this risk, we may be subject to substantial claims against our product or services that we may provide. The development, manufacture and sale, lease or use of products or provision of services in a medical setting entails significant risks of product liability or other negligence or malpractice claims. Although we maintain insurance to cover us in the event of liability claims, and as of the date of this annual report on Form 10-K, no such claims have been asserted or threatened against us, our insurance may not be sufficient to cover all possible future liabilities regarding our product, or from performing tests with our product or other non- proprietary products. Accordingly, we may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale, lease or use of our products or the provision of services. A successful product liability or negligence or medical malpractice claim or series of claims brought against us that result in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations. In addition, product liability and other malpractice insurance is expensive and may not always be available to us on acceptable terms, if at all. We may implement a product recall or voluntary market withdrawal or stop shipment of our product due to product defects or product enhancements and modifications, which would significantly increase our costs. The manufacturing and marketing of **QuantaFlo** ~~our cardiac and vascular testing product~~ and any future products that we may develop involves an inherent risk that our products may prove to be defective. In that event, we may voluntarily implement a recall or market withdrawal or stop shipment or may be required to do so by a regulatory authority. A recall of **QuantaFlo** ~~our cardiac and vascular testing product~~ or one of our future products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall or as a result of the damage to our reputation for quality and

safety. Further any product recall, voluntary market withdrawal or shipment stoppage of our product could significantly increase our costs and have a material adverse effect on our business. If we fail to properly manage our anticipated growth, our business could suffer. Our growth has placed, and will continue to place, a significant strain on our management and on our operational and financial resources and systems. Failure to manage our growth effectively could cause us to over- invest or under- invest and result in losses or weaknesses. Additionally, our anticipated growth will increase the demands placed on our supplier, resulting in an increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. An information security incident, including a cybersecurity breach, could have a negative impact on our business or reputation. To meet business objectives, we rely on both internal information technology systems and networks, and those of third parties and their vendors, to process and store sensitive data, including confidential research and patient data that may be subject to legal protection. The extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of these information technology systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We continually assess these threats and make investments ~~to~~ **34to** increase internal protection, detection, and response capabilities, as well as ensure our third- party providers have required capabilities and controls, to address this risk. To date, we have not experienced any material impact to our business or operations resulting from information or cybersecurity attacks; however, because of the frequently changing attack techniques, along with the increased volume and sophistication of the attacks, there is the potential for us to be adversely impacted. This impact could result in reputational, competitive, operational or other business harm as well as financial costs and regulatory action. ~~35Adverse~~ -- **Adverse** developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. **Although** ~~At December 31, 2022,~~ we **took** ~~held approximately $ 30. 1 million of U. S. Treasury bills, and the remainder of our cash was held in non- interest bearing bank accounts, primarily at First Republic Bank and Edward Jones, and we are taking~~ steps to diversify ~~further. Although we~~ **our banking relationships and** are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our lenders or counterparties to any financial instruments (such as letters of credit) were to be placed into receivership, we may be unable to access such funds. In addition, if any of our customers, suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of government securities with interest rates below current market interest rates, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect our company, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile. We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition. ~~36We~~ **35We** operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products or service offerings could become obsolete or uncompetitive. The market for medical systems, equipment and other devices and services is highly competitive. We compete with many medical service companies in the United States and internationally in connection with our vascular testing product and products under development. We face competition from numerous companies in the diagnostic area, as well as competition from academic institutions, government agencies and research institutions. Most of our current and potential competitors have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize **QuantaFlo** ~~our cardiac and vascular testing product~~ or any other future products, if and when they are approved for sale or license, or service offerings that we may develop. Our future success will depend largely upon our ability to anticipate and keep pace with developments and advances. Current or future competitors could develop alternative technologies or products or service offerings that are more effective, easier to use or more economical than what we

or any potential licensee develop. If our technologies or products or service offerings become obsolete or uncompetitive, our related revenues would decrease. This would have a material adverse effect on our business, financial condition and results of operations. Changes in, or interpretations of, tax rules and regulations may adversely affect our effective tax rates. We are subject to income and other taxes in the United States. Significant judgment is required in evaluating our provision for income taxes or in claiming tax credits or taking other tax positions. During the ordinary course of business, there are many transactions for which the ultimate tax determination is uncertain or if we were to be audited, the Internal Revenue Service may not agree with our tax positions. For example, there could be changes in the valuation of our deferred tax assets and liabilities or changes in the relevant tax, accounting, and other laws, regulations, principles and interpretations. Although we believe our tax estimates and practices are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income tax provisions and accruals. The results of an audit or litigation, or the effects of a change in tax policy in the United States, could have a material effect on our operating results in the period or periods for which that determination is made. In addition, new income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our earnings. Any new taxes could adversely affect our business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. We are currently a " smaller reporting company, " and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors. We are a " smaller reporting company, " as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will remain a smaller reporting company for so long as either our annual revenues are less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business day of our second fiscal quarter, or our ~~annual revenues are greater than $ 100. 0 million during the most recently completed fiscal year and our~~ voting and non- voting common stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter. For so long as we remain a smaller reporting company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include: ● being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; and ● reduced disclosure obligations regarding executive compensation. We have taken advantage of reduced reporting burdens in this annual report on Form 10- K. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our