Risk Factors Comparison 2024-03-29 to 2023-03-31 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the risks described below, in addition to the other information included or incorporated by reference in this Form 10- K, including our financial statements and the related notes. If any of the following risks materialize, our business, financial condition, results of operations or growth prospects could be materially adversely affected, and the value of an investment in our common stock may decline significantly. Risks Related to Our Financial Condition, Liquidity and Indebtedness Our financial condition, including our substantial indebtedness, raises substantial doubt regarding our ability to continue as a going concern. Since inception, we have not achieved profitable operations or positive cash flows from operations. Our accumulated deficit totaled $ ~~607~~ **668** . ~~2~~ **9** million as of December 31, ~~2022~~ **2023** . During the year ended December 31, ~~2022~~ **2023** , we had a net loss of $ ~~62~~ **61** . ~~5~~ **6** million and negative cash flows from operations of $ ~~48~~ **40** . ~~7~~ **2** million. As of December 31, ~~2022~~ **2023** , we had $ ~~45~~ **13** . ~~6~~ **2** million in cash and cash equivalents **and working capital of $ 12. 4 million** . Additionally, we have a substantial amount of indebtedness ~~primarily~~ comprised of $ ~~56~~ **67** . 6 million aggregate principal amount of **5. 00 %** Notes and **$ 0. 7 million** ~~a secured promissory note in an~~ aggregate principal amount of **2** ~~$ 34~~ . **50 %** ~~9 million (the " Secured Note~~ **Notes outstanding** ~~")~~ . As a result of our financial condition, we have determined that, as of the date of this Form 10- K filing, there is substantial doubt about our ability to continue as a going concern, as we do not currently have adequate financial resources ~~to pay our outstanding debt obligation under the Notes and~~ to fund our forecasted operating costs for at least twelve months from the **date of the** filing of this Form 10- K. The report of our independent registered public accountant on our financial statements as of **December 31, 2023 and 2022** and for **each of the** ~~the~~ **three** years **in the period** ended December 31, ~~2022~~ **2023** ~~and 2021~~ also includes explanatory language describing the existence of substantial doubt about our ability to continue as a going concern. The presence of this going concern explanatory language could adversely affect our ability to raise additional debt or **19s** equity financing, as well as to further develop and market our products, all of which could have a material adverse impact on our business, results of operations and financial condition. See Part II, Item 7, ~~"~~ Management ~~'~~ **'** s Discussion and Analysis of Financial Condition and Results of Operations- **"** Capital Resources and Liquidity " **and Part II, Item 8, Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation** of this Form 10- K ~~and Note 1, Organization and Nature of Business; Basis of Presentation; Principles of Consolidation~~ for additional information. Management currently believes that it will be necessary for us to secure additional funds to continue our existing business operations and to fund our obligations. ~~We may choose~~ **While we continue** to ~~raise~~ **explore** additional **funding in the form** ~~funds during 2023 through a variety~~ of **potential** equity and / or debt financing arrangements ~~; however, there are currently no commitments in place for~~ **or similar transactions** ~~future financing and there can be no assurance that we will be able to obtain funds on commercially acceptable terms, if at all. We are in default of payment obligations under the terms of our Notes, which matured on March 15, 2023 and became due and payable. The Notes matured on March 15, 2023 and became due and payable. On March 9, 2023, the Company entered into a Forbearance Agreement (the " Forbearance Agreement "), which became effective on March 13, 2023, with the holders of approximately 85 % of the Company' s outstanding Notes (collectively, the " Ad Hoc Noteholder Group ") and, the trustee for the Notes (the " Trustee "). Other holders of the Notes may become a party to the Forbearance Agreement by executing and delivering to the Company a joinder to the Forbearance Agreement. Pursuant to the Forbearance Agreement, the members of the Ad Hoc Noteholder Group have agreed, and have directed the Trustee, to forbear from exercising their rights and remedies under the indenture governing the Notes (the " Indenture ") in connection with certain events of default under the Indenture, including, but not limited to, the failure to timely pay in full the principal of any Note when due and payable on March 15, 2023 and the failure to pay any interest on any Note when due and payable. The Forbearance Agreement is effective for the period commencing on March 13, 2023 and ending on March 29, 2023. On March 29, 2023, the Company and the Ad Hoc Noteholder Group agreed to further extend the forbearance period under the Forbearance Agreement to April 5, 2023. See Part II, Item 7, " Management' s Discussion and Analysis of Financial Condition and Results of Operations- Capital Resources and Liquidity- Convertible Notes " of this Form 10- K for additional information regarding the Forbearance Agreement. As discussed in this Form 10- K, there is substantial doubt about our ability to continue as a going concern, as we do not currently have adequate financial resources to pay our outstanding debt obligations under the Notes and to fund our forecasted operating costs for at least twelve months from the filing of this Form 10- K. While the Company continues to explore additional funding~~ , there can be no assurance the necessary financing will be available on terms acceptable to **us** ~~the Company~~ , or at all. If **we** ~~the Company raises~~ **raise** funds by issuing equity securities, dilution to stockholders may result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of common stock. If **we** ~~the Company raises~~ **raise** funds by issuing **additional** debt ~~securities~~ , ~~these~~ **it is likely any new** debt ~~securities~~ would have rights, preferences and privileges senior to ~~those of preferred and~~ common stockholders. The terms of ~~debt securities or borrowings~~ **borrowing** could impose significant restrictions on our operations. ~~Similarly, there can be no assurance that market conditions and refinancing alternatives will be sufficient to settle or refinance the Notes.~~ The capital markets have in the past, and may in the future, experience periods of upheaval that could impact the availability and cost of equity and debt financing. ~~Financial market instability or disruptions to the banking system due to bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and Signature Bank, may also adversely affect our ability to enter into financing arrangements and facilities.~~ In addition, ~~recent and anticipated future~~ increases in federal fund rates set by the Federal Reserve **, such as the significant increases experienced throughout 2022 and 2023** , which serve as benchmark rates on borrowing, and other general economic

conditions **have impacted, and in the future** may **further** impact **,** the cost of debt financing or refinancing existing debt. **If** ~~Although we are actively considering all available strategic alternatives to maximize value, if~~ we are unable to obtain adequate capital resources to fund operations ~~and address our outstanding debt obligations under the Notes~~ , we would not be able to continue to operate our business pursuant to our current plans ~~. In particular, if we are unable to address our outstanding debt obligations under the Notes, or otherwise obtain an extension under the Forbearance Agreement, prior to the expiration of the forbearance period specified in the Forbearance Agreement, then the Trustee may exercise its rights and remedies under the Indenture and declare the principal of, and all accrued and unpaid interest on, the Notes to be due and payable immediately~~ . This may require us to, among other things, materially modify our operations to reduce spending; sell assets or operations; delay the implementation of, or ~~revising~~ **revise** certain aspects of, our business strategy; ~~file a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code in order to implement a restructuring;~~ or discontinue our operations entirely. ~~Additionally, we cannot provide any assurance that we will be able to obtain any extensions under the Forbearance Agreement. We may seek the protection of the Bankruptcy Court, which may harm our business, adversely affect our ability to retain key personnel, and result in a significant loss of value for our stockholders.~~ We have **substantial indebtedness** ~~engaged financial and legal advisors to assist us in~~ , ~~among~~ **which could have important consequences to our business. We have a substantial amount of indebtedness primarily comprised of our 5. 00 % Notes. As of December 31, 2023, we had $ 67. 6 million aggregate principal amount of 5. 00 % Notes outstanding, which mature on December 15, 2026. We pay interest on** ~~other~~ -- **the 5** ~~things, analyzing various strategic alternatives to address our liquidity and capital structure~~ . ~~However~~ **00 % Notes by payment- in- kind (" PIK ")** , **through the issuance of additional 5. 00 % Notes (" PIK Notes "). The indenture governing the 5. 00 % Notes (the " 5. 00 % Notes Indenture ") provides that we may be required to repay amounts due under the 5. 00 % Notes Indenture in the event that** there **is an event of default for the 5. 00 % Notes that results in the principal, premium and interest, if any, becoming due prior to the maturity date for the 5. 00 % Notes. There** can be no assurance that **we** ~~the strategic review~~ will be ~~successful~~ **able to repay this indebtedness when due** , **or that we will be able to refinance this indebtedness on acceptable terms or at all. In addition, this indebtedness could, among other things: • heighten our vulnerability to adverse general economic conditions** and **heightened competitive pressures; • require us to dedicate** a ~~filing vulnerability to adverse general economic conditions and heightened competitive pressures;• require us to dedicate a~~ larger portion of our cash flow from operations to interest payments,limiting the availability of cash for other purposes;• limit our flexibility in planning for,or reacting to,changes in our business and industry; ~~and~~ • impair our ability to obtain additional financing in the future for working capital,capital expenditures,acquisitions,general corporate purposes or other purposes; **and** • impact our ability to continue as a going concern ~~;• necessitate~~ **.Additionally,our failure to repurchase 5.00 % Notes at** a ~~restructuring under Chapter 11~~ **time when the repurchase is required by the 5** . ~~Servicing our debt could require~~ **00 % Notes Indenture (whether upon** a ~~significant amount of cash~~ **fundamental change or otherwise** under ~~Chapter 11 may~~ **the 5. 00 % Notes Indenture) would constitute a default under the 5. 00 % Notes Indenture. A default under the 5. 00 % Notes Indenture or the fundamental change itself could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to** be ~~unavoidable. Seeking Bankruptcy Court protection could~~ **accelerated after any applicable notice or grace periods, we may not** have **sufficient funds to repay the indebtedness, repurchase the 5. 00 % Notes or make cash payments upon conversions thereof. Servicing our debt will require** a ~~material adverse effect~~ **significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Our ability to make scheduled payments** on **the principal of** ~~our~~ **or to refinance our indebtedness, primarily the 5. 00 % Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our** business **may not continue to generate cash flow from operations in the future 20s sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow** , **we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. For example, we are in default of payment obligations under the terms of our 2. 50 % Notes, which matured on March 15, 2023 and became due and payable. As a result, we consummated a series of transactions to allow for the restructuring of our capital structure (the " Restructuring Transactions "), including the 2. 50 % Notes, a secured promissory note with the Jack W. Schuler Living Trust (the " Schuler Trust ") (the " Secured Note ") and the then outstanding Series A Preferred Stock, as well as an amendment to a Securities Purchase Agreement that the Company entered into with the Schuler Trust in March 2022 (the " March 2022 Securities Purchase Agreement "), which resulted in significant dilution to the ownership interests of our existing stockholders. Our ability to repay our remaining indebtedness will depend on the capital markets and our** financial condition **at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms** , **which could** ~~results~~ **result in a default on our debt obligations. We are in default** of **payment obligations under the terms of our 2. 50 % Notes, which matured on March 15, 2023 and became due and payable. As discussed in Part II, Item 7, Management' s Discussion and Analysis of Financial Condition and Results of** ~~operations~~ **Operations - " Capital Resources** and ~~liquidity~~ **Liquidity - Convertible Notes " of this Form 10- K, the principal of the 2** . ~~So long~~ **50 % Notes was due March 15, 2023. As of December 31, 2023, approximately $ 0. 7 million remains in default and accruing interest at 2. 50 %. To the extent we deliver shares upon conversion of the 5. 00 % Notes, the ownership interests of existing stockholders could be diluted and our stock price may be adversely impacted. Upon conversion of the 5. 00 % Notes, we will pay or deliver,** as the **case may** ~~process related to a Chapter 11 proceeding continues, our senior management would~~ be **, cash, shares** ~~required to spend a significant amount~~ of ~~time and effort dealing with the reorganization instead of focusing exclusively on our business operations. Bankruptcy Court~~ -- **our** ~~protection also might make it more difficult to retain management and other key personnel necessary to the success and growth of our business. The longer a Chapter 11 proceeding continues, the more likely it is that our customers would lose confidence in our ability to reorganize our businesses successfully~~

~~and would seek to establish alternative commercial relationships. Additionally, all of our indebtedness is senior to the existing~~ common stock ~~in our~~ **or** ~~capital structure. As~~ a **combination of cash and** ~~result, if we seek relief under Chapter 11, existing~~ shares of our common stock ~~may be canceled~~, ~~with a very limited recovery or no recovery~~ **at the Company' s election. To the extent we choose to deliver shares upon conversion of some** ~~for~~ **or** ~~holders~~ **all** of **the 5. 00 % Notes, this will result in a dilution to the ownership interests of existing stockholders and may depress** our ~~common~~ stock **price** ~~. Moreover, if we execute a restructuring outside of Chapter 11, such transaction could result in substantial dilution to existing holders of our common stock. Therefore, trading in our securities is highly speculative and poses substantial risks~~. Risks Related to Our Business and Strategy We have limited revenues from our products and no assurance of future revenues. We have received limited revenue from sales of the Accelerate Pheno system and the Accelerate PhenoTest BC Kit. As a result, during the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~, we experienced losses from operations. Our future revenues are dependent on the successful commercialization of our products and there can be no assurance that we will be successful at the levels necessary to cover the costs of operations. If we are unsuccessful in generating sufficient revenues from our current and future products, we will likely continue to experience losses from operations and negative cash flow. We have a history of losses and expect to continue to incur losses in the future, and we cannot be certain that we will achieve or sustain profitability. Until we received FDA approval to market the Accelerate Pheno system, we were a development- stage company and therefore incurred significant losses in prior years. While we are currently commercializing the Accelerate Pheno system and the Accelerate Arc system outside of the United States, we have incurred significant costs in connection with the development and commercialization of our technology **and expect to continue to incur further costs in the development and commercialization of our future products, including the Accelerate Wave system** . There is no assurance that we will achieve sufficient revenues to offset anticipated operating costs, and we expect to continue to incur losses in the future. Our ability to achieve or sustain profitability depends on numerous factors including the market acceptance of our products, product quality, future product development and our market penetration and margins. If we are unsuccessful in generating sufficient revenues from our products, we will likely continue to experience losses from operations and negative cash flow. Although we anticipate deriving revenues from the sale of our products, no assurance can be given that these products can be sold on a net profit basis. If we achieve profitability, we cannot give any assurance that we will be able to sustain or increase profitability on a quarterly or annual basis in the future. **21s** Our future profitability and continued existence are dependent in large part upon the successful commercialization of the Accelerate Pheno system and further development and commercialization of associated test kits, the Accelerate Arc **and Accelerate Wave** ~~system~~ **systems** ~~and future products~~. Our principal business strategy involves the successful commercialization of the Accelerate Pheno system and further development and commercialization of associated test kits, the Accelerate Arc module and BC kit and future products, including **the Accelerate Wave system** ~~our next generation AST instrument platform~~. On June 30, 2015, we declared our conformity to the European In Vitro Diagnostic Directive 98 / 79 / EC and applied a CE Mark to the Accelerate Pheno system and the Accelerate PhenoTest BC kit for in vitro diagnostic use. On February 23, 2017, the FDA granted our de novo request to market our Accelerate Pheno system and Accelerate PhenoTest BC kit. We have and will continue to dedicate a significant amount of resources to market and sell the Accelerate Pheno system. Likewise, we plan to continue our investment in the development of additional test kits and the commercialization of the Accelerate Pheno system in the United States and other jurisdictions in which we intend to pursue marketing authorization. There can be no assurance that we will successfully commercialize the Accelerate Pheno system, any associated test kits, including the Accelerate PhenoTest BC kit, or further develop and commercialize complimentary products such as **the** PhenoTest BC Kit, AST configuration, the Accelerate Arc system, including the **related** ~~Accelerate Arc~~ BC kit, and future products **, such as the Accelerate Wave system** . Any failure to do so could lead to an impairment of certain of our intellectual property, inventory, property and equipment, and may result in our ceasing operations. We may also be required to expend significantly more resources than planned in this process and, as a result, we may have to cease investing in the Accelerate Pheno ~~system~~, ~~the~~ Accelerate Arc **or Accelerate Wave** ~~system~~ **systems ,** or developing other products. Additionally, our efforts to educate hospitals on the benefits of our products require significant resources, and we may experience reluctance from hospitals to purchase our products. If we fail to successfully commercialize our products, we may never receive a return on the significant investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance we have made, and on further investments we intend to make, and may fail to generate revenue and gain economies of scale from such investments. Furthermore, the potential market for our products may not expand as we anticipate or may even decline based on numerous factors, including the introduction of superior alternative product or other factors beyond our control ~~. For example, the market for our products was adversely affected by the COVID- 19 pandemic. See " Risks Related to Our Business and Strategy — The COVID- 19 pandemic has had, and may continue to have, a significant adverse impact on our commercial operations and also exposes our business to other risks " for additional information~~. If we are unable to adequately expand the market for our products, this failure would have a material adverse effect on our ability to execute on our business plan and ability to generate revenue. We have entered into the Sales and Marketing Agreement with BD and will substantially depend on BD for the successful commercialization of our products. As part of our collaboration with BD pursuant to the Sales and Marketing Agreement, BD will perform certain sales, tactical marketing, technical service call forwarding, order preparation, research and development support and / or regulatory activities on our behalf as our exclusive sales agent for certain of our products, including the Accelerate Pheno system, Accelerate Arc system and related BC Kits. The successful commercialization of our products, including our ability to generate revenue from our arrangement with BD, will depend on BD' s ability to successfully perform the responsibilities assigned to it pursuant to the Sales and Marketing Agreement. While BD is largely responsible for the speed and scope of sales and marketing efforts, we cannot assure you that BD will dedicate the resources necessary to successfully perform its responsibilities pursuant to the Sales and Marketing Agreement, and our ability to cause BD to increase the speed and scope of its efforts may be limited. In addition, sales and marketing efforts could be

negatively impacted by the delay or failure by us to obtain additional supportive clinical trial data for our products. We cannot predict the success of our collaboration with BD, and there can be no assurance that the efforts of BD will meet our expectations or result in any significant product sales or cost savings within the anticipated time frame or at all. In the event that BD fails to perform under the Sales and Marketing Agreement, or if the Sales and Marketing Agreement is terminated, this could delay our product commercialization efforts, which would materially and adversely affect our business, financial condition, results of operations and cash flows. The termination of the Sales and Marketing Agreement could also require us to revise our commercialization and business strategy going forward and divert management attention and resources. In addition, the termination of the Sales and Marketing Agreement could materially impact our ability to enter into additional collaboration agreements with new partners on favorable terms, if at all. **22s** Our future product candidates have not obtained marketing authorization from the FDA, and they may never obtain such marketing authorization or other regulatory clearance. Our success in part depends on our ability to obtain additional product marketing authorizations from the FDA for product candidates in our pipeline, including our **Accelerate Wave** ~~next- generation Pheno~~ system. If our attempts to obtain marketing authorization or other regulatory clearance are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business. Our future product candidates may not be sufficiently sensitive or specific to obtain, or may prove to have other characteristics that preclude our obtaining, marketing authorization from the FDA or regulatory clearance. The process of obtaining regulatory clearance is expensive and time- consuming and can vary substantially based upon, among other things, the type, complexity and novelty of our product candidates. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations or changes in regulatory review for each submitted product application may cause delays in the clearance of, or receipt of marketing authorization from the FDA for, a product candidate or rejection of a regulatory application altogether. The FDA has substantial discretion in the de novo review and clearance processes and may refuse to accept any application or may decide that our data is insufficient for clearance and require additional pre- clinical, clinical or other studies. In addition, varying interpretations of the data obtained from pre- clinical and clinical testing could delay, limit or prevent marketing authorization from the FDA or regulatory clearance of a product candidate. Any marketing authorization from the FDA or regulatory clearance we ultimately obtain may be limited or subject to restrictions or post- market commitments that render the product candidate not commercially viable. We may not be able to correctly estimate or control our future operating expenses,which could lead to cash shortfalls,and ~~impact~~ our ability to continue as a going concern.Our operating expenses may fluctuate significantly in the future as a result of a variety of factors,many of which may be outside of our control.These factors include,but are not limited to:• the expenses we incur for research and development required to maintain and improve our technology,including the continuing development of the Accelerate Pheno ~~and~~ **system,the** Accelerate Arc ~~systems~~ **system** ,and development costs for new products ~~,including the Accelerate Wave system~~ ;• the expenses we incur in connection with the development,marketing authorization and regulatory clearance of the use of the Accelerate Pheno system to test on additional specimen types ~~and our Accelerate Arc system~~ ,as well as in connection with the development of new products ~~,including the Accelerate Wave system~~ ;• the costs of preparing,filing,prosecuting,defending and enforcing patent claims and other intellectual property related costs,including litigation costs and the results of such litigation;• the expenses we incur in connection with commercialization activities,including product marketing,sales and distribution expenses;• the costs incurred to build manufacturing capabilities;• the expenses to implement our sales strategy;• the costs to attract and retain personnel with the skills required for effective operations;and • the costs associated with being a public company.Our budgeted expense levels are based in part on our expectations concerning future revenues from sales of the Accelerate Pheno system,the Accelerate Arc system,as well as our assessment of the future investments needed to expand our commercial organization and support research and development activities in connection with the Accelerate Pheno ~~and~~ **system,the** Accelerate Arc ~~systems~~ **system and** ~~,as well as~~ future products ~~,including the Accelerate Wave system~~ .We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue.Accordingly, **a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our cash levels.** If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline. From time to time, we estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development goals. These goals may include the commencement or completion of clinical trials and the submission of regulatory filings **, including those related to the ongoing development of our Accelerate Wave system** . From time to time, we may publicly announce the expected timing of some of these goals. All of these goals are, and will be, based on a variety of assumptions. The actual timing of these goals can vary significantly **23s** compared to our estimates, in some cases for reasons beyond our control. We may **also** experience numerous unforeseen events that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including the uncertainties and risks set forth in this Form 10- K and in our other filings with the SEC. For example, on October 21, 2022, the Company filed a Current Report on Form 8- K announcing it ~~has~~ **had** been in recent discussions with the FDA regarding its Accelerate Arc Products. Pursuant to such discussions, the FDA has challenged the Company' s commercialization of the Accelerate Arc Products in the United States as a Class I device exempt from 510 (k) clearance requirements. The Company is in active dialogue with the FDA to determine the appropriate regulatory pathway. While these discussions are ongoing, the Company has put on hold in the United States its sales and marketing efforts of the Accelerate Arc Products **. See " Risks Related to Government Regulation- The regulatory processes applicable to our products and operations are expensive, time- consuming, and uncertain and may prevent us from obtaining required authorizations for the commercialization of our products " for additional information** . If we do not meet our goals as publicly announced, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline. We may not be able to enhance the capabilities of our current and new products to keep pace with our industry' s rapidly changing technology and customer requirements. Our industry is characterized by rapid technological changes, frequent new product introductions and

enhancements and evolving industry standards. Our future success will depend significantly on our ability to enhance our current products and develop or acquire and market new products that keep pace with technological developments and evolving industry standards as well as respond to changes in customer needs. New technologies, techniques or products could emerge that might offer better combinations of price and performance than the products and systems that we plan to sell. It is critical to our success that we anticipate changes in technology and customer requirements and physician, hospital and healthcare provider practices and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost- effective basis. At the same time, however, we must carefully manage our introduction of new products. If potential customers believe that such new products will offer enhanced features or be sold for a more attractive price, they may delay purchases of existing products until such new products are available. Further, there can be no assurance that we will be successful in developing or acquiring product enhancements or new products to address changing technologies and customer requirements adequately, that we can introduce such products on a timely basis or that any such products or enhancements will be successful in the marketplace. If we are unable to successfully develop or acquire new products or if the market does not accept our products, or if we experience difficulties or delays in the final development and commercialization of our products, we may be unable to attract additional customers for our products or strategic partners to license our products. The failure of our current or any future diagnostic products to perform as expected could significantly impair our reputation and the public image of our products, and we may be subject to legal claims arising from any defects or errors. Our success will depend on the market' s confidence that our technologies can provide reliable, high- quality diagnostic results. We believe that our customers are likely to be particularly sensitive to any defects or errors in the Accelerate Pheno system **or any future diagnostic products, including the Accelerate Wave system** . As is typical of complex diagnostic systems **,** we occasionally experience support issues or other performance problems with the Accelerate Pheno system. We have also experienced customer returns of our Accelerate Pheno system, some of which related to quality issues. We could face warranty and liability claims against us and our reputation could suffer as a result of such failures. We cannot assure you that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future. In addition, the FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. A recall, material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could cause us to incur significant costs, divert the attention of our key personnel or cause other significant customer relations problems. In the past, we have experienced disappointing or negative publication results regarding the efficacy of our products. Such negative publicity could diminish our reputation and future sales of our products, which could have a material impact on our financial performance. **24s** If treatment guidelines for bacterial infections change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for our product candidates. If treatment guidelines for bacterial infections change, or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA or other regulatory clearance for our product candidates. If treatment guidelines change so that different treatments become desirable, the Accelerate Pheno system may no longer provide the information sought by physicians, and we could be required to seek marketing authorization from the FDA or other regulatory clearance for a revised product. We may not be able to correctly..... material impact on our cash levels. Breaches of our information technology systems could have a material adverse effect on our operations and potentially result in liability, depending on the type of breach and information compromised. We rely on information technology systems to process, transmit and store electronic information, which may include protected health information, in our day- to- day operations. In addition, our research and development operations are highly dependent on our information technology and storage. Our products also include software and data components. Our information technology systems have been subjected to computer viruses or other malicious codes and phishing attacks, and we expect to be subject to similar viruses and codes in the future. Attacks on our information technology systems or products could result in our intellectual property, unsecured protected health information, and other confidential information being lost or stolen, including the disclosure of our trade secrets, disruption of our operations, loss of valuable research and development data, the need to notify individuals whose information was disclosed, increased costs for security measures or remediation costs and diversion of management attention and other negative consequences. While we will continue to implement protective measures to reduce the risk of and detect future cyber incidents, cyber- attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. There can be no assurance that our protective measures will prevent future attacks that could have a significant impact on our business. There also can be no assurance that our cyber insurance will be sufficient to cover the total loss or damage caused by a cyber- attack. In addition, the costs of responding to and recovering from such incidents may not be covered by insurance. Failure to comply with a variety of U. S. and international privacy laws to which we are subject could harm the Company. Any failure by us or our vendor or other business partners to comply with federal, state or international privacy, data protection or security laws or regulations relating to the collection, use, retention, security and transfer of personally identifiable information could result in regulatory or litigation- related actions against us, legal liability, fines, damages, ongoing audit requirements and other significant costs. A significant data privacy regulation is the General Data Protection Regulation **,** which applies to the processing of personal information collected from individuals located in the European Union ~~,~~ and has created new compliance obligations and has significantly increased fines for noncompliance. Substantial expenses and operational changes may be required in connection with maintaining compliance with such laws, and in particular certain emerging privacy laws are still subject to a high degree of uncertainty as to their interpretation and application. We are dependent on our key employees. If we are unable to recruit, train and retain qualified personnel, we may not achieve our goals. Because of the complex and technical nature of our products and the dynamic market in which we compete, our future success depends on our ability to recruit, train and retain key personnel,

including our senior management, research and development, science and engineering, manufacturing and sales and marketing personnel. ~~In particular~~ **For example** , we are highly dependent on the management and business expertise of Jack Phillips, our President and Chief Executive Officer. We do not maintain key person life insurance for Mr. Phillips or any of our employees. Our industry is very competitive for qualified personnel. To the extent that the services of Mr. Phillips would be unavailable to us, we may be unable to employ another qualified person with the appropriate background and expertise to replace Mr. Phillips on terms suitable to us. Our growth depends, in particular, on attracting, retaining and motivating highly trained sales personnel with the necessary scientific background and ability to understand our systems and pathogens at a technical level. In addition, we may need additional employees at our manufacturing facilities to meet demand for our products as we scale up our sales and marketing operations. Like many companies, we have experienced an increased level of employee attrition **since** ~~, which is largely attributable to dislocations caused by~~ the COVID- 19 pandemic. We have various programs designed to improve employee retention, but there is no assurance that we will not continue to experience elevated employee attrition levels, which could negatively impact our ability to develop, implement, **25s** support and sell our products ~~. We may not successfully manage the transitions associated with certain of our executive officers, which could have an adverse impact on us. On March 9, 2023, Steve Reichling notified us of his decision to resign from his role as our Chief Financial Officer, effective March 31, 2023. In connection with Mr. Reichling' s resignation, we appointed David Patience to serve as our Chief Financial Officer, effective April 1, 2023. Leadership transitions may be inherently difficult to manage, and an inadequate transition to our new Chief Financial Officer may cause disruption within the Company. In addition, our financial performance and ability to meet operational goals and strategic plans may be adversely impacted. This may also impact our ability to retain and hire other key members of management~~ . Our industry is highly competitive, and we may not be successful in competing with our competitors. We currently face competition from new and established competitors and expect to face competition from others in the future, including those with new products, technologies or techniques. The industry in which we compete is subject to rapid technological changes, and we face and expect to continue to face strong competition for our products. Many of our competitors and potential competitors may have substantially greater research and development, financial, manufacturing, customer support, sales and marketing resources, larger customer bases, longer operating histories, greater name recognition and more established relationships in the industry than we do. In addition, some of our competitors may, individually or together with companies affiliated with them, have greater human and scientific resources than we do. Our competitors could develop new products or technologies that are more effective than the Accelerate Pheno system, the Accelerate Arc system and any of our other products or product candidates. Additionally, we expect to face further competitive pressure resulting from the emergence of new ID or AST techniques or tests. For example, we are aware that some hospitals have begun using manual methods created through laboratory developed tests, which have been validated for internal hospital- specific use to deliver ID and AST results. Any of these newly developed products, technologies, and techniques may offer a better combination of price and performance than our products and systems. Our failure to compete effectively could materially and adversely affect our business, financial condition and operating results. We generate a portion of our future revenue internationally and are subject to various risks relating to our international activities which could adversely affect our operating results. We market and sell the Accelerate Pheno system in other countries outside of the United States. In order to market our products in certain foreign jurisdictions, we, or our distributors or partners, must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical studies and commercial sales and distribution of our products. The approval procedure varies among countries and can involve additional testing. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all, which could harm our ability to expand into markets outside the United States. In addition, engaging in international business involves a number of other difficulties and risks, including: • required compliance with existing and changing foreign healthcare and other regulatory requirements and laws, such as those relating to patient privacy or handling of bio- hazardous waste; • required compliance with anti- bribery laws, such as the U. S. Foreign Corrupt Practices Act and the U. K. Bribery Act, data privacy requirements, labor laws and anti- competition regulations; • export and import restrictions; • various reimbursement and insurance regimes; • laws and business practices favoring local companies; • longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • political, economic and social instability, including instability resulting from the ongoing ~~war~~ **wars** between Russia and Ukraine **and between Israel and Hamas** , as well as continued and any new sanctions against Russia; • potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers; • foreign exchange controls; • fluctuations due to changes in foreign currency exchange rates; • difficulties and costs of staffing and managing foreign operations; and • impediments with protecting or procuring intellectual property rights. In particular, further escalation or expansion of ~~the~~ ongoing **international** ~~war~~ **wars** ~~between Russia~~ and ~~Ukraine~~ **conflicts** could impact our European business operations, including disrupting our sales channels and marketing activities, as well as negatively impacting the demand for our products. In addition, changes in policies and / or laws of the United States or foreign governments resulting in, among **26s** other changes, higher taxation, tariffs or similar protectionist laws, currency conversion limitations, limitations on business operations, or the nationalization of private enterprises could reduce the anticipated benefits of international operations and could have a material adverse effect on our ability to expand internationally. Our employees, independent contractors, principal investigators, consultants, commercial partners, vendors and other agents may engage in misconduct or other improper activities, including non- compliance with legal standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, principal investigators, consultants, commercial partners, vendors and other agents **, including BD** . Misconduct by these parties could include intentional, reckless or negligent failures to: (i) comply with the laws and regulations of the FDA, CMS, the HHS Office of Inspector General, Office for Civil Rights and other similar foreign regulatory bodies; (ii) provide true, complete and

accurate information to the FDA and other similar regulatory bodies; (iii) comply with manufacturing requirements of the FDA and other similar regulatory bodies and manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws and regulations in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately, or disclose unauthorized activities to us. These laws may impact, among other things, our activities with principal investigators and research subjects, as well as our sales, marketing and education programs. In particular, the promotion, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, unauthorized use of protected health information and data breaches, and other abusive practices. These laws may restrict or prohibit a wide range of activities related to pricing, discounting, **sales,** marketing and promotion, patient support, royalty, consulting, research and other business arrangements, as well as the improper use of patient information obtained in the course of clinical studies. We currently have **a compliance program that includes** a code of conduct applicable to all of our employees and foreign distributors, but it is not always possible to identify and deter employee and / or commercial partner misconduct, and our code of conduct and the other ~~precautions~~ **policies and practices** we ~~take~~ **have put into place** to ~~detect~~ **identify, address,** and prevent ~~this activity~~ **inappropriate conduct** 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, disgorgement, individual imprisonment, corporate integrity agreements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations. Any of these actions or investigations could result in substantial costs to us, including legal fees, and divert the attention of management from operating our business. Our estimates of market opportunity and forecasts of market growth may prove to be inaccurate, and even if the market in which we compete achieves the forecasted growth, our business could fail to grow at similar rates, if at all. Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Any estimates and forecasts in this Form 10- K relating to the size and expected growth of our market, total available market, estimated test and placement volume and estimated pricing, may prove to be inaccurate, which may have negative consequences, such as overestimation of our potential market opportunity. Even if the market in which we compete meets our size estimates and forecasted growth, our business could fail to grow at similar rates, if at all. We are exposed to risks associated with long- lived assets that may become impaired and result in an impairment charge. The carrying amounts of long- lived assets are affected whenever events or changes in circumstances indicate that the carrying amount of any asset may not be recoverable. Property and equipment includes Accelerate Pheno systems (also referred to as instruments) used for sales demonstrations, instruments under rental agreements and instruments used for research and development. Similarly, the recoverability of the book value of **instrument- related** inventory could be impacted by changes in growth expectations and require a reduction in their carrying value to the lower of cost or market. Adverse events or changes in circumstances may affect the estimated discounted future cash flows expected to be derived from long- lived assets. If at any time we determine that an impairment has occurred, we will **27s** be required to reflect the impaired value as a charge, resulting in a reduction in earnings, such impairment is identified and a corresponding reduction in our net asset value. In the future **,** we may incur ~~,~~ impairment charges. A material reduction in earnings resulting from such a charge could cause us to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline. Providing instrument systems to our customers through reagent rental agreements may harm our liquidity. Many of our systems are provided to customers via " reagent rental " agreements, under which customers are generally afforded the right to ~~use~~ **rent** the instrument ~~in return for~~ **and the rental fee is paid through** a commitment **by the customer** to purchase minimum quantities of reagents and test kits over a period of time. Accordingly, we must either incur the expense of manufacturing instruments well in advance of receiving sufficient revenues from test cartridges to recover our expenses or obtain third party financing sources for the purchase of our instrument. The amount of capital required to provide instrument systems to customers depends on the number of systems ~~placed~~ **subject to such arrangements** . Our ability to generate capital to cover these costs depends on the amount of our revenues from sales of reagents and test cartridges sold through our reagent rental agreements. We do not currently sell enough reagents and test cartridges to recover all of our fixed expenses, and therefore we currently have a net loss. If we cannot sell a sufficient number of reagents and test cartridges to offset our fixed expenses, our liquidity will continue to be adversely affected. If we fail to estimate customer demand properly, our financial results could be harmed. Our products are manufactured based on estimates of customers' future demand and our manufacturing lead times are very long. This could lead to a significant mismatch between supply and demand, giving rise to product shortages ~~or ,~~ excess inventory **or further instrument- related inventory write- downs** , and make our demand forecast more uncertain. In order to have shorter shipment lead times for our customers, we ~~may and~~ have built up inventory for anticipated growth which has not occurred, or may build up inventory to serve what we believe is pent- up demand. In periods with limited available capacity **,** we may and have placed inventory orders significantly in advance of our normal lead times, which could negatively impact our financial results. Additionally, ~~consumer~~ **customer** behavior ~~during the COVID- 19 pandemic, has~~ **changes due to significant events and economic conditions have historically** made it more difficult for us to estimate future demand ~~, and these challenges may be more pronounced in the future~~ . In estimating demand, we make various assumptions, any of which may and have been incorrect. If we are unable to accurately anticipate demand for our products, our business and financial results could be adversely impacted **. For example, excess inventory write- downs were recorded during the year ended December 31, 2023, as well as during the year ended December 31, 2021, as a result of excess quantities of instrument inventory on hand above and beyond our forecast of future demand for those products** . Situations that may result in excess or obsolete inventory include: • changes in business

and economic conditions, including downturns in our target markets and / or overall economy; • changes in consumer confidence caused by changes in market conditions, including changes in the credit market; • a sudden and significant decrease in demand for our products; • a higher incidence of inventory obsolescence because of rapidly changing technology or customer requirements; • our introduction of new products resulting in lower demand for older products; • less demand than expected for newly- introduced products; or • increased competition, including competitive pricing actions. The cancellation or deferral of customer purchase orders could result in our holding excess inventory, which could adversely affect our gross margins. In addition, because we often sell a substantial portion of our products in the last month of each quarter, we may not be able to reduce our inventory purchases in a timely manner in response to customer cancellations or deferrals. We could be required to **further** write- down our inventory to the lower of cost or net realizable value, and we could experience a reduction in average selling prices if we incorrectly forecast product demand, any of which could harm our financial results. Conversely, if we underestimate our customers' demand for our products, our partners may not have adequate lead- time or capacity to increase production and we may not be able to obtain sufficient inventory to fill customers' orders on a timely basis. We may also face supply constraints caused by natural disasters or other **28s** factors as discussed in this " Risk Factors " section. In such cases, even if we are able to increase production levels to meet customer demand, we may not be able to do so in a cost- effective or timely manner. If we fail to fulfill our customers' orders on a timely basis, or at all, our customer relationships could be damaged, we could lose revenue and market share and our reputation could be damaged. The COVID- 19 pandemic has ~~had,~~ **adversely affected our business** and **a resurgence of COVID- 19 or the occurrence of another health epidemic or pandemic** may ~~continue to~~ have **an** ~~, a significant~~ adverse impact on our ~~commercial operations and also exposes our~~ business ~~to in other~~ -- **the** ~~risks~~ **future** . **Our business** ~~In late 2019 , a novel strain of coronavirus (including our workforce, supply chain and customer base, has been adversely affected by~~ COVID- 19 ~~) was reported to have surfaced~~ in ~~Wuhan, China, and spread globally. In March 2020,~~ the ~~World Health Organization declared~~ **past and a resurgence of** COVID- 19 ~~a global~~ **or the occurrence of another health epidemic or** pandemic ~~. The COVID- 19 outbreak resulted in government authorities around the world implementing numerous measures to try to reduce the spread of COVID- 19, such as travel bans and restrictions, quarantines, shelter- in- place, stay- at- home or total lock- down (or similar) orders and business limitations and shutdowns. New cases and hospitalizations have risen and fallen throughout the course of this pandemic. More recently, the emergence and spread of new variants of COVID- 19 that are significantly more contagious than previous strains initially led many~~ - **may adversely affect us** ~~government authorities and businesses to reimplement prior restrictions~~ in ~~an effort to lessen the spread of COVID- 19 and its variants. While most of these~~ -- **the future** ~~restrictions have been lifted, uncertainty remains as to whether additional restrictions may be initiated or again reimplemented in response to surges in COVID- 19 cases. The lingering impact of the COVID pandemic continues to create significant volatility throughout the global economy, including supply chain constraints, labor supply issues and higher inflation. Accordingly, it is unclear at this point the full impact COVID- 19 and its variants will have on the global economy and on our Company~~ . The COVID- 19 pandemic, containment measures, and downstream impacts to hospital staffing and financial stability ~~have caused, and are continuing to cause, business slowdowns in affected areas, both regionally and worldwide, as well as disruptions to global supply chains and workforce participation. These effects have~~ significantly impacted our business and results of operations, starting in the first quarter of 2020 and continuing through 2022, albeit to a lesser degree. For example, we ~~have~~ experienced diminished access to our customers, including hospitals, which ~~has~~ severely limited our ability to sell and, to a lesser degree, implement previously contracted Accelerate Pheno systems. More recently, hospital turnover resulting from burnout and financial challenges driven by inflation and other factors ~~have further~~ **continued to** ~~diverted~~ -- **divert** the attention of hospital decision makers ~~. In addition, in certain months with high rates of COVID- 19 hospitalization, our Accelerate PhenoTest BC Kit orders declined as many hospitals curtailed elective surgeries to respond to COVID- 19. The emergence of COVID- 19 variants, vaccine hesitancy~~ and **impact** ~~the prevalence of breakthrough cases of infection among fully vaccinated people adds additional uncertainty regarding~~ our ~~access to customers and prospects, demand for our products, and~~ ability ~~to implement our products. See " Management' s Discussion and Analysis of Financial Condition and Results of Operations- COVID- 19 and Supply Chain Impacts Update " in Part II, Item 7 of this Form 10- K for additional information. In addition to the negative impact on new sales and implementations of the Accelerate Pheno system and demand for our consumable test kits, our business, operations, and workforce have been and may be further impacted in several ways, including, but not limited to, the following: • delays in product development or reductions in manufacturing production as a result of inventory and supply chain shortages; • increased supplier costs caused by ongoing shortages and inflation in materials used in our products; • interruptions, availability or delays in global shipping to transport our products; • regulatory approval delays due to regulators reviewing a large volume of COVID- 19 related medical devices and drugs; • delays in obtaining grants to assist our product development efforts because granting agencies are primarily focused on research and development activities directly related to COVID- 19; • increased regulatory restrictions or continued market volatility could hinder our ability to execute strategic business activities, as well as negatively impact our stock price; • significant disruption of global financial markets, which could cause fluctuations in currency exchange rates or negatively impact our ability to access capital markets; • inability~~ to access capital markets on terms that are not ~~significantly~~ detrimental to our business ~~because our revenue growth rate has slowed due to our inability to sell and implement the Accelerate Pheno system as forecasted prior to the pandemic at a stage in our maturation when we are cash flow negative and have significant indebtedness; • negative impact on our workforce productivity, product development, and research and development due to difficulties resulting from our personnel working remotely; • increased employee attrition caused by employees seeking permanent remote positions or other pandemic related reasons; and • illnesses to key employees, or a significant portion of our workforce, which may result in inefficiencies, delays, and disruptions in our business~~ . **It is possible that a resurgence** ~~Any of these developments may adversely affect our business, harm our reputation, or result in legal or regulatory actions against us. Further, the spread~~ of COVID- 19 ~~has caused~~ **or the occurrence of another health epidemic or pandemic will adversely**

affect our business, our workforce, our supply chains and distribution networks or otherwise impact our ability to conduct business in the future. Further, to the extent our customers', suppliers' or service providers' businesses are adversely affected by such occurrences, they might delay or reduce purchases from us **or impact our ability** to ~~modify~~ **meet customer demand or development timelines, which could adversely affect** our business ~~practices (including employee travel, employee work locations,~~ and ~~cancellation~~ **results** of **operations. The effects** ~~physical participation in meetings, events and conferences), and we may take further actions as may be required by government authorities or that we determine are in the best interests~~ of **ongoing** ~~our~~ **or** ~~employees, customers, suppliers,~~ **future health epidemics or pandemics on our** business **remain** ~~partners and others. There is no certainty that such measures will be sufficient to mitigate the risks posed by the virus, and our ability to perform critical functions could be harmed. The potential direct and indirect effects of COVID- 19 also may impact many of our other risk factors discussed herein. The degree to which the COVID- 19 pandemic ultimately impacts our business, results of operations, cash flows and financial position will depend on future developments, which are highly~~ uncertain ~~, continuously evolving~~ and **subject** ~~cannot be predicted. This includes, but not limited~~ to **change** ~~, the duration and spread of the pandemic and its severity; the emergence and severity of its variants, including the Omicron variant and its subvariants; the actions to contain the virus or treat its impact, such as the availability and efficacy of vaccines (particularly with respect to emerging strains of the virus) and potential hesitancy to use them; the financial impact of COVID- 19 on hospitals, including to their budget priorities; hospital staffing issues; general economic factors, such as increased inflation; global supply chain constraints and the related increase in costs; labor supply issues; and how quickly and to what extent normal economic and operating conditions can resume~~ . Disruptions in the supply of raw materials, consumable goods or other key product components, or issues associated with their quality from our single source suppliers, could result in a significant disruption in sales and profitability. We must manufacture or engage third parties to manufacture components of our products in sufficient quantities and on a timely basis, while maintaining product quality, acceptable manufacturing costs and complying with regulatory requirements. ~~Our~~ **Certain of our** components are custom- made by only a few outside suppliers ~~. In~~ **and, in** certain instances, we have a sole source supply for key product components ~~of the Accelerate Pheno system~~ . We may be unable to satisfy our forecast demand from existing suppliers for our products, or we may be unable to find alternative suppliers for key product components or ancillary items at reasonably comparable prices. If this occurs, we may be unable to manufacture our products **, meet key development milestones,** and / or meet our customers' needs in a timely manner or at all. Additionally, we have entered into supply agreements with most of our suppliers to help ensure component availability and flexible purchasing terms with respect to the purchase of such components. If our suppliers discontinue production of a key component for one or more of our products, we may be unable to identify or secure a viable alternative on reasonable terms, or at all, which could limit our ability to manufacture our products. While we may be able to modify our product candidates to utilize a new source of components, we may need to secure marketing authorization from the FDA or other regulatory clearance for the modified product, and it could take considerable time and expense to perform the requisite tasks prior to seeking such authorization. In determining the required quantities of our products and our manufacturing schedule, we will need to make significant judgments and estimates regarding factors such as market trends and any seasonality with respect to our sales. Because of the inherent nature of estimates, there could be significant differences between our estimates and the actual amounts of products that we require. This can result in shortages if we fail to anticipate demand, or excess inventory and write- offs if we order more than we need. Reliance on third- party manufacturers entails risk to which we would not be subject if we manufactured these components ourselves, including: • reliance on third parties for regulatory compliance and quality assurance; **29s** • possible breaches of manufacturing agreements by the third parties because of factors beyond our control; • possible regulatory violations or manufacturing problems experienced by our suppliers; • possible termination or non- renewal of agreements by third parties, based on their own business priorities, at times that are costly or inconvenient for us; • the potential obsolescence and / or inability of our suppliers to obtain required components; • the potential delays and expenses of seeking alternate sources of supply or manufacturing services; • the inability to qualify alternate sources without impacting performance claims of our products; • reduced control over pricing, quality and timely delivery due to the difficulties in switching to alternate suppliers or assemblers; and • increases in prices of raw materials and key components. For example, we are currently experiencing unprecedented cost increases from many of our suppliers, primarily as a result of labor and supply disruptions and increased inflation. The areas of cost increases include raw materials, components, and value- add supplier labor. We currently have sufficient inventory of Accelerate Pheno system instruments to limit the impact of cost increases on such devices. However, we are being impacted by cost increases to components and raw materials necessary for the production of our consumable test kits. Our kits require these components and raw materials, and many of our supply contracts permit the supplier to pass on certain inflation increases to us. Moreover, our ability to pass on cost increases to our consumable test kit customers is limited by long- term contractual price commitments. Prolonged elevated supply costs and further cost increases may further impact our cost to manufacture our Accelerate Pheno **and Accelerate Arc systems and to develop our Accelerate Wave** system ~~instruments~~ . The supply cost increases we are experiencing and may experience in the future may materially reduce our gross profit margins, thereby negatively impact our overall financial results. ~~The manufacturing operations for our products use highly technical processes involving unique, proprietary techniques. In addition, the manufacturing equipment we use would be costly to repair or replace and could require substantial lead time to repair or replace. Any interruption in our operations or decrease in the production capacity of our manufacturing facility or the facilities of any of our suppliers because of equipment failure, natural disasters such as earthquakes, tornadoes and fires, or otherwise, would limit our ability to meet customer demand for our products. In the event of a disruption, we may lose customers and we may be unable to regain those customers thereafter. Our insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.~~ We ~~have~~ **previously** identified a material weakness in our internal control over financial reporting, and if we **fail** ~~are unable~~ to ~~remediate such material weakness~~ **maintain an effective system of internal control** , we may not be able to

accurately or timely report our financial condition or results of operations. In connection with the audit of our consolidated financial statements for the year ended December 31, 2022, we identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. ~~The material weakness we identified prevented us~~ **During 2023, management, with oversight** from ~~identifying a misclassification of the Notes on our condensed consolidated balance sheets in our interim financial statements as of and for the three~~ -- **the** ~~months ended March 31~~ **Audit and Governance Committee** , **completed** ~~2022, three~~ -- **the implementation of our previously disclosed remediation plan that included a** ~~and six months ended June 30, 2022 and three and nine months ended September 30, 2022. Our internal~~ control ~~structure did not have a control~~ to review the ~~evaluation~~ **accounting treatment** of ~~the classification of its~~ outstanding debt instruments **on a quarterly basis** in accordance with applicable accounting guidance ~~at each reporting period~~ . **We have concluded that** ~~If we are unable to successfully remediate our existing or any future material weaknesses in~~ our internal control over financial reporting **was effective as of December 31** , **2023. Completion of remediation does not provide assurance that** ~~or~~ **our** ~~identify any additional material weaknesses~~ **remediation or other controls will continue to operate properly. If we are unable to maintain effective internal control over financial reporting** , the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable listing requirements, investors may lose confidence in our financial reporting, and the share price of our common stock may decline as a result. In addition, we could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources. See ~~"~~ **Part II, Item 9A,** Controls and Procedures- **"** Management' s Report on Internal Control over Financial Reporting " ~~in Part II, Item 9A~~ of this Form 10- K for further information on the **remediated** material weakness ~~identified and our remediation plans~~ . Risks related to Our Intellectual Property If we are unable to effectively protect our intellectual property, our business would be harmed. In addition to patent protection, we rely on trademark, copyright, trade secret protection and confidentiality agreements to protect intellectual property rights related to our proprietary technologies, both in the United States and in other countries. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. ~~We~~ **As of December 31, 2023, we** ~~own~~ **owned** ~~22~~ **23** issued U. S. patents and ~~five pending U. S. patent applications, including provisional and non- provisional filings. We also own~~ 30 non- U. S. patents and ~~have four~~ **had three** pending applications **as well as** ~~. We own 41~~ registered marks in the United States and foreign countries. In addition to our patents and trademarks, we possess an array of unpatented proprietary technology and know- how, and we license **30s** intellectual property rights to and from third parties. The strength of patents in our field involves complex legal and scientific questions. In addition, patent law continuously evolves and might change the legal framework under which our patent claims would be interpreted and adjudicated in the future. Uncertainty created by these questions and potential legal changes means that our patents may provide only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, competitors could purchase our products and attempt by reverse engineering to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of the protections provided by our intellectual property rights. If our intellectual property, including licensed intellectual property, does not adequately protect our market position against competitors' products and methods, our competitive position could be adversely affected, as could our business. Further, if we are unable to prevent unauthorized disclosure of our non- patented intellectual property, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage. In addition, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. We may not be successful in our currently pending or future patent applications, and even if such applications are successful, we cannot guarantee that the resulting patents will sufficiently protect our products and proprietary technology. We cannot assure you that any of our currently pending or future patent applications will result in issued patents with claims that adequately cover our products and technologies in the United States or in other foreign countries, and we cannot predict how long it will take for such patents to be issued. Further, issuance of a patent is not conclusive as to its inventorship or scope, and there is no guarantee that our issued patents will include claims that are sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Further, we cannot be certain that all relevant prior art relating to our patents and patent applications has been identified. Accordingly, there may be prior art that can invalidate our issued patents or prevent a patent from issuing from a pending patent application, or will preclude our ability to obtain patent claims that have a scope broad enough to provide meaningful protection from our competitors. Even if patents do successfully issue and even if such patents cover our products and technologies, we cannot assure you that other parties will not challenge the validity, enforceability or scope of such issued patents in the United States and in foreign countries, including by proceedings such as reexamination, inter- partes review, interference, opposition, or other patent office or court proceedings. The strength of patents in our field involves complex legal and scientific questions. Moreover, we cannot assure you that if such patents were challenged in court or before a regulatory agency that the patent claims will be held valid, enforceable, to be sufficiently broad to cover our technologies or to provide meaningful protection from our competitors. Nor can we assure you that the court or agency will uphold our ownership rights in such patents. Accordingly, we cannot guarantee that we will be successful in defending challenges made against our patents and patent applications. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents, or narrowing of claim scope, such that we could be deprived of patent protection necessary for the successful commercialization of our products and technologies, which could adversely affect

our business. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our inventions, provide exclusivity for our products and technologies or prevent others from designing around our claims. Others may independently develop similar or alternative products and technologies or duplicate any of our products and technologies. These products and technologies may not be covered by claims of issued patents for which we are the right holder. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product under patent protection could be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to make the inventions covered by our pending patent applications, or that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, ~~an~~ interference **or derivation** ~~proceeding~~ **proceedings** in the United States can be initiated by a third party to **31s** determine who ~~was~~ **has** the ~~first~~ **right** to ~~invent any of~~ the subject matter covered by the **claims of our** patent ~~claims of our~~ applications **and / or patents. We may not prevail in such proceedings**. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however **,** the life of a patent, and the protection it affords, is limited. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive and time consuming. Third parties may infringe or misappropriate our intellectual property, including our existing patents and patent claims that may be allowed in the future. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. Further, we may not be able to prevent misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. If we file an infringement action against a third party, that party may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patent claims such that they no longer cover our ~~product~~ **products** ~~candidates~~. They may also put our pending patent applications at risk of not issuing or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Enforcing our intellectual property rights through litigation is very expensive and time- consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time and reduce employee productivity. Furthermore, because of the substantial amount of discovery required in connection with U. S. intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations. We could face claims that our proprietary technologies infringe on the intellectual property rights of others. Due to the significant number of U. S. and foreign patents issued to, and other intellectual property rights owned by, entities operating in the industry in which we operate, we believe that there is a risk of litigation arising from allegations of infringement of these patents and other rights. Third parties may assert infringement or other intellectual property claims against us ~~or~~ **,** our licensees **, or our customers**. In addition, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after the earliest filing date for which a benefit is claimed. For this reason, and because publications in the scientific literature often lag behind actual discoveries, despite our best efforts we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications or that we were the first to invent the technology. Another party may have filed or may in the future file patent applications covering our products or technology similar to ours. If another party has filed a U. S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U. S. Patent and Trademark Office to determine priority of invention in the United States **, or a derivation proceeding to determine rights to the relevant claimed subject matter**. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if the other party had independently arrived at the same or similar invention prior to our own invention, **or had filed applications directed to such applications before us,** resulting in a loss of our U. S. patent position with respect to such inventions. We may have to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe on a third party' s proprietary rights. In addition, even if such claims are without merit, defending a lawsuit may result in substantial expense to us and divert the efforts of our technical and management personnel. We may also be subject to significant damages or injunctions against development and sale of some **or all** of our products. Furthermore, claims of intellectual property infringement may require us to enter into royalty or license agreements with third parties, and we may be unable to obtain royalty or license agreements on commercially acceptable terms, if at all. **32s** We may be subject to claims by third parties asserting that our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed **others'** intellectual property, including trade secrets or other proprietary information, of any such employee' s former employer. Litigation may be necessary to defend against these claims. In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property in the performance of their work to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact develops intellectual property that we regard as our own. Relevant 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. 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. Risks Related to Our Research and Development Activities We have ~~We have~~ made and intend to make significant additional investments in research and development,but there is no guarantee that any of these investments will ultimately result in commercial products that will generate revenues.The Accelerate Pheno system integrates several of our component products,systems and processes.We have dedicated significant resources on research and development activities into the Accelerate Pheno ~~system~~ , ~~the~~ Accelerate Arc ~~system~~ and **Accelerate Wave** ~~a next generation Pheno system~~ **systems** ,and we intend to spend significantly more on research and development activities **,including for such systems** . ~~Notwithstanding these investments,we anticipate~~ **There can also be no assurance** that we will ~~have~~ **be able** to ~~spend~~ **develop** additional ~~funds~~ **types of tests and instruments** in the **future nor whether** ~~research and development of the~~ **these will result in commercial products that will** ~~Accelerate Pheno system,the Accelerate Arc system,and our next generation~~ **generate** ~~instrument~~ **revenues.We have** a single research and development facility and we may be unable to continue to conduct our research and development activities if we lose this facility. If our facility or our equipment were damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed. We currently conduct all of our research and development and product development activities **, other than those outsourced to third party providers,** in our ~~existing~~ **Tucson, Arizona** facility ~~in Tucson, Arizona~~ . If this facility were to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages or otherwise, or if our business is disrupted for any other reason, ~~including as a result of the COVID- 19 pandemic,~~ we may not be able to continue the development of future products or test our products as promptly as our potential customers expect, or possibly not at all, and we would have no other means of conducting such activities until we were able to restore such capabilities at the current facility or develop an alternative facility. Further, in such an event, we may lose revenue and significant time during which we might otherwise have conducted research and development and product development activities and, we may not be able to maintain our relationships with our licensees or customers. The manufacture of components of our products involves complex processes, sophisticated equipment and strict adherence to specifications and quality systems procedures. Any unforeseen manufacturing problems, such as contamination of our facility, equipment malfunction or failure to strictly follow procedures or meet specifications, could result in delays or shortfalls in **the** production of our products. Identifying and resolving the cause of any manufacturing issues could require substantial time and resources. If we are unable to keep up with future demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue growth could be impaired and market acceptance of our product candidates could be adversely affected. While we carry a nominal amount of business interruption insurance to cover lost revenue and profits, this insurance does not cover all possible situations. If we have underestimated our insurance needs with respect to an **33s** interruption, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our licensees or customers. We use hazardous materials in some of our research, development and manufacturing processes and face the accompanying risks and regulations governing environmental safety. Our operations are subject to complex and stringent environmental, health, safety and other governmental laws and regulations that both public officials and private individuals may seek to enforce. In particular, our research activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials are in material compliance with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated, and we may not be in compliance with these regulations. In addition, existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, causing us to incur additional compliance costs and / or change the manner in which we operate. We could be held liable for any damages that might result from any accident or release involving hazardous materials. We have made and intend to make..... revenues. Risks Related to Government Regulation Legislative and Administrative Action May Have an Adverse Effect on Our Company Political, economic and regulatory influences are subjecting the health care industry in the U. S. to fundamental change. We cannot predict what other legislation relating to our business or to the health care industry may be enacted, including legislation relating to third- party reimbursement, or what effect such legislation may have on our business, prospects, operating results and financial condition. We expect federal and state legislators to continue to review and assess alternative health care delivery and payment systems, and possibly adopt legislation affecting further changes in the health care delivery system. Such laws may contain provisions that may change the operating environment for hospitals and managed care organizations. Health care industry participants may react to such legislation by curtailing or deferring expenditures and initiatives, including those relating to our products. Future legislation could result in modifications to the existing public and private health care insurance systems that would have a material adverse effect on the reimbursement policies discussed above. If enacted and implemented, any measures to restrict health care spending could result in decreased revenue from our products and decrease potential returns from our research and development initiatives. Furthermore, we may not be able to successfully neutralize any lobbying efforts against any initiatives we may have with governmental agencies. We and our suppliers, contract manufacturers and customers are subject to various governmental laws and regulations, and we may incur significant expenses to comply with, and experience delays in our product commercialization as a result of, these laws and regulations. Our operations are affected by various state, federal, and international healthcare, environmental, anti- corruption, fraud and abuse (including anti- kickback and false claims laws), privacy, and employment laws as well as international political sanctions. Violations of these laws and sanctions can result in criminal or civil penalties, including substantial fines and, in some cases, exclusion from participation in federal health care programs such as Medicare and Medicaid. In some cases, the violation of such laws could potentially lead to individual liability and imprisonment. We are also subject to extensive regulation by the FDA pursuant to the **FDCA** ~~Federal Food, Drug, and~~

~~Cosmetic Act~~ , by comparable agencies in foreign countries and by other regulatory agencies and governing bodies. Following the introduction of a product, these and other government agencies will periodically review our manufacturing processes, product performance and compliance with applicable requirements. We are also subject to various U. S. healthcare related laws regulating sales, contracting, marketing, and other business arrangements and the use and disclosure of individually identifiable health information. These include but are not limited to: • The federal Anti- Kickback Statute, **a criminal law,** which prohibits persons **and entities** from knowingly and willfully offering **, paying** , providing, soliciting, or receiving any remuneration, directly or indirectly, in **cash or in kind, in** exchange for or to induce **or reward** the referral of an individual, or the purchasing, leasing, **34s** ordering, recommending, furnishing or arranging for a good or service, for which payment may be made under a federal health care program, such as Medicare or Medicaid **. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations of the federal Anti- Kickback Statute can result in significant civil monetary penalties and criminal fines, as well as imprisonment and exclusion from participation in federal healthcare programs. • The federal False Claims Act, which imposes significant civil penalties, treble damages and potential exclusion from participation in federal healthcare programs against any person or entity that, among other things, knowingly presents, or causes to be presented, to the federal government claims for payment that are false or fraudulent or for making a false record or statement material to an obligation to pay the federal government or for knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government Further, a violation of the federal Anti- Kickback Statute can serve as a basis for liability under the federal civil False Claims Act. The qui tam provisions of the False Claims Act allow private individuals to bring actions on behalf of the federal government and to share in any monetary recovery. There is also the federal Criminal False Claims Act, which is similar to the federal Civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government** . • The federal Stark law, which prohibits physicians from referring patients to receive " designated health services " payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership / investment interests and compensation arrangements. **Violation of the federal Stark law can result in significant civil monetary penalties and exclusion from participation in the federal healthcare programs.** • The Eliminating Kickbacks in Recovery Act, which makes it a federal crime to knowingly and willfully solicit or receive any remuneration **(including kickbacks, bribes, or rebates)** in return for referring a patient to a recovery home, clinical treatment facility, or laboratory **where the services are covered by a " health care benefit program, " which includes private payers** , or pay or offer any remuneration to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory. **Violations of the law may result in penalties per occurrence and imprisonment.** • **Federal criminal statutes created by** HIPAA **impose criminal liability for** , ~~prohibits~~ **among other things,** knowingly and willfully (i) executing **(or attempting to execute)** a scheme to defraud any health care benefit program, including private payers, or (ii) falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for items or services under a health care benefit program. • HIPAA, as amended by **HITECH** ~~the Health Information Technology for Economic and Clinical Health Act of 2009~~ , which also restricts the use and disclosure of protected health information, mandates the adoption of standards relating to the privacy and security of protected health information, and requires us to report certain security breaches to health care provider customers with respect to such information where we are acting as a HIPAA business associate to that customer. • The federal Physician Payment Sunshine Act, which requires **applicable** manufacturers of certain medical devices **that may be reimbursed by Medicare, Medicaid, or CHIP, among others,** to **annually** track **and report** payments or other transfers of value ~~given~~ **provided** to U. S. licensed physicians ~~or~~ **, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse- midwives, and U. S.** teaching hospitals **as well as certain ownership** and **investment interest held in** ~~to report this data to CMS annually for subsequent public disclosure. • The federal False Claims Act, which imposes liability on any person or entity that, among other~~ -- **the manufacturer** ~~things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment~~ by **physicians and** ~~a federal health care program. The qui tam provisions of the~~ **their immediate family members** ~~False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government and to share in any monetary recovery~~ . Similar requirements have been adopted by many states and foreign countries. Violations of any of these laws can lead to additional legal risk such as risk of plaintiff class actions, state ~~Attorney~~ **attorney** ~~General~~ **general** actions, and investigations by the **FTC** ~~Federal Trade Commission~~ , among others. Failure to comply with applicable requirements, or later discovery of previously unknown problems with our products or manufacturing processes, including our failure or the failure of one of our contract manufacturers to take satisfactory corrective action in response to an adverse inspection, can result in, among other things: • administrative or judicially imposed sanctions; • injunctions or the imposition of civil penalties; • recall or seizure of our products; • ~~reportable events~~ **corrective field actions for our products; • submission of reports to FDA or other regulatory authorities** ; • total or partial suspension of production or distribution; • withdrawal or suspension of marketing clearances or approvals; **35s** • clinical holds **for investigations** ; • **untitled letters or** warning letters; • refusal to permit the import or export of our products; • criminal prosecution; and • exclusion or debarment from participation in federal health care programs such as Medicare and Medicaid. Any of these actions, in combination or alone, could prevent us from marketing, distributing and selling our products. In addition, we have developed and configured **our business** , and we intend to market our products **,** to meet customer needs created by these various **laws and** regulations. Any significant change in these regulations could reduce demand for our products. **New legislation could also be enacted, and / or** ~~Governmental~~ **governmental** agencies may also impose new requirements **under existing laws,** regarding registration, labeling or prohibited materials that may require us to modify or re- register **, or seek new approvals or clearances for,** products already on the market ~~or~~ **, may**

otherwise adversely impact our ability to market **our products, or may otherwise reduce demand for** our products. If materials used in our products become unavailable because of new governmental regulations, substitute materials may be less effective and may require significant cost to incorporate in our product. In addition, a product defect or regulatory violation could lead to a government- mandated or voluntary recall by us. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources, could cause the price of our shares of common stock to decline, expose us to product liability or other claims (including contractual claims from parties to whom we sold products) and harm our reputation with customers. The use of our diagnostic products by our customers is also affected by ~~the Clinical Laboratory Improvement Amendments (“~~ CLIA ~~”)~~ and related federal and state regulations that provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality assurance, quality control and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some laboratories, hospitals, providers or other customers with laboratories from using some or all of our diagnostic products. Maintaining adequate sales of our product may depend on the availability of adequate reimbursement to our customers from third- party payers, including government programs such as Medicare and Medicaid, private insurance plans, and managed care programs. Maintaining and growing sales of our ~~product, if~~ approved **products** ~~, may depend~~ **depends** in part on the availability of adequate **coverage and** reimbursement ~~to~~ **of** our ~~customers from~~ **products by** third- party payers, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Hospitals, clinical laboratories and other healthcare provider customers that may purchase our products generally bill various third- party payers to ~~cover~~ **reimburse** all or a portion of the costs and fees associated with diagnostic tests, including the cost of the purchase of our products. We currently expect that all of our diagnostic tests will be performed in a hospital inpatient setting, where governmental payers, such as Medicare, generally reimburse hospitals a single bundled payment that is based on the patient’ s diagnosis under ~~a~~ **the MS- DRG** classification system ~~known as the Medicare severity diagnosis- related groups (MS- DRGs) classification~~ for all items and services provided to the patient during a single hospitalization, regardless of whether our diagnostic tests are performed during such hospitalization. As a result, our customers’ access to adequate ~~payment~~ **reimbursement** by government and private insurance plans is central to the acceptance of our products. We may be unable to sell our **approved** products ~~, if approved,~~ on a profitable basis if third- party payers **refuse to cover our products or** reduce their current levels of ~~payment~~ **reimbursement,** or if our costs of production ~~increase~~ **increases** faster than increases in reimbursement levels. Additionally, third- party payers are increasingly reducing reimbursement for medical products and services. In addition, the U. S. government, state legislatures, and foreign governments have and may continue to implement cost- containment measures and more restrictive policies, including price controls and restrictions on reimbursement. ~~For example~~ **Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products. Further** , the Budget Control Act of 2011 (the “ Budget Control Act ”) established a process to reduce federal budget deficits through an automatic “ sequestration ” process if deficit reductions targets are not otherwise reached. Under the terms of the Budget Control Act, sequestration **36s** imposes cuts to a wide range of federal programs, including Medicare, which is subject to a two percent cut. The Bipartisan Budget Act of 2013 extended the two percent sequestration cut for Medicare through fiscal year 2023, and a bill signed by President Obama on February 15, 2014 further extended this cut for an additional year, through fiscal year 2024. The **Bipartisan Budget Act of 2015, approved in November 2015, extended sequestration an additional year to 2025, Medicare reimbursements were lowered, and other changes were made to compliance measures. The Bipartisan Budget Act of 2019 signed by President Trump in August 2019 also extended sequestration for another two years to fiscal year 2029. The** Coronavirus Aid, Relief, and Economic Security (**“** CARES **”**) Act, signed into law in March 2020, included critical relief from sequestration cuts as it applies to Medicare payments, exempting Medicare from the effects of sequestration from May 1, 2020, through **March** ~~Dec.~~ 31 ~~, 2020. The moratorium was extended until April 1~~ , 2022. Cuts of 1 % were imposed from April 1 through June 30, 2022. As of July 1, 2022, cuts of two percent were reimposed **and are set to remain in effect until 2031 unless unless additional Congressional action is taken. To offset the temporary suspension during the COVID- 19 pandemic, in 2030, the sequestration will be 2. 25 % for the first half of the year, and 3 % in the second half of the year** . While we cannot predict whether third- party reimbursement to our customers will be adequate, cost- containment measures and similar efforts by third- party payers, including government programs such as Medicare and Medicaid, could substantially impact the sales of our products and potentially limit our net revenue and results. We may be adversely affected by healthcare policy changes, including additional healthcare reform and changes in managed healthcare. Healthcare reform and the growth of managed care organizations have been considerable forces in the medical diagnostics industry and in recent political discussions. These forces have placed, and are expected to continue to place, constraints on the levels of overall pricing for healthcare products and services as well as the coverage available by public and private insurance and thus, could have a material adverse effect on the future profit margins of our products or the amounts that we are able to receive from third parties for the licensing of our products. Changes in the United States healthcare market could also force us to alter our approach to selling, marketing, distributing and servicing our products and customer base. In and outside the United States, changes to government reimbursement policies could reduce the funding that healthcare service providers have available for diagnostic product expenditures, which could have a material adverse impact on the use of the products we are developing and our future sales, license and royalty fees and profit margin. For example, the ACA requires CMS to reduce payments to hospitals reimbursed under Medicare’ s Inpatient Prospective Payment System (“ IPPS ”) that have excess readmissions. This and other applicable requirements set forth under the ACA and its current and future implementing regulations may significantly increase

our costs, and / or reduce our customer' s ability to obtain adequate reimbursement for tests performed with our products, which could adversely affect our business and financial condition. In addition to direct impacts from reimbursement cuts, sales of our products could be negatively impacted if reimbursement cuts reduce microbiology budgets. While the ACA is intended to expand health insurance coverage to uninsured persons in the United States, other elements of this legislation that are still being developed and refined, such as Medicare provisions aimed at improving quality and decreasing costs, comparative effectiveness research, an independent payment advisory board, and pilot programs to evaluate alternative payment methodologies, make it difficult to determine the overall impact on sales of our products. In addition to uncertainty regarding the impact of implementation of the ACA, there are some continued legal challenges to the ACA that, if successful, could call into question the legitimacy of the ACA and its future applicability. In recent years, other legislative, regulatory, and political changes aimed at regulating healthcare delivery in general and clinical laboratory tests in particular have been proposed and adopted in the United States. Reimbursement for the laboratory industry is under significant pressure. In January 2015, HHS announced a plan to shift the Medicare program and the healthcare system at large, toward paying providers based on quality, rather than the quantity of care provided to patients. In 2017, Medicare' s clinical laboratory reimbursement system became tied to private market rates with the start of the effective period for the Protecting Access to Medicare Act of 2014 (" PAMA "), changing the payment environment for clinical laboratory tests. The measures implemented by PAMA and ACA regulations can result in reduced prices, added costs, and decreased test utilization for our customers, although the full impact on our business of the ACA, changes to the IPPS, PAMA, and other applicable laws, regulations, and policies is uncertain. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect of any future legislation or **37s** regulation will have on our industry generally, our ability to successfully commercialize our products, and our overall business operations. Continued changes in healthcare policy could substantially impact the sales of our tests, increase costs and divert management' s attention from our business. For example, any expansion in the government' s regulation of the United States healthcare system could result in decreased profits to us, lower reimbursements to our customers for laboratory testing or reduced medical procedure volumes. ~~Additionally, CMS has created a number of waivers that impact the provision and reimbursement of healthcare services as a result of the COVID- 19 Public Health Emergency (" PHE "). It is not clear to the extent these waivers will remain in effect once the PHE has ended. We cannot predict the impact that the extension or termination of these waivers may have on our business.~~ The regulatory processes applicable to our products and operations are expensive, time- consuming, and uncertain and may prevent us from obtaining required ~~approvals~~ **authorizations** for the commercialization of our products. Our products are regulated as medical ~~device~~ **devices** ~~products~~ by the FDA and comparable agencies of other countries. In particular, **the FDCA and implementing** FDA regulations govern activities **for devices** such as ~~product~~ **design,** development, ~~product~~ testing, ~~product~~ **manufacturing, storage, distribution,** labeling, ~~product storage~~ **registration and listing** , premarket clearance or approval, ~~manufacturing,~~ advertising, promotion, ~~product~~ sales, **and** reporting **for devices, including reporting** of certain ~~product failures~~ **malfunctions, deaths,** and ~~distribution~~ **injuries associated with the device, and reporting of certain recalls and corrective field actions** . Some of our products, depending on their intended use, will require approval of a **PMA** ~~premarket approval~~ application ~~(" PMA ")~~ or clearance of a 510 (k) notification **, or granting of a request for de novo classification** from the FDA prior to marketing. The FDA has committed to review most 510 (k) decisions within 90 days, but the review may be delayed due to requests for additional information. A decision may take significantly longer, and clearance is never assured. The PMA process is much more costly, lengthy and uncertain. The FDA has committed to review most PMAs within 180 days where an advisory panel is not required and within 320 days where an advisory panel is required, but the review may be delayed due to requests for additional information. A decision may take significantly longer, and approval is never assured. In the 510 (k) clearance process, the FDA must determine that a proposed device is " substantially equivalent " to a device legally on the market, known as a " predicate " device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based ~~, in part,~~ on extensive data, including technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for **Class III** devices that are deemed to pose the greatest risk **, including devices for which general controls would be insufficient, and special controls cannot be developed, to provide a reasonable assurance of safety and effectiveness of the device** , such as life- sustaining, life- supporting or implantable devices **, or devices that otherwise present a potential unreasonable risk of illness or injury** . However, some devices are automatically **classified as Class III and** subject to the PMA pathway regardless of the level of risk they pose, because **there is no legally marketed predicate device to which** ~~they~~ - **the proposed device may demonstrate substantial equivalency** ~~have not previously been classified into a lower risk class by the FDA.~~ Manufacturers of these devices may request that the FDA review such devices in accordance with the de novo classification procedure, which allows a manufacturer whose novel device would otherwise require the submission and approval of a PMA prior to marketing to request down- classification of the device on the basis that the device presents low or moderate risk. If the FDA agrees with the down- classification, the applicant will then receive authorization to market the device. This device type can then be used as a predicate device for future 510 (k) submissions. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: • we may not be able to demonstrate to the FDA' s satisfaction that our product candidates ~~are~~ **provide a reasonable assurance of** ~~safe~~ **safety** and ~~effective~~ **effectiveness** ~~, sensitive and specific diagnostic tests,~~ for their intended ~~users~~ - **uses, or that our product candidates are substantially equivalent to a predicate device** ; • the data from our pre- clinical studies and clinical trials may be insufficient to support clearance or approval **, or de novo classification** , where required; and • the manufacturing process or facilities we or our contract manufacturers use may not meet applicable requirements. With respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain 510 (k) clearances **or de novo classification** with respect to those products. The process of obtaining regulatory clearances or approvals, or completing

the de novo classification process, to market a medical device can be costly and time consuming, and we may not be able to successfully obtain pre- market reviews on a timely basis, if at all. Further, even if we were to obtain regulatory clearance, **approval or de novo classification,** it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those **important or commercially attractive** uses **that were not cleared, approved or de novo classified** . **38s** On October 21, 2022, the Company announced it has been in recent discussions with the FDA regarding its Accelerate Arc Products. Pursuant to such discussions, the FDA has clarified that the Company must obtain a 510 (k) clearance in order to continue marketing and distributing the Accelerate Arc Products in the United States. The Company had been listing the Accelerate Arc Products as a Class I device exempt from 510 (k) clearance requirements. Additionally, the FDA requested that the Company promptly take certain corrective actions, including, among other things, (i) discontinuing the U. S. marketing and distribution of the Accelerate Arc Products for positive blood culture processing and subsequent identification by mass spectrometry for diagnostic use; (ii) removing and / or correcting all U. S. promotional information within the Company' s control (e. g., website, labeling, social media, sales associate information, or other promotional material) regarding the diagnostic use of the Accelerate Arc Products as Class I devices or as devices intended as positive blood culture processing devices for subsequent identification of microorganisms by mass spectrometry; and (iii) revising / removing the Company' s registration and listing of the Accelerate Arc Products as Class I devices. The Company intends to continue to fully cooperate with the FDA, including promptly taking the corrective actions requested by the FDA. On October 21, 2022, the Company also submitted a pre- submission package to the FDA, which is intended to obtain FDA feedback regarding the Company' s contemplated submission of an application for 510 (k) clearance for the Accelerate Arc Products. The Company cannot, however, give any assurances that FDA will be satisfied with the Company' s actions taken in response to the matters raised by the FDA in its discussions. The Company also cannot give any assurances as to the timing of the FDA' s response to the Company' s pre- submission package or whether the Company will be successful in obtaining 510 (k) clearance for the Accelerate Arc Products. Clinical trial data is typically required to support a PMA **or de novo classification request** and is sometimes required for a 510 (k) pre- market notification. Although many 510 (k) pre- market notifications are cleared without clinical data, in some cases, the FDA requires clinical data to support **a demonstration of** substantial equivalence. Clinical trials are expensive and time- consuming. In addition, the commencement or completion of any clinical trials may be delayed or halted for any number of reasons, including product performance, changes in intended use, changes in medical practice and the opinion of evaluator Institutional Review Boards ~~. Additionally, since 2009, the FDA has significantly increased the scrutiny applied to its oversight of companies subject to its regulations by hiring new investigators and increasing inspections of manufacturing facilities~~ . The FDA has also undertaken initiatives related to enhancement of the 510 (k) review process and has proposed significant changes to the regulation of laboratory developed tests (" LDTs "). **In particular, on October 3, 2023, the FDA proposed to regulate LDTs as medical devices, and to phase out its historical exercise of enforcement discretion for such tests. If the proposed rule is finalized, laboratories offering LDTs would be expected to come into compliance with FDA regulation of medical devices over a period of time. Even if the proposed rule is not finalized, the FDA could seek to increase its oversight of LDTs as medical devices under existing regulations.** We continue to monitor these developments and analyze how they will impact the **clearance** approval **and classification** of our products **, as well as the demand for our products by customers** . These and other actions proposed by the FDA' s Center for Devices and Radiological Health **(" CDRH ")** could result in significant changes to the 510 (k) process, which could complicate the ~~product~~ **clearance,** approval **and de novo classification** ~~process~~ **processes** , although we cannot predict the effect of such changes and cannot ascertain if such changes will have a substantive impact on the **clearance,** approval **or de novo classification** of our products. If we fail to adequately respond to the increased scrutiny and ~~streamlined~~ **changes to the** 510 (k) submission process, our business may be adversely impacted. Failure to comply with the applicable requirements can result in, among other things, **untitled letters,** warning letters, administrative or judicially imposed sanctions such as injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, refusal to grant premarket clearance ~~or~~ **,** PMA **approval or de novo classification** for devices, withdrawal of marketing clearances or approvals, or criminal prosecution. With regard to products for which we seek 510 (k) clearance ~~or~~ **,** PMA approval **or de novo classification** from the FDA, any failure or material delay to obtain such clearance ~~or~~ **,** approval **or de novo classification** could harm our business. If the FDA were to disagree with our regulatory assessment and conclude that approval ~~or~~ **,** clearance **or de novo classification** is necessary to market the ~~products~~ **devices** , we could be forced to cease marketing the products and seek approval ~~or~~ **,** clearance **or de novo classification before continuing to market such devices** . Once clearance ~~or~~ **,** approval **or de novo classification** has been obtained for a product, there is an obligation to ensure that all applicable FDA and other regulatory requirements continue to be met. In addition, it is possible that the current regulatory framework could change or additional **laws or** regulations could arise at any stage during our product development or marketing, which may adversely affect our ability to obtain or maintain **clearance,** approval **or de novo classification** of our products ~~. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510 (k) regulatory pathway, the FDA initiated an evaluation of the program, and in January 2011, announced several proposed actions intended to reform the review process governing the clearance of medical devices. The FDA undertook these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several " Medical Device Regulatory Improvements " and miscellaneous reforms that are further intended to clarify and improve medical device regulation both pre- and post- approval~~ . Any delay in, or failure to receive or maintain, clearance ~~or~~ **,** approval **or de novo classification** for our product candidates could prevent us from generating revenue from these product candidates. Additionally, the FDA and other regulatory authorities have **39s** broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our

product candidates and dissuade our customers from using our product candidates, if and when they are authorized for marketing. Our manufacturing facility located in Tucson, Arizona, where we assemble and produce our products, may be subject to regulatory inspections by the FDA and other federal and state and foreign regulatory agencies. For example, this facility is subject to ~~Quality System Regulations (" QSR~~ **QSRs** ~~")~~ of the FDA and is subject to annual inspection and licensing by the State of Arizona. If we fail to maintain this facility in accordance with the QSR requirements, international quality standards or other regulatory requirements, our manufacturing process could be suspended or terminated, which would prevent us from being able to provide products to our customers in a timely fashion. Sales of our diagnostic product candidates outside the United States are subject to foreign regulatory requirements governing clinical studies, vigilance reporting, marketing approval, manufacturing, product licensing, pricing and reimbursement. These regulatory requirements vary greatly from country to country. As a result, the time required to obtain approvals outside the United States may differ from that required to obtain FDA marketing authorization from the FDA, and we may not be able to obtain foreign regulatory approvals on a timely basis or at all. Marketing authorization from the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure clearance or approval by regulatory authorities in other countries or by the FDA. Foreign regulatory authorities could require additional testing. Failure to comply with foreign regulatory requirements, or to obtain required clearances or approvals, could impair our ability to commercialize our diagnostic product candidates outside of the United States. Global health crises ~~, such as the current COVID- 19 global pandemic,~~ may divert regulatory resources and attention away from approval processes for our products. This could materially lengthen the regulatory approval process of new products, which would delay expected commercialization of such new products. Modifications to our products, if cleared or approved, may require new 510 (k) clearances or pre- market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained. Any modification to a **510 (k)- cleared or de novo classified** device ~~authorized for marketing~~ that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510 (k) clearance **, unless a predetermined change control plans (" PCCP ")** ~~or~~ **for the device has been cleared. If a PCCP has been cleared for the device** , ~~possibly~~ **then the manufacturer may make changes to the device consistent with the cleared PCCP without submitting a new 510 (k)** , **even though such changes would typically require 510 (k) clearance. If the modification would result in the device becoming a different type of device, including a novel device or a Class III device, then a de novo classification request or PMA, rather than a new 510 (k), may be required. Similarly, any modification to a PMA-** ~~approval~~ **approved device that affects the safety or effectiveness** of **the device, including significant modifications to the manufacturing process, labeling of the product, or design of the device, requires** a PMA supplement or new PMA **, unless a PCCP has been approved for the device. If a PCCP has been approved for a PMA- approved device, then changes may be made to the device consistent with the approved PCCP without submitting a PMA supplement, even though such changes would typically require a PMA supplement** . The FDA requires ~~every~~ **each** manufacturer to make ~~this~~ **the** determination ~~in~~ **initially whether a new 510 (k), de novo classification request, or PMA is required for a modification to a device, or whether** the ~~first instance~~ **modification may be documented without further FDA premarket review** , but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances **, de novo classifications,** or **PMA** approvals are necessary. If the FDA disagrees with our determination and requires us to submit new 510 (k) notifications, **de novo classifications,** PMA supplements or PMAs for modifications to previously cleared **, de novo classified,** or approved products for which we conclude that new clearances **, de novo classification,** or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant ~~regulatory~~ fines or penalties. Furthermore, the FDA' s ongoing review of the 510 (k) program may make it more difficult for us to make modifications to any products for which we obtain clearance **or de novo classification** , either by imposing more strict requirements on when a manufacturer must submit a new 510 (k) for a modification to a previously cleared **or de novo classified** product, or by applying more onerous review criteria to such submissions. The practical impact of the FDA' s continuing scrutiny of the 510 (k) program remains unclear. **40s** We rely on third parties to conduct studies of our products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily. We rely on third parties, including ~~medical~~ **clinical** investigators, to conduct studies on our products. Our reliance on these third parties for clinical development activities will reduce our control over these activities. These third parties may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. If applicable, our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain marketing authorization from the FDA or **other** regulatory ~~clearance~~ **authorities** for our products. A recall of our products, either voluntarily or at the direction of the FDA, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products. **In addition,** ~~Manufacturers~~ **manufacturers** may, under their own initiative, recall a product **for any reason, including** if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Under the FDA' s medical device reporting regulations, we are required to report to the FDA any incident in which **information reasonably suggests that** our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, **such malfunction** would likely cause or contribute to death or serious injury. Repeated product malfunctions may result

in a voluntary or involuntary product recall. Recalls of any of our products would divert managerial and financial resources, have an adverse effect on our reputation, and may impair our ability to produce our products in a cost- effective and timely manner in order to meet our customers' demands. **Additionally, under the FDA' s regulations for corrections and removals, we are required to report to the FDA any field correction or other recall action that is initiated to reduce a risk to health, or to remedy a violation of the FDCA caused by the device which may present a risk to health.** Depending on the corrective action we take to redress a product' s deficiencies or defects, the FDA may require, or we may decide that we will need to obtain, new approvals ~~or ,~~ clearances **or de novo classification** for the device before we may market or distribute the corrected device. Seeking such approvals ~~or ,~~ clearances **or de novo classification** may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA **untitled letters,** warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our ability to market our products in the future. Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and may harm our reputation. Risks Related to Our Common Stock ~~broker- dealers from making a market~~ in ~~or otherwise seeking or generating interest in our common stock and might deter certain institutions and persons from investing in our securities at all.For these -- the reasons and others,delisting~~ **form of common stock of the Company.Repayment in shares** ~~could~~ **would likely** ~~adversely affect our business,financial condition and liquidity.We have significantly increased -~~ **increase Jack Schuler' s beneficial ownership** ~~the total number of authorized shares of common stock under our certificate of incorporation,which could cause significant dilution .~~ **Jack Schuler also holds** ~~Our management believes the successful achievement of our business objectives may require additional financing through one or a combination of the issuance of common stock in public or private equity offerings,debt financings,exercise of common stock warrants~~ **Warrants** ~~,collaborations,licensing arrangements,grants and government funding and strategic alliances.To effectuate~~ that **would also** ~~,in May 2023,we sought and obtained authorization from stockholders to~~ increase **his beneficial ownership if exercised** ~~the total number of authorized shares of common stock under our certificate of incorporation by 250,000,000 for a total of 450,000,000 shares.The future issuance of all or part of our remaining authorized common stock may result in substantial dilution to our stockholders and may adversely affect the market price of our common stock .~~Future issuances or sales of shares of our common stock may depress the price of our shares and be dilutive to our existing stockholders.We cannot predict whether future issuances of shares of our common stock or the availability of shares for resale in the open market will decrease the market price per share of our common stock.Any sales by us or by our existing stockholders of a substantial number of shares of our common stock in the public market,or the perception that such sales might occur,may cause the market price of our shares to decline.The exercise of any outstanding options or warrants,the issuance of future equity awards to retain and incentivize employees,the ~~issuance of our common stock upon the~~ conversion **of ~~or~~ our ~~exchange of~~ Series A Preferred Stock** ~~our -~~ **or** ~~convertible notes~~ **in connection with acquisitions,** and any other issuances of our common stock could have an adverse effect on the market price of the shares of our common stock.To the extent that we raise additional funds through the issuance and sale of equity or convertible debt securities **,including shares of our common stock through our ATM Program,** the issuance of such securities will result in dilution to our stockholders.Investors purchasing shares or other securities in the future may also have rights superior to existing stockholders.In addition,we have a significant number of options,warrants and restricted stock units outstanding.If the holders of these options,or warrants exercise,or the restricted stock units are released,our stockholders may incur further dilution.We **may** ~~are likely to~~ require additional capital in the future,and you may incur dilution to your stock holdings.We have primarily relied upon capital from the sale of our securities to fund our operations.Although we have now commercialized the Accelerate Pheno system in the United States,Europe,and certain other regions,there can be no assurance that our commercialization efforts will be successful or that we will not continue to incur operating losses.We may require additional capital to continue to operate as a going concern in the near- term and may require additional capital in the future to expand our product offerings,expand our sales and marketing ~~42s~~ infrastructure,increase our manufacturing capacity,fund our operations,and continue our research and development activities.Our future funding requirements will depend on many factors,including:• our ability to address existing obligations,including our ~~2.50 % Notes and 5.00 %~~ Notes;• our ability to obtain marketing authorization from the FDA or clearance from the FDA to market our product candidates;• market acceptance of our product candidates,if cleared;• the cost and timing of establishing sales,marketing and distribution capabilities;• the cost of our research and development activities;• the ability of healthcare providers to obtain coverage and adequate reimbursement by third- party payers for procedures using our products;• the cost and timing of marketing authorization or regulatory clearances;• the cost of goods associated with our product candidates;• the cost of customer disruptions due to supply disruptions;• the effect of competing technological and market developments;and • the extent to which we acquire or invest in businesses,products and technologies,including entering into licensing or collaboration arrangements for product candidates.If we require additional capital,we may attempt to raise it through a variety of strategies,including the issuance and sale of additional shares of our common stock.Issuances of additional shares of our common stock or preferred stock in the future,whether in connection with a rights offering,follow- on offering or otherwise,would dilute existing stockholders and may adversely affect the market price of our common stock.We cannot assure you that we will be able to obtain additional funds on acceptable terms,or at all.Debt financing,if available,may involve covenants restricting our operations or our ability to incur additional debt.Any debt or additional equity financing that we raise may contain terms **that are not favorable to us or our stockholders.If we raise additional funds through collaboration and licensing arrangements with third parties,it may be necessary to relinquish some rights to our technologies or our**

products,or grant licenses on terms that are not favorable to us.If we are unable to raise adequate funds,we may have to liquidate some or all of our assets or delay,reduce the scope of or eliminate some or all of our product development.If we do not have,or are not able to obtain,sufficient funds,we may be required to delay additional product development or license to third parties the rights to commercialize our products or technologies that we would otherwise seek to commercialize ourselves.We also may have to reduce marketing,customer support or other resources devoted to our product candidates or cease operations.Any of these factors could harm our operating results.Provisions in our certificate of incorporation and bylaws Our stock price has been volatile and may continue to be volatile and traded on low volumes. The trading price of our common stock has been, and is likely to continue to be, highly volatile. Factors that may contribute to volatility in the price of our common stock include, but are not limited to: • difficulties in resolving our continuing financial condition and our ability to obtain additional capital to meet our financial obligations; • low trading volume currently prevailing in the market for our shares; • concentration of our stock with one individual large shareholder who could decide to materially reduce his position; • the substantial current short interest in our stock; • ~~the duration and severity of the COVID- 19 pandemic and its effects on~~ our **failure to meet applicable Nasdaq listing standards** ~~business, financial condition, results of operations~~ and ~~cash flows~~ **the possible delisting of our common stock from Nasdaq** ; • adverse regulatory decisions, including failure to receive regulatory approvals for any of our product candidates; • our success in commercializing our product candidates, if and when approved; • the introduction of new products or product enhancements by us or others in our industry; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments or restructurings; **43s** • disputes or other developments with respect to our or others' intellectual property rights; • product liability claims or other litigation; • quarterly variations in our results of operations or those of others in our industry; • sales of large blocks of our common stock, including sales by our executive officers and directors; • changes in senior management or key personnel; • changes in laws or regulations which adversely affect our industry or us; • changes in earnings estimates or recommendations by securities analysts; and • changes in general market, economic, and political conditions in the U. S., and global economies or financial markets, including those resulting from natural disasters, terrorist attacks, acts of war ~~(including the ongoing war between Russia and Ukraine)~~ , other geopolitical uncertainties, public health concerns (including health epidemics **, pandemics** or outbreaks of communicable diseases ~~, such as the COVID- 19 pandemic~~), and responses to such events. The market value of your investment in our common stock may rise or fall sharply at any time because of this volatility and also because of significant short positions that may be taken by investors from time to time in our common stock. During the year ended December 31, ~~2022~~ **2023** ~~, the sale price for our common stock ranged from $ 0. 51 to $ 5. 15 per share, and during the year ended December 31, 2021~~ , the sale price for our common stock ranged from $ 4. ~~27~~ **17** to $ ~~15~~ **10** . ~~00~~ **30** per share **, and during the year ended December 31, 2022, the sale price for our common stock ranged from $ 5. 10 to $ 51. 50 per share. Share prices shown reflect the Company effected one- for- ten Reverse Stock Split which occurred on July 11, 2023** . The market prices for securities of medical technology companies like ~~us~~ **ours** historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition, in the past, following periods of volatility in the market price of a company' s securities, securities class- action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our product offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management' s attention and resources. Furthermore, negative public announcements of the results of hearings, motions or other interim proceedings or developments could have a negative effect on the market price of our common stock. The ~~short interest in our common stock is high, which may lead to further volatility in our stock price. As of December 31, 2022, the number of shares of our common stock shorted was high as compared to the number of shares in the public float. A significant concentration of short interest can be a contributing factor resulting in high volatility in our stock price and volume fluctuations. The~~ ownership of our common stock is highly concentrated. As of December 31, ~~2022~~ **2023** , our directors and executive officers beneficially owned in the aggregate, approximately ~~34~~ **48** % of our outstanding common stock, including ~~23~~ **40** % beneficially owned, directly or indirectly, by our director, Jack Schuler. As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock. Certain of our major shareholders hold their shares in certificate form, further limiting trading volume. **Provisions** ~~In addition, Jack Schuler holds Secured Notes, which the Company may, at its option, repay~~ in **our Amended and Restated Certificate of Incorporation, as amended** (~~i~~ **our " Charter "**) ~~cash or~~ **and Amended and Restated Bylaws** (~~ii~~ **as amended, our " Bylaws "**) in the form of common stock of..... in our certificate of incorporation and bylaws and Delaware law may delay or prevent acquisition of our Company, which could adversely affect the value of our common stock. Provisions contained in our **Charter** ~~certificate of incorporation~~ and ~~bylaws~~ **Bylaws** , as well as provisions of the Delaware General Corporation Law **(" DGCL ")** , could delay or make it more difficult to remove incumbent directors or for a third party to acquire us, even if a takeover would benefit our stockholders. For example, our board of directors may fill any vacancy on the board of directors, whether such vacancy occurs as a result of an increase in the number of directors or otherwise. Special meetings of the stockholders may be called only by the President, a Vice President, our board of directors or the holders of not less than one- tenth of all the shares entitled to vote at

the meeting. Additionally, our board of directors has the authority to cause us to issue, without any further vote or action by the stockholders, up to 5. 0 million shares of preferred stock, par value $ 0. 001 per share, in one or more series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, **44s** limitations or restrictions thereof, of the shares of such series ~~. For example, in September 2021, we issued 3, 954, 546 shares as Series A Preferred Stock as discussed further below~~. The issuance of shares of preferred stock may have the effect of delaying, deferring or preventing a change in control of our Company without further action by the stockholders, even where stockholders are offered a premium for their shares. Moreover, we are subject to the provisions of Section 203 of the **DGCL** ~~General Corporation Law of the State of Delaware~~, 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 Series A Preferred Stock has..... stockholders and may depress our stock price . General Risk Factor Current macroeconomic conditions and the uncertain economic outlook may remain challenging for the foreseeable future. Global economic conditions **, which have led to market disruptions and significant volatility in credit and capital markets,** may remain challenging and uncertain for the foreseeable future, including **inflation** ~~as a result of the ongoing COVID- 19 pandemic~~ , ~~the~~ **global health crises, international** ~~war~~ **wars** ~~between Russia~~ and ~~Ukraine~~ **disputes** , and disruptions to the banking system due to bank failures ~~, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and Signature Bank. This had led to market disruptions and significant volatility in credit and capital markets~~. These conditions not only limit our access to capital but also make it difficult for our customers, our vendors and us to accurately forecast and plan future business activities, and they could cause U. S. and foreign hospitals and other customers to slow spending on our products, which would delay and lengthen sales cycles. Some of our customers rely on government research grants to fund technology purchases. If negative trends in the economy affect the government' s allocation of funds to research, there may be less grant funding available for certain of our customers to purchase technologies from us. Certain of our customers may face challenges gaining timely access to sufficient credit or may otherwise be faced with budget constraints, which could result in decreased purchases of our products or in an impairment of their ability to make timely payments to us. If our customers do not make timely payments to us, we may be required to assume greater credit risk relating to those customers and increase our allowance for doubtful accounts, and our days sales outstanding would be negatively impacted. Although we maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments, we may not continue to experience the same loss rates that we have in the past.