Risk Factors Comparison 2024-03-28 to 2023-03-21 Form: 10-K

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You should carefully consider the risks described below before making an investment decision. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. The risks described below are not the only ones that we may face. Additional risks that are not currently known to us or that we currently consider immaterial may also impair our business, financial condition or results of operations. In assessing these risks, you should also refer to the other information contained in this Form 10- K, including our financial statements and related notes. Risk Factors ~~Relating~~ **Related** to Our Business **There is substantial doubt about our ability to continue as a going concern. We will require significant additional financing to fund operating expenses and implement our business plan. Such financing, if available, may be dilutive. We have incurred significant and recurring losses from operations for the past several years and had an accumulated deficit of $ 167, 761, 883 as of December 31, 2023. We had cash and cash equivalents of $ 8, 728, 660 as of December 31, 2023 and need to raise significant additional capital to meet our operating needs. Our short- term obligations as of December 31, 2023 were $ 3, 951, 031, consisting primarily of aggregate accounts payable and accrued expenses of $ 2, 973, 729 and operating lease obligations of $ 517, 427. As of December 31, 2023, we also had a short- term note payable of $ 150, 408 that bears interest at an annual percentage rate of 9. 25 % and long- term operating lease obligations of $ 2, 188, 979 with a weighted average remaining lease term of 3. 99 years. We do not expect to generate sufficient operating revenue to sustain our operations in the near term. During the year ended December 31, 2023, we incurred negative cash flows from operations of $ 13, 189, 390. Although we have attempted to improve our operating margin by bolstering revenues and curtailing expenses and continue to seek ways to generate revenue through business development activities, there is no guarantee that we will be able to improve our operating margin sufficiently or achieve profitability in the near term. These conditions raise substantial doubt about our ability to continue as a going concern within one year after the date our consolidated financial statements included in this annual report on Form 10- K are issued. We are evaluating alternatives to obtain the required additional funding to maintain future operations. These alternatives may include, but are not limited to, equity financing, issuing debt, entering into other financing arrangements, or monetizing operating businesses or assets. These possibilities, to the extent available, may be on terms that result in significant dilution to our existing stockholders or that result in our existing stockholders losing part or all of their investment. Despite these potential sources of funding, we may be unable to access financing or obtain additional liquidity under acceptable terms, if at all. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities and we could default on existing payment obligations, which would have a material adverse effect on our financial condition and results of operations, and may ultimately be required to cease our operations and liquidate our business. The use of AI in our business is subject to risks associated with new and rapidly evolving technologies and industries, may result in reputational harm or liability, and may not result in the development of commercially viable therapies, drugs or treatments. Our business model relies on the use of AI to support the development of optimal cancer therapies. Using AI and our proprietary biobank of 150, 000 tumor samples, categorized by patient type, we make optimized, high- confidence drug- response predictions regarding drug compounds to enable a more informed selection of drug / tumor combinations. While we believe that AI may potentially enable more efficient drug research and clinical development than the conventional model, our approach is novel and has not yet been widely studied. Our use of AI is subject to risks and challenges associated with new, disruptive, and rapidly evolving technologies and industries, which may affect its adoption and the success of our business. The algorithms we use may be flawed, our datasets may be insufficient or contain biased information, and inappropriate or controversial data practices by us or others could impair the acceptance of AI solutions. These deficiencies could undermine the predictions or analysis that AI applications produce, subjecting us to competitive harm, legal liability, and brand or reputational harm. Additionally, changes in laws and regulations could impact the usefulness of our solution and could necessitate modifications in our business to accommodate such changes. The regulatory landscape for AI is continually evolving, and both the FDA and the European Medicines Agency are in the process of issuing comprehensive guidance on AI software which may change how our product is regulated. Our approach may not result in time savings, higher success rates or reduced costs as we expect it to, and if not, we may not attract collaborators or develop new drugs as quickly or cost- effectively as expected and, therefore, we may not be able to commercialize our approach as expected at this time. We have entered into, and may enter into additional, collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues. We may enter into collaborations, in- licensing arrangements, joint ventures, strategic alliances, partnerships or other arrangements to develop products and to pursue new markets. Proposing, negotiating and implementing collaborations, in- licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost- effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not**

result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. Our ability to generate revenues from these arrangements will depend in part on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. Additionally, we may not be in a position to exercise sole decision- making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our future collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with any future collaborators, they may act in their self- interest, which may be adverse to our best interests, and they may breach their obligations to us. In addition, we may have limited control over the amount and timing of resources that any future collaborators devote to our or their future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements will be contractual in nature and will generally be terminable under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium. If we enter into in- bound intellectual property license agreements, we may not be able to fully protect the licensed intellectual property rights or maintain those licenses. Future licensors could retain the right to prosecute and defend the intellectual property rights licensed to us, in which case we would depend on the ability of our licensors to obtain, maintain and enforce intellectual property protection for the licensed intellectual property. These licensors may determine not to pursue litigation against other companies or may pursue such litigation less aggressively than we would. Further, entering into such license agreements could impose various due diligence, commercialization, royalty or other obligations on us. Future licensors may allege that we have breached our license agreement with them, and accordingly seek to terminate our license, which could adversely affect our competitive business position and harm our business prospects. Our limited operating history with respect to our drug discovery solutions makes evaluation of our business difficult. Our drug discovery, drug development and clinical research services were launched with the initial investment in Helomics during the first quarter of 2018 and have not generated significant revenue to date. Our ability to implement a successful business plan with respect to drug discovery, drug development and clinical research services remains unproven **,** and **we may** ~~no~~ **not** ~~assurance can be given that we will~~ ever generate sufficient revenues to sustain our business. We have a limited operating history which makes it difficult to evaluate our performance. Our prospects should be considered in light of these risks, and the expenses, technical obstacles, difficulties, market penetration rate, and delays frequently encountered in connection with the development of new businesses. These factors include uncertainty as to whether we will be able to: • Succeed in uncertain markets; • Respond effectively to competitive pressures; • Successfully address intellectual property issues of others; • Protect and expand our intellectual property rights; and • Continue to develop and upgrade our products. In connection with developing our drug discovery solutions, we have committed ~~and will continue to commit~~ significant capital to investments in early- stage companies, all of which may be lost, and ~~which may~~ **our ability to continue to commit capital in other early- stage companies will** require us to raise significant additional capital **. Our** ~~, and our~~ entering into new lines of business ~~will~~ **could** result in significant diversion of management resources, all of which may result in failure of our business. We have committed significant capital and management resources to developing our drug discovery solutions and other new business areas, and we intend to continue to devote significant capital and management resources to new businesses. Therefore, we could invest significant capital in business enterprises with no certainty when or whether we will realize a return on these investments. **Any** ~~Investments~~ **investments** using cash will deplete our capital resources, meaning we will be required to raise significant amounts of new capital. ~~There is~~ **We may** ~~no~~ **not** ~~assurance that we will~~ be successful in raising sufficient capital, and the terms of any such financing ~~will~~ **may** be dilutive to our stockholders. We may also acquire technologies or companies by issuing stock or other equity securities rather than, or in addition to, payment of cash, which may have the result of diluting our stockholders' investments. Further, the energy and resources of our officers and personnel may be substantially diverted to new lines of business, which are unproven. If these businesses are unsuccessful or require too great of a financial investment to be profitable, our business may fail. We rely on sole suppliers for some of the materials used in our **business** ~~molecular diagnostic tests~~, and we may not be able to find replacements or transition to alternative suppliers in a timely manner. We rely on sole suppliers for certain materials used ~~to perform our molecular diagnostic tests. We also purchase reagents used~~ in our **business** ~~molecular diagnostic tests from sole- source suppliers~~. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective, or the alternative sources will be available in a timely manner. If these suppliers can no longer provide us with the materials **used in** ~~needed to perform~~ our **business** ~~molecular diagnostic tests~~, if the materials do not meet required quality specifications, or if we cannot obtain acceptable substitute materials, an interruption in ~~molecular diagnostic test processing~~ **our products and services provided to customers** could occur. Any such interruption may directly impact our revenue and cause us to incur higher costs. If we are sued for product liability or errors and omissions liability, we could face substantial liabilities that exceed our resources. The marketing, sale, and use of our **products** ~~molecular diagnostic tests~~ could lead to product liability claims ~~if someone were to~~ **. These claims could** allege that the **products** ~~molecular diagnostic test~~ failed to perform as ~~it was~~ **they were** designed. We may also be subject to liability for errors in the results we provide to physicians or for a misunderstanding of, or inappropriate reliance upon, the information we provide. A product liability or errors and omissions liability claim could result in substantial damages and be costly and time consuming for us to defend. Although we maintain product liability and errors and omissions insurance, we cannot be certain that our insurance would fully protect us from the financial impact of defending against these types of claims

or any judgments, fines, or settlement costs arising out of such claims. Any product liability or errors and omissions liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could cause injury to our reputation or cause us to suspend sales of our products and solutions. The occurrence of any of these events could have a material adverse effect on our business, financial condition, and results of operations. If our R & D and commercialization efforts for our PEDAL platform ~~takes~~ **take** longer than expected, the commercial revenues that use this platform could also be delayed. Our drug discovery solutions business offers various services to pharma, diagnostics, and biotech companies. These services use our PEDAL platform. This platform is the subject of active R & D to further improve them for commercial use in order to help our clients in their drug discovery, biomarker, and clinical trial activities. We could face delays in this R & D ~~, for~~ **. For** example: ~~•~~ we may not be able to secure access to and approval to use clinical data from academic hospital partners in a timely manner; ~~•~~ clinical testing volume (number of specimens coming to us for testing) may not grow sufficiently to drive additional data generation as well as further development of the biobank; ~~•~~ patient consent to use the patient' s data and tumor material for R & D may not be sufficient to support R & D; and ~~•~~ we may not be able to attract and retain the appropriately qualified staff to perform the necessary R & D. We have a limited operating history with the drug discovery solutions business, particularly in connection with services using our PEDAL platform, as these are new to the market, which makes it difficult to forecast our future revenues. Although we are committed to the buildout of this business for the long term, we cannot predict at this time, with any certainty, the future viability of this business unit. We face significant competition **to our STREAMWAY System** in the surgical fluid waste management industry, including competition from companies with considerably greater resources than ours, and if we are unable to compete effectively with these companies, our market share may decline, and our business could be harmed. The surgical fluid waste management industry is highly competitive **,** with numerous competitors ranging from well- established manufacturers to innovative start- ups. Several of our competitors have significantly greater financial, technological, engineering, manufacturing, marketing, and distribution resources than we do. Their greater capabilities in these areas may enable them to compete more effectively on the basis of price and production and more quickly develop new products and technologies. Companies with significantly greater resources than ours may be able to reverse engineer our products and / or circumvent our intellectual property position. Such action, if successful, would greatly reduce our competitive advantage in the marketplace. We believe our ability to compete successfully with our STREAMWAY System depends on a number of factors, including, without limitation, our technical innovations of unlimited suction and unlimited capacity capabilities, our innovative and advanced research and development capabilities, strength of our intellectual property rights, sales and distribution channels, and advanced manufacturing capabilities. We plan to employ these and other elements as we develop our products and technologies, but there are many other factors beyond our control. We may not be able to compete successfully in the future, and increased competition may result in price reductions, reduced profit margins, loss of market share, and an inability to generate cash flows that are sufficient to maintain or expand our development and marketing of new products, which could adversely impact the trading price of the shares of our common stock. If demand for our STREAMWAY System or molecular diagnostic tests is unexpectedly high or if we experience problems in scaling our operations, there **may** ~~is no assurance that there will not~~ be supply interruptions or delays that could limit the growth of our revenue. We have contracted with a manufacturing company that follows ISO compliance regulations of the FDA and that can manufacture products at high volumes. However, if demand for our product is higher than anticipated, **then** ~~there is no assurance that~~ we or our manufacturing partners ~~will~~ **may not** be able to produce the product in sufficiently higher quantity to satisfy ~~demands~~ **demand** . Likewise, as demand for our molecular diagnostic tests ~~grow~~ **grows** , we will need to continue to scale our testing capacity and processing technology to expand our customer service, billing, and systems processes and to enhance our internal quality assurance program. We will also need additional certified laboratory scientists and other scientific and technical personnel to process higher volumes of our molecular diagnostic tests. We cannot guarantee that increases in scale, related improvements, and quality assurance will be implemented successfully or that appropriate personnel will be available. Failure to implement necessary procedures, transition to new processes, or hire the necessary personnel could result in higher costs of processing tests or an inability to meet demand. **We may** ~~There can be no~~ **not** ~~assurance that we will~~ be able to perform our testing on a timely basis at a level consistent with demand, **and** ~~or that~~ our efforts to scale our operations **may** ~~will not~~ negatively affect the quality of test results. If we encounter difficulties in scaling our operations as a result of, among other things, quality control and quality assurance issues and availability of reagents and raw material supplies, we will likely experience reduced sales, increased repair or re- engineering costs, defects, and increased expenses due to switching to alternate suppliers. Any of these results would reduce our revenues and gross margins. Although we attempt to match our capabilities to estimates of marketplace demand, to the extent demand materially varies from our estimates, we may experience constraints in our operations and delivery capacity, which could adversely impact revenue in a given fiscal period. Any supply interruptions or inadequate supply would have a material adverse effect on our results of operations. If we encounter difficulty meeting market demand or quality standards **,** our reputation could be harmed, and our future prospects and business could suffer, causing a material adverse effect on our business, financial condition, and results of operations ~~. We may require additional financing to fund operating expenses and fulfill our business plan. Such financing, if available, will be dilutive. We have not achieved profitability and anticipate that we will continue to incur net losses at least through the remainder of 2023. We may need to raise additional capital to finance operating expenses, invest in our sales organization and new product development, compete in the international marketplace, and develop the strategic assets of our Helomics businesses, especially over the longer term. We may attempt to raise these funds through equity or debt financing that may include public offerings, private placements, alternative offerings, or other means. Such additional financing would be dilutive to existing stockholders, and there is no assurance that such financing would be available upon terms acceptable to us or at all. If such financing or adequate funds from operations are not available, we would be forced to limit our business activities, which would have a material adverse effect on our results of operations and financial condition.~~

~~These possibilities, to the extent available, may be on terms that result in significant dilution to our existing shareholders or that result in our existing shareholders losing part or all of their investment. Our business and operations have been and may continue to be materially and adversely affected by the COVID- 19 pandemic. The COVID- 19 worldwide pandemic has presented substantial public health challenges. In response to the crisis, emergency measures have been imposed by governments worldwide, including mandatory social distancing and the shutdown of non- essential businesses. These measures have adversely impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets, and our business and operations have been and will likely continue to be materially and adversely affected. The Company continues to experience some disruption due to the global supply chain caused by COVID- 19. As a result of COVID- 19, the Company has also experienced disruption due staffing shortages within the service and healthcare industries and negative impacts on the demand for our products and services. For example, some customers are managing inventory and capital more conservatively and our suppliers continue to ask for pre- delivery deposits. The Company is monitoring and taking actions to mitigate potential risks of these shortages and delays which may impact the Company' s ability to obtain new contracts, the fulfillment of product demand and to meet its contract obligations. The extent to which COVID- 19 may impact the Company' s financial condition and results of operations remains uncertain and is dependent on numerous evolving factors, including the measures being taken by authorities to mitigate against the spread of COVID- 19, the emergence of new variants and the effectiveness of vaccines and therapeutics. The continuation or re- implementation of these measures remains uncertain. These factors may remain prevalent for a significant period of time even after the pandemic subsides, including due to a continued or prolonged recession in the U. S. or other major economies. The impacts of the COVID- 19 pandemic, as with any adverse public health developments, could have a material adverse effect on our business, results of operations, liquidity or financial condition and heighten or exacerbate risks described in this Annual Report on Form 10- K~~ . We are dependent on a few key executive officers for our success. Our inability to retain those officers would impede our business plan and growth strategies, which would have a negative impact on our business ~~and the value of~~ **, financial condition,** ~~an~~ **and** ~~investment~~ **results of operations** . Our success depends on the skills, experience, and performance of key members of our management team. ~~We heavily depend~~ **Were we to lose** ~~on~~ **one or more members of** our management team ~~: Raymond F. Vennare, our Chief Executive Officer (" CEO "), Bob Myers, our Chief Financial Officer (" CFO "), and Pamela Bush, or~~ **for any reason** ~~Chief Business Officer (" CBO "). We have entered into employment agreements with the CEO, CFO and CBO, and we may expand our relatively small number of executives. Were we to lose one or more of these key individuals~~ , we would be ~~forced~~ **required** to expend significant time and money **to find** ~~in the pursuit of~~ a replacement, which could result in both a delay in the implementation of our business plan and the diversion of our limited working capital. We **may** ~~can give no~~ **not** ~~assurance that we would~~ be able to find satisfactory replacements for ~~these key individuals~~ **members of our management team** at all, or on terms that are not unduly expensive or burdensome to us. **Such loss** ~~We may fail to realize the anticipated benefits~~ of **a key member** ~~the zPREDICTA acquisition. The success of our~~ **or members** ~~November 2021 acquisition~~ of ~~zPREDICTA will depend, in part,~~ **our management team without adequate replacements would have a negative impact** on our ~~ability to realize growth opportunities and synergies from combining our companies, Predictive Oncology and zPREDICTA. The integration will be a time consuming and expensive process and may disrupt our operations if it is not completed in a timely and efficient manner. In addition, we may not achieve anticipated synergies or other benefits of the acquisition. Following the acquisition, we operate as a combined organization utilizing common information and communication systems, operating procedures, financial controls, and human resources practices. We may encounter the following integration difficulties, resulting in costs and delays: • failure to successfully manage relationships with customers and other important relationships; • failure of customers to continue using our services; • difficulties in successfully integrating our management teams and employees; • challenges encountered in managing larger operations; • failure to manage our growth and growth strategies; • diversion of the attention of management from other ongoing~~ business ~~concerns; • incompatibility of technologies and systems; and • incompatibility of business cultures. If our combined operations do not meet the expectations of our existing or prospective customers, then these customers and prospective customers may cease doing business with us altogether, which would harm our results of operations~~ , financial condition, ~~business prospects reputation. If our management team is not able to develop strategies~~ and **results** ~~implement a business plan that successfully addresses these difficulties, we may not realize the anticipated benefits~~ of **operations** ~~the acquisition~~ . ~~Risks~~ **Risk Factors** Related to Our Intellectual Property Our business is dependent upon proprietary intellectual property rights, which if we were unable to protect, could have a material adverse effect on our business. We rely on a combination of patent, trade secret and other intellectual property rights, contractual restrictions, and other measures to protect our intellectual property. We currently own and may in the future own or license additional patent rights or trade secrets in the U. S., with non- provisional patents elsewhere in the world that cover certain of our products. We rely on patent laws and other intellectual property laws, nondisclosure and other contractual provisions, and technical measures to protect our products and intangible assets. 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. While we apply for patents covering our products and technologies and uses thereof, we may fail to apply for patents on important products and technologies in a timely fashion, or at all, or we may fail to apply for patents in relevant jurisdictions. Others could seek to design around our current or future patented technologies. These intellectual property rights are important to our ongoing operations and ~~no assurance can be given that~~ any measure we implement ~~will~~ **may not** be sufficient to protect our intellectual property rights. Further, competitors could willfully infringe upon our intellectual property rights, design around our protected technology, or develop their own competitive technologies that arguably fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. Also, with respect to our trade secrets and proprietary know- how, we cannot be certain that the confidentiality agreements we have entered into with employees will not be breached, or that we will have adequate

remedies for any breach. In addition, we may lose the protection afforded by these rights through patent expirations, legal challenges, or governmental action. If our intellectual property does not adequately protect us against competitors' products and methods, our competitive position could be adversely affected, as could our business and the results of our operations. To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our overall business. If we become subject to intellectual property actions, it could hinder our ability to deliver our products and services and our business could be negatively impacted. We could be subject to legal or regulatory actions alleging intellectual property infringement or similar claims against us. Companies may apply for or be awarded patents or have other intellectual property rights covering aspects of our technologies or businesses. Litigation may be necessary for us to enforce our patents and proprietary rights or to determine the scope, coverage, and validity of the proprietary rights of others. The outcome of any litigation or other proceeding is inherently uncertain and might not be favorable to us, and we might not be able to obtain licenses to technology that we require on acceptable terms, or at all. Moreover, if it is determined that our products infringe on the intellectual property rights of third parties, we could be prevented from marketing our products. While we are currently not subject to any material intellectual property litigation, any future litigation alleging intellectual property infringement could be costly, particularly in light of our limited resources. Similarly, if we determine that third parties are infringing on our patents or other intellectual property rights, our limited resources may prevent us from litigating or otherwise taking actions to enforce our rights. Any such litigation or inability to enforce our rights could require us to change our business practices, hinder or prevent our ability to deliver our products and services, and result in a negative impact to our business. Expansion of our business via product line enhancements or new product lines to drive increased growth in current or new markets may be inhibited by the intellectual property rights of our competitors and / or suppliers. Our inability to successfully mitigate those factors may significantly reduce our market opportunity and subsequent growth. Any litigation that may be necessary in the future could result in substantial costs and diversion of resources and could have a material adverse effect on our business, financial condition, and operating results. **If we breach our license agreements it could have a material adverse effect on our commercialization efforts for our product candidates. A portion of our patent portfolio is in- licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and / or patent applications owned by other companies or institutions. The license agreements impose specified diligence, milestone payment, royalty, and other obligations on us and requires that we meet development timelines, or to exercise diligent or commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license. Our rights with respect to in- licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the License Agreement. We are likely to enter into additional license agreements to in- license patents and patent applications as part of the development of our business in the future, under which we may not retain control of the preparation, filing, prosecution, maintenance, enforcement, and defense of such patents. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed. Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third- party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability. Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements. If our intellectual property agreements are terminated, or if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours. Moreover, if our intellectual property agreements are terminated, our former licensors and / or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. This could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects. Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Depending upon the timing, duration, and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch- Waxman Amendments, and similar legislation in the European Union. The Hatch- Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on**

our business. Further, recent judicial decisions in the U. S. raised questions regarding the award of patent term adjustment (PTA) for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted. Changes in patent law, including recent patent reform legislation, could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In September 2011, the America Invents Act (AIA) was enacted in the United States, resulting in significant changes to the U. S. patent system. An important change introduced by the AIA was a transition to a " first- to- file " system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions. Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower burden of proof in USPTO proceedings compared to the burden of proof in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our existing and future collaborators or licensors and the enforcement or defense of our issued patents. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, there is complexity and uncertainty related to European patent laws. For example, the European Patent Convention was amended in April 2010 to limit the time permitted for filing divisional applications. In addition, the EPO patent system is relatively stringent in the type of amendments that are allowed during prosecution. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Even if we are successful in defending against these types of claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. Some of our competitors may be able to sustain the costs of this type of litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. We may not be able to enforce our intellectual property rights throughout the world. The laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States, and many companies have encountered significant challenges in establishing and enforcing their proprietary rights outside of the United States. These challenges can be caused by the absence of rules and methods for the establishment and enforcement of intellectual property rights outside of the United States. In addition, the legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to healthcare. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology

and the enforcement of intellectual property. Beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (UPC). Under the unitary patent system, European applications will have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC- based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long- term effects of any potential changes. Risk Factors ~~Relating~~ **Related** to Regulation Our business is subject to intense governmental regulation and scrutiny, both in the U. S. and abroad. The production, marketing, and R & D of our products is subject to extensive regulation and review by the FDA and other governmental authorities both in the United States and abroad. In addition to testing and approval procedures, extensive regulations also govern marketing, manufacturing, distribution, labeling, and record keeping. If we do not comply with applicable regulatory requirements, violations could result in warning letters, non- approvals, suspensions of regulatory approvals, civil penalties and criminal fines, product seizures and recalls, operating restrictions, injunctions, and criminal prosecution. Periodically, legislative or regulatory proposals are introduced that could alter the review and approval process relating to medical products. It is possible that the FDA will issue additional regulations further restricting the sale of our present or proposed products. Any change in legislation or regulations that governs the review and approval process relating to our current and future products could make it more difficult and costlier to obtain approval for new products, or to produce, market, and distribute existing products **. Any such change could also result in a failure to obtain necessary approvals for our current or future products, which would negatively impact our financial condition and results of operations** . If the FDA begins to enforce regulation of our molecular diagnostic tests, we could incur substantial costs and delays associated with trying to obtain pre- market clearance or approval and costs associated with complying with post- market requirements. Clinical laboratory tests like our molecular diagnostic tests are regulated under CLIA as well as by applicable state laws. ~~Most~~ **The FDA has historically taken the position that it has the authority to regulate** Laboratory Developed Tests (" LDTs ") ~~are currently~~ **as medical devices under the Federal Food, Drug, and Cosmetic Act, but it has a long- standing policy of** not **exercising general enforcement discretion with regard to LDTs. Accordingly, LDTs have effectively not been** subject to the FDA' s regulation (although reagents, instruments, software, or components provided by third parties and used to perform LDTs may be subject to regulation). ~~In October 2014~~ **However, in September 2023** , the FDA **published** ~~issued two draft guidance documents: " Framework for Regulatory Oversight of Laboratory Developed Tests ", which provides an overview of how the FDA would regulate LDTs through~~ a **proposed rule** ~~risk- based approach, and " FDA Notification and Medical Device Reporting for Laboratory Developed Tests ", which provides guidance on how the FDA intends to collect information on existing LDTs, including adverse event reports. On January 13, 2017, the FDA also issued a discussion paper~~ on LDTs **that** ~~. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers~~ would **end** ~~be subject to medical device registration, listing, and adverse event reporting requirements. The risk- based classification considers the LDT' s intended use, technological characteristics, and the risk to patients if the LDT were to fail. Pursuant to the Framework for Regulatory Oversight draft guidance, LDT manufacturers would be required to either submit a pre- market application and receive~~ the FDA' s ~~approval before an~~ **prior policy of enforcement discretion with respect to** ~~LDT~~ **LDTs** ~~may be marketed or submit a pre- market notification in advance of marketing~~ . ~~These~~ -- **The** ~~requirements~~ **proposed rule** would ~~be phased~~ - **phase out** ~~in, starting with higher risk LDTs, following the issuance of~~ the FDA' s ~~final guidance~~ **enforcement discretion policy in five stages over a four- year period from the effective date of the rule. In Phase 1 (effective** ~~on~~ **one year after the rule is finalized), enforcement discretion would end with respect to medical device reporting and correction and removal reporting requirements. In Phase 2 (effective two years post- finalization), enforcement discretion would end with regard to other device requirements, including registration and listing, labeling, and investigational devices, except for quality systems and premarket review. In Phase 3 (effective three years post- finalization), enforcement discretion would end with regard to quality systems requirements. In Phase 4 (effective three and a half years post- finalization, but not before October 1, 2027), enforcement discretion would end with regard to compliance with premarket review requirements for high- risk tests (i. e., tests subject to premarket approval). Finally, in Phase 5 (effective four years post- finalization, but not before April 1, 2028), enforcement discretion would end with regard to premarket review requirements for moderate- risk and low- risk tests. Unlike previous proposals, the proposed rule does not " grandfather in " any existing tests. At** this ~~topic, which the FDA has identified as a priority. The draft guidance provides that LDTs that are already marketed at the~~ time ~~the final guidance is issued would not be withdrawn from the market during the FDA' s review process. There is no timeframe within which the FDA must issue its final guidance~~ , ~~but issuance of this final guidance has been identified among a list of~~ the **proposed rule** ~~FDA' s priorities. As of the date of this filing, the FDA~~ has not ~~issued~~ **been finalized, and** its **ultimate content (including whether** ~~final guidance. In August 2020, however,~~ the **rule** ~~U. S. Department of Health and Human Services -- the parent agency for FDA -- announced that the FDA "~~ will **go into effect** ~~not require premarket review of LDTs absent notice- and- comment rulemaking, as opposed to through guidance documents, compliance manuals, website statements, or other informal issuances. " It is unclear~~ at **all** ~~this time whether the Biden Administration will rescind or reverse this policy. It is also unclear at this time when, or if, the FDA will finalize its plans to end enforcement discretion (e. g., via notice and comment rulemaking or otherwise~~) **remains unknown** ~~, and even then, the new regulatory requirements are expected to be phased - in over time. Nevertheless, the FDA may attempt to regulate certain LDTs on a case - by - case basis at any time~~ . Legislative proposals addressing the FDA' s oversight of LDTs have been introduced in previous Congresses **, including the " Verifying Accurate Leading- edge IVCT Development Act, " or VALID Act** , and we expect that new legislative proposals will be introduced from time - to - time. The likelihood that Congress will pass such legislation and the extent to which such legislation may affect the FDA' s plans to regulate certain LDTs as medical devices is difficult to predict at this time. If the FDA

ultimately regulates certain LDTs, whether via final guidance, final regulation, or as instructed by Congress, our molecular diagnostic tests may be subject to certain additional regulatory requirements. The cost of conducting clinical trials and otherwise developing data and information to support pre- market applications may be significant. If we are required to submit applications for our currently marketed tests, we may be required to conduct additional studies, which may be time- consuming and costly and could result in our currently marketed tests being withdrawn from the market. If our tests are allowed to remain on the market, but there is uncertainty in the marketplace about our tests, and if we are required by the FDA to label them investigational, or if labeling claims the FDA allows us to make are limited, orders may decline, and reimbursement may be adversely affected. Continued compliance with the FDA' s regulations would increase the cost of conducting our business, and subject us to heightened regulation by the FDA and penalties for failure to comply with these requirements. In sum, we cannot predict the timing or form of any such guidance or regulation, or the potential effect on our existing molecular diagnostic tests or our tests in development, or the potential impact of such guidance or regulation on our business, financial condition, and results of operations. If we fail to comply with Federal, State, and foreign laboratory licensing requirements, we could lose the ability to perform our tests or experience disruptions to our business. We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, or treatment of disease. CLIA regulations mandate specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, and quality assurance. CLIA certification is also required in order for our business to be eligible to bill Federal and State healthcare programs, as well as many private third- party payors, for our molecular diagnostic tests. To renew these certifications, we are subject to survey and inspection every two years. Moreover, CLIA inspectors may make random inspections of our clinical reference laboratories. Pennsylvania laws also require that we maintain a license and establish standards for the day- to- day operation of our clinical reference laboratory in Pittsburgh, Pennsylvania. In addition, our Pittsburgh laboratory is required to be licensed on a test- specific basis by certain other states. If we were unable to obtain or lose our CLIA certificate or State licenses for our laboratories, whether as a result of revocation, suspension, or limitation, we would no longer be able to perform our molecular diagnostic tests, which could have a material adverse effect on our business, financial condition, and results of operations. If we were to lose our licenses issued by the States in which we are required to hold licenses, we would not be able to test specimens from those States. New molecular diagnostic tests we may develop may be subject to new approvals by governmental bodies, and we may not be able to offer our new molecular diagnostic tests to patients in such jurisdictions until such approvals are received. Complying with numerous statutes and regulations pertaining to our molecular diagnostics business is an expensive and time- consuming process, and any failure to comply could result in substantial penalties. We are subject to regulation by both the Federal government and the States in which we conduct our molecular diagnostics business, including: • The Food, Drug, and Cosmetic Act, as supplemented by various other statutes; • The Prescription Drug Marketing Act of 1987, the amendments thereto, and the regulations promulgated thereunder and contained in 21 C. F. R. Parts 203 and 205; • CLIA and State licensing requirements; • Manufacturing and promotion laws; • Medicare and Medicaid billing and payment regulations applicable to clinical laboratories; • The Federal Anti- Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal healthcare program; • The Federal Stark physician self- referral law (and ~~state~~ **State** equivalents), which prohibits a physician from making a referral for certain designated health services covered by the Medicare program, including laboratory and pathology services, if the physician or an immediate family member has a financial relationship with the entity providing the designated health services, unless the financial relationship falls within an applicable exception to the prohibition; • The Federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which established comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, and amendments made in 2013 to HIPAA under the Health Information Technology for Economic and Clinical Health Act, which strengthen and expand HIPAA privacy and security compliance requirements, increase penalties for violators, extend enforcement authority to state attorneys general, and impose requirements for breach notification; • The Federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or ~~state~~ **State** healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a ~~state~~ **State** healthcare program, unless an exception applies; • The Federal False Claims Act, which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the ~~federal~~ **Federal** government; • Other Federal and State fraud and abuse laws, prohibitions on self- referral, fee- splitting restrictions, prohibitions on the provision of products at no or discounted cost to induce physician or patient adoption, and false claims acts, which may extend to services reimbursable by any third- party payor, including private insurers; • The prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other party; • The rules regarding billing for diagnostic tests reimbursable by the Medicare program, which prohibit a physician or other supplier from marking up the price of the technical component or professional component of a diagnostic test ordered by the physician or other supplier and supervised or performed by a physician who does not " share a practice " with the billing physician or supplier; and • State laws that prohibit other specified practices related to billing **,** such as billing physicians for testing that they order, waiving coinsurance, co- payments, deductibles, and other amounts owed by patients, and ~~billing~~ **being reimbursed at** a ~~State~~ **higher amount from Medicare,** Medicaid **, and other Federal** ~~program~~ **programs ,** ~~at a price that is higher~~ than what ~~is~~ **we** ~~charged~~ **charge** ~~to~~ other payors. We have implemented policies and procedures designed to comply with these laws and regulations. We periodically conduct internal reviews of our compliance with these laws. Our compliance is also subject to governmental review. The growth of our business may increase the potential of violating these laws, regulations, or our internal

policies and procedures. The risk that we are found in violation of these, or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. **Possible** ~~Violations~~ **violations** of Federal or State regulations may ~~incur~~ **spur** ~~investigation~~ **investigations** or enforcement ~~action~~ **actions** by the FDA, Department of Justice, State agencies, or other legal authorities, and **confirmed violations** may result in substantial civil, criminal, or other **fees, penalties or** sanctions. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert managements' attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to civil and criminal penalties, damages, and fines, we could be required to refund payments **we** received ~~by it~~, we could face possible exclusion from Medicare, Medicaid and other Federal or State healthcare programs, and we could even be required to cease operations. Any of the foregoing consequences could have a material adverse effect on our business, financial condition, and results of operations. If we use hazardous materials in a manner that causes contamination or injury, we could be liable for resulting damages. We are subject to Federal, State, and local laws, rules and regulations governing the use, discharge, storage, handling, and disposal of biological material, chemicals, and waste. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, remediation costs, and any related penalties or fines. This liability could exceed our resources or any applicable insurance coverage we may have. The cost of compliance with these laws and regulations may become significant, and our failure to comply may result in substantial fines or other consequences, and either could have a significant impact on our operating results. The healthcare regulatory and political framework is uncertain and evolving. Healthcare laws and regulations are rapidly evolving and may change significantly in the future, which could adversely affect our financial condition and results of operations. For example, in March 2010, the Patient Protection and Affordable Care Act, (" ACA "), was adopted, which is a healthcare reform measure that provided healthcare insurance for approximately 30 million additional Americans. The ACA includes a variety of healthcare reform provisions and requirements that became effective at varying times through 2018 and substantially changed the way healthcare is financed by both governmental and private insurers, which may significantly impact our industry and our business. For instance, the ACA requires " Applicable Manufacturers " to disclose to the Secretary of the Department of Health & Human Services drug sample distributions and certain payments or transfers of value to covered recipients (physicians and teaching hospitals) on an annual basis. " Applicable Manufacturers " and " Applicable Group Purchasing Organizations " must also disclose certain physician ownership or investment interests. The data submitted will ultimately be made available on a public website. Based upon the structure of our relationship with our clients, we may be included in the definition of " Applicable Manufacturer " for purposes of the disclosure requirements or may provide services that include the transfer of drug samples and / or other items of value to covered recipients. As such, we may be required to disclose or provide information that is subject to disclosure. There may be certain risks and penalties associated with the failure to properly make such disclosures, including but not limited to the specific civil liabilities set forth in the ACA, which allows for a maximum civil monetary penalty per " Applicable Manufacturer " of $ 1, 150, 000 per year. There may be additional risks and claims made by third parties derived from an improper disclosure that are difficult to ascertain at this time. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. ~~The U. S. Supreme Court is currently reviewing the constitutionality of the ACA, although it is unclear when a decision will be made. Further, it is possible that additional governmental action will be taken in response to the COVID- 19 pandemic. Risks~~ **Risk Factors** Related to the Securities Markets and Ownership of Our Common Stock Our certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware will be the exclusive forum for certain legal actions between us and our stockholders, which could limit our stockholders' ability to obtain a judicial forum viewed by the stockholders as more favorable for disputes with us or our directors, officers, or employees. Our certificate of incorporation, as amended, provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (1) any derivative action or proceeding brought on behalf of the corporation, (2) any action asserting a claim of breach of a fiduciary duty owed by any director or officer of the corporation to the corporation or the corporation' s stockholders, (3) any action asserting a claim against the corporation arising pursuant to any provision of the General Corporation Law or the corporation' s ~~Certificate~~ **certificate** of ~~Incorporation~~ **incorporation** or ~~Bylaws~~ **bylaws**, or (4) any action asserting a claim against the corporation governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, as amended, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for ~~federal~~ **Federal** and ~~state~~ **State** courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the ~~federal~~ **Federal** securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees. If a court were to find the choice of forum provision contained in our certificate of incorporation, as amended, to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, ~~results of operations, and~~ financial condition **, and results of operations**. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to **our** management **team**. Our common stock could be delisted from ~~The NASDAQ~~ **the Nasdaq** Capital Market,

which delisting could hinder your ability to obtain accurate quotations on the price of our common stock or dispose of our common stock in the secondary market. On May 13, 2022, we received a letter from the Listing Qualifications Department ~~(the " Staff ")~~ of **Nasdaq** ~~The NASDAQ Stock Market LLC (" NASDAQ ")~~ informing **us** ~~the Company~~ that because the closing bid price for **our** ~~the Company' s~~ common stock listed on ~~NASDAQ~~ **Nasdaq** was below $ 1. 00 for 30 consecutive trading days, **we did** ~~the Company does~~ not comply with the minimum closing bid price requirement for continued listing on ~~The NASDAQ~~ **the Nasdaq** Capital Market under NASDAQ Marketplace Rule 5550 (a) (2), requiring a minimum bid price of $ 1. 00 per share (the " Minimum Bid Price Requirement "). The letter stated that we had 180 days, or until November 9, 2022, to regain compliance by maintaining a closing bid price of at least $ 1. 00 for a minimum of 10 consecutive trading days. **This deadline was subsequently extended by Nasdaq to May 8, 2023.** On ~~November 10~~ **April 23** , ~~2022~~ **2023** , ~~Nasdaq notified us that while the Company had not~~ **we effected a 20- for- 1 reverse stock split to cure this deficiency. As a result, our stock price increased significantly, and we** regained compliance with the Minimum Bid Price Requirement **. However** , ~~it~~ **since the reverse stock split, our stock price has declined and, as of March 18, 2024, our closing stock price** was **$ 2** ~~eligible for an additional 180- day calendar period, or until May 8, 2023, to regain compliance~~ . **70 per** ~~Nasdaq' s determination was based on our meeting the continued listing requirement for market value of publicly held shares~~ - **share. If we subsequently fail to meet** ~~and all other applicable requirements for initial listing on The Nasdaq Capital Market, with the exception of~~ the Minimum Bid Price Requirement ~~, and our~~ - **or another** ~~written notice to Nasdaq of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary. If at any time before May 8, 2023 the bid price of the Company' s common stock closes at or above $ 1. 00 per share for a minimum of 10 consecutive business days, NASDAQ will provide written notification that the Company has achieved compliance with the Minimum Bid Price Requirement~~ **requirement** ~~. If we do not regain compliance with the Minimum Bid Price Requirement by May 8, 2023, the Staff will provide written notification to us that our common stock will be subject to delisting. In the event of such notification, we may appeal the Staff' s determination to delist our securities, but there can be no assurance the Staff would grant our request~~ for continued listing **on Nasdaq** ~~. The Company intends to continue actively monitoring the bid price for its common stock between now and May 8~~ , **we could be delisted** ~~2023 and will consider available options to resolve the deficiency and regain compliance with the Minimum Bid Price Requirement, including effectuating a reverse stock split~~ . In the event our common stock is delisted from ~~The NASDAQ~~ **the Nasdaq** Capital Market and we are also unable to maintain listing on another alternate exchange, trading in our common stock could thereafter be conducted **through one** ~~in FINRA' s OTC Bulletin Board~~ or **more** ~~in the~~ over- the- counter markets ~~in the so- called pink sheets~~ . In such event, the liquidity of our common stock would likely be impaired, not only in the number of shares which could be bought and sold, but also through delays in the timing of the transactions, and there would likely be a reduction in our coverage by security analysts and the news media, thereby resulting in lower prices for our common stock than might otherwise prevail. ~~If, in an attempt to resolve our listing standards deficiency and regain compliance with Nasdaq' s Minimum Bid Price Requirement, we elect to pursue and conduct a reverse stock split, the impact of the reverse stock split on the future market price of our common stock and our ability to maintain the listing of our common stock on Nasdaq will be uncertain. If we elect to pursue and conduct a reverse stock split in an attempt to resolve our listing standards deficiency and regain compliance with Nasdaq' s Minimum Bid Price Requirement, we cannot assure stockholders that the proposed reverse stock split will sufficiently increase our stock price or be completed before Nasdaq commences delisting procedures. The effect of a reverse stock split on our stock price cannot be predicted with any certainty, and the history of reverse stock splits for other companies, including those in our industry, is varied, particularly since some investors may view a reverse stock split negatively. It is possible that our stock price after a reverse stock split will not increase in the same proportion as the reduction in the number of shares outstanding, causing a reduction in our overall market capitalization. Further, even if we implement a reverse stock split, our stock price may decline due to various factors, including our future performance and general industry, market and economic conditions. This percentage decline, as an absolute number and as a percentage of our overall market capitalization, may be greater than would occur in the absence of a reverse stock split. If we continue to fail to meet Nasdaq' s listing requirements, Nasdaq may suspend trading and commence delisting proceedings. In addition, a reverse stock split may decrease the liquidity of our common stock and result in higher transaction costs. The liquidity of our common stock may be negatively impacted by the reduced number of shares outstanding after a reverse stock split, which would be exacerbated if the stock price does not increase following the reverse stock split. In addition, a reverse stock split would increase the number of stockholders owning " odd lots " of fewer than 100 shares, trading in which generally results in higher transaction costs. Accordingly, a reverse stock split may not achieve the desired results of increasing marketability and liquidity. The implementation of a reverse stock split would not have an effect on the actual or intrinsic value of our business or a stockholder' s proportional ownership interest (subject to the treatment of fractional shares). However, should the overall value of our common stock decline after a reverse stock split, then the actual or intrinsic value of shares held by stockholders will also proportionately decrease as a result of the overall decline in value.~~ Limitations on director and officer liability and indemnification of our officers and directors by us may discourage stockholders from bringing a suit against a director. Our ~~Certificate~~ **certificate** of ~~Incorporation~~ **incorporation** and ~~Bylaws~~ **bylaws** provide, with certain exceptions as permitted by governing state law, that a director or officer shall not be personally liable to us or our stockholders for breach of fiduciary duty as a ~~Director~~ **director** , except for acts or omissions ~~which~~ **that** involve intentional misconduct, fraud, knowing violation of law, or unlawful payments of dividends. These provisions may discourage stockholders from bringing a suit against a director for breach of fiduciary duty and may reduce the likelihood of derivative litigation brought by stockholders on our behalf against a director. In addition, our certificate of incorporation and bylaws may provide for mandatory indemnification of directors and officers to the fullest extent permitted by governing state law **,which may subject us to** ~~in the future offer additional shares of our common stock or other~~ securities ~~convertible into or exchangeable~~ **litigation.The market** for our common stock **may be characterized by significant price volatility when compared to seasoned issuers,and we expect that our share price will**

be more volatile than a seasoned issuer for the indefinite future . **In the past** ~~Although no assurances can be given that we will consummate a future financing~~ , **plaintiffs have often initiated securities class action litigation against companies following periods of volatility** in the **market price** ~~event we do,or in the event we sell shares~~ of ~~common stock or other~~ - **their** securities **.We may** ~~convertible into shares of our common stock~~ in the future ~~,additional~~ **be the target of similar litigation.Securities litigation could result in substantial costs** and **liabilities and** ~~potentially substantial dilution~~ could ~~occur~~ **divert management' s attention and resources** .The exercise of outstanding warrants,and issuance of equity awards may have a dilutive effect on our stock,and negatively impact the price of our common stock.As of December 31, ~~2023~~ **2022** ,we had ~~1~~ **36** , ~~806~~ **328** , ~~589~~ **731** warrants outstanding at a weighted average exercise price of $ ~~21~~ **7** . ~~52~~ **31** per share.We are able to grant stock options,restricted stock,restricted stock units,stock appreciation rights,bonus stock,and performance awards under our 2012 ~~Stock~~ **Equity** Incentive ~~Plan.Under the 2012 Stock Incentive Plan,47,664 shares were issuable under outstanding incentive awards at December 31,2023,and 94,878 shares remained~~ . We do not expect to pay cash dividends for the foreseeable future, and we may never pay dividends; investors must rely on stock appreciation, if any, for any return on investment in our common stock. We currently intend to retain any future earnings to support the development and expansion of our business and do not anticipate paying cash dividends in the foreseeable future. Our payment of any future dividends will be at the discretion of our ~~Board~~ **board** of ~~Directors~~ **directors** after **considering** ~~taking into account~~ various factors, including but not limited to, our financial condition, operating results, cash needs, growth plans, and the terms of any credit agreements that we may be a party to at the time. In addition, our ability to pay dividends on our common stock **is** ~~may be~~ limited by ~~state law~~ **the Delaware General Corporation Law, which provides that dividends may only be lawfully paid out of a corporation' s " surplus, " which is generally defined as the amount by which total assets exceed total liabilities** . Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, **and the availability of a liquid trading market in our shares** as the only way to realize certain returns on their investment. ~~As a result, investors must rely on stock appreciation and a liquid trading market for any return on investment in our common stock.~~ Our ~~Board~~ **board** of ~~Directors~~ **directors** ' ability to issue undesignated preferred stock and the existence of anti- takeover provisions may depress the value of our common stock. Our authorized capital includes 20 million shares of preferred stock. Of this amount, 2, 300, 000 shares have been designated as series B convertible preferred stock, of which 79, 246 shares are outstanding. The remaining authorized shares are undesignated preferred stock. Our ~~Board~~ **board** of ~~Directors~~ **directors** has the power to issue any or all of the shares of undesignated preferred stock, including the authority to establish one or more series and to fix the powers, preferences, rights, and limitations of such class or series, without seeking stockholder approval. Further, as a Delaware corporation, we are subject to provisions of the Delaware General Corporation Law regarding business combinations. We may, in the future, consider adopting additional anti- takeover measures. The authority of our ~~Board~~ **board** of ~~Directors~~ **directors** to issue undesignated stock and the anti- takeover provisions of Delaware law, as well as any future anti- takeover measures adopted by us, may, in certain circumstances, delay, deter, or prevent takeover attempts and other changes in control not approved by our ~~Board~~ **board** of ~~Directors~~ **directors** . As a result, our stockholders may lose opportunities to dispose of their shares at favorable prices generally available in takeover attempts or that may be available under a merger proposal and the market price, voting, and other rights of the holders of common stock may also be affected. **Our stock price may be volatile, and you could lose all or part of your investment. The trading price of our common stock may fluctuate substantially and will depend on several factors, including those described in this " Risk Factors " section, many of which are beyond our control and may not be related to our operating performance. These fluctuations could cause you to lose all or part of your investment in our securities. In addition, the stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, as well as general economic, political and market conditions such as recessions or interest rate changes, may seriously affect the market price of our common stock, regardless of our actual operating performance. Further, in the past, following periods of volatility in the overall market and the market prices of particular companies' securities, securities class action litigations have often been instituted against these companies. Litigation of this type, if instituted against us, could result in substantial costs and a diversion of our management' s attention and resources. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.** General Risk Factors **Business disruptions could harm our operations, lead to a decline in revenue and increase our costs. Our operations could be disrupted by political and / or civil unrest, acts of war or other military actions, such as recent and ongoing conflicts in Israel / Gaza and Ukraine, epidemics or pandemics, such as a potential resurgence of the COVID- 19 pandemic, and other natural or man- made disasters and catastrophic events. Geopolitical and domestic political developments and other events beyond our control, can increase economic volatility globally and disrupt supply chains we rely on. Our operations could be harmed and our costs could increase if manufacturing, logistics or other operations are disrupted for any reason, including economic, business, labor, environmental, public health, or political issues. We monitor and act as necessary to mitigate potential risks of shortages and delays that may impact our ability to obtain new contracts, fulfill product demands and meet our contract obligations. The extent to which business disruptions may impact our financial condition and results of operations remains uncertain and is dependent on numerous evolving factors.** Our success is dependent on our ability to attract and retain technical personnel, sales and marketing personnel, and other skilled management. Our success depends to a significant degree on our ability to attract, retain, and motivate highly skilled and qualified personnel. Failure to attract and retain necessary technical, sales and marketing personnel, and skilled management could adversely affect our business. If we fail to attract, train, and retain sufficient numbers of these highly qualified people, our business, financial condition, and results of operations could be materially and adversely affected. Our ability to use net operating loss and tax credit carryforwards and certain built- in losses to reduce future tax payments is limited by provisions of the Internal Revenue Code and may be subject to further limitation because of prior or

future offerings of our stock or other transactions. Sections 382 and 383 of the United States Internal Revenue Code of 1986, as amended (the " Code ") contain rules that limit the ability of a company that undergoes an ownership change, which is generally an increase in the ownership percentage of certain stockholders in the stock of a company by more than 50 % over a three- year period, to utilize its net operating loss and tax credit carryforwards and certain built- in losses recognized in years after the ownership change. These rules generally operate by focusing on ownership changes involving stockholders owning directly or indirectly 5 % or more of the stock of a company and any change in ownership arising from a new issuance of stock by that company. Generally, if an ownership change, as defined by Section 382 of the Code, occurs, the yearly taxable income limitation on the use of net operating loss and tax credit carryforwards and certain built- in losses is equal to the product of the applicable long- term tax- exempt rate and the value of stock immediately before the ownership change. **The** ~~Based on prior equity transactions, the~~ Company **performed a** ~~believes it has experienced multiple ownership changes including in 2021 as defined by~~ Section 382 **analysis as** of **December 31,** ~~the Code. We have not assessed the potential impact of Sections 382 and 383 for 2021~~ **2023 which resulted in the limitation and expiration of a substantial portion of the Company' s loss carryforwards. In addition, the current net operating loss (" NOL ") carryforwards might be further limited by future issuances of** ~~or~~ **our** ~~other years~~ **common stock** . Costs incurred because we are a public company may affect our profitability. As a public company, we incur significant legal, accounting, and other expenses and are subject to the SEC' s rules and regulations relating to public disclosure that generally involve a substantial expenditure of financial resources. In addition, the Sarbanes- Oxley Act of 2002, as well as rules subsequently implemented by the SEC, require changes in corporate governance practices of public companies. Full compliance with such rules and regulations requires significant legal and financial compliance costs and makes some activities more time- consuming and costlier, which may negatively impact our financial results. To the extent our earnings suffer as a result of the financial impact of our SEC reporting or compliance costs, our ability to develop an active trading market for our securities could be harmed. Shares eligible for future sale may adversely affect the market. From time to time, certain stockholders may be eligible to sell some or all of their shares of common stock pursuant to Rule 144, promulgated under the Securities Act **,** subject to certain limitations. In general, pursuant to Rule 144 as in effect as of the date of this filing, a stockholder (or stockholders whose shares are aggregated) who has satisfied the applicable holding period and is not deemed to have been one of our affiliates at the time of sale, or at any time during the three months preceding a sale, may sell their shares of common stock. Any substantial sale, or cumulative sales, of our common stock pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our securities. We **may be unable to provide** ~~expect volatility in the price of our common~~ stock **- based** , which may subject us to securities..... performance awards under our 2012 Equity Incentive **incentives to our employees without an increase in** ~~Plan. Under the 2012 Stock Incentive Plan, 1, 064. 393~~ shares ~~were issuable under outstanding incentive awards at December 31, 2022, and 2, 894, 413 shares remained~~ available for issuance ~~pursuant to future incentive grants~~ . ~~The exercise~~ **Due to the low number** of ~~outstanding warrants, and~~ **shares remaining available for** issuance **, we** ~~of equity awards~~ may **be unable to provide stock- based incentives to our employees. Any increase in shares issuable will be subject to stockholder approval, which may not be obtained. Not obtaining stockholder approval could materially impact our ability to provide stock- based incentives to our employees, which could mean that we** have **to pay more cash** ~~a dilutive effect on our stock~~ , **which is currently limited.** ~~and negatively impact the price of our common stock~~ Acquisitions involve risks that could result in adverse changes to operating results, cash flows, and liquidity. We may desire to make strategic acquisitions in the future. However, we may not be able to identify suitable acquisition opportunities, or we may be unable to obtain the consent of our stockholders and therefore, may not be able to complete such acquisitions. We may pay for acquisitions with our common stock or with convertible securities, which may dilute ~~shareholders~~ **stockholders** ' investment in our common stock, or we may decide to pursue acquisitions that our investors may not agree with. In connection with potential acquisitions, we may agree to substantial earn- out arrangements. To the extent we defer the payment of the purchase price for any acquisition through a cash earn- out arrangement, cash flows ~~will~~ **could** be reduced in subsequent periods. In addition, acquisitions may expose us to operational challenges and risks, including: • the ability to profitably manage acquired businesses or successfully integrate the operations of acquired businesses, as well as the acquired business' s financial reporting and accounting control systems into our existing platforms; • increased indebtedness and contingent purchase price obligations associated with an acquisition; • the ability to fund cash flow shortages that may occur if anticipated revenue is not realized or is delayed, whether by general economic or market conditions, or unforeseen internal difficulties; • the availability of funding sufficient to meet increased capital needs; • diversion of management' s time and attention from existing operations; and • the ability to retain or hire qualified personnel required for expanded operations. Completing acquisitions may require significant management time and financial resources because we may need to assimilate widely dispersed operations with different corporate cultures. In addition, acquired companies may have liabilities that we failed to or were unable to discover in the course of performing due diligence investigations. **Also,** ~~We cannot assure the shareholders' that~~ the indemnification granted by sellers of acquired companies ~~will~~ **may not** be sufficient in amount, scope, or duration to fully offset the possible liabilities associated with businesses or properties we assume upon consummation of an acquisition. We may learn additional information about our acquired businesses that could have a material adverse effect on us, such as unknown or contingent liabilities and liabilities related to compliance with applicable laws. Any such liabilities, individually or in the aggregate, could have a material adverse effect on our business. Failure to successfully manage the operational challenges and risks associated with, or resulting from, acquisitions could adversely affect our results of operations, cash flows, and liquidity. Borrowings or issuances of convertible securities associated with these acquisitions may also result in higher levels of indebtedness, which could adversely impact our ability to service our debt within the scheduled repayment terms. Security breaches, loss of data **,** and other disruptions to our business or the business of our third- party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and reputation. Our business requires

that we collect and store sensitive data, including protected health and credit card information and proprietary business and financial information. We face a number of risks relative to the protection of, and the service providers' protection of, this critical information, including loss of access, inappropriate disclosure, and inappropriate access, as well as risks associated with our ability to identify and audit such events. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance, or other activities. While we **do not believe we** have not experienced any such attack or breach, if such event would occur and cause interruptions in our operations, our networks could be compromised and the information we store on those networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Unauthorized access, loss, or dissemination could disrupt our operations, including collecting, processing, and preparing company financial information, managing the administrative aspects of our business, and damaging our reputation, any of which could adversely affect our business. In addition, the interpretation and application of consumer, health- related, and **general** data protection laws in the United States are often uncertain, contradictory, and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government- imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems, and compliance procedures in a manner adverse to our business. Additionally, ~~in connection with the COVID- 19 pandemic,~~ many of our employees have the ability to work remotely, which may increase the risk of security breaches, loss of data, and other disruptions as a consequence of more employees accessing sensitive and critical information from remote locations. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures in connection with security incidents, we may suffer loss of reputation, financial loss, and civil or criminal fines or other penalties. In addition, these breaches and other forms of inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. If our information technology and communications systems fail or we experience a significant interruption in our ~~operation~~ **operations** , our reputation, business, and results of operations could be materially and adversely affected. The efficient operation of our business is dependent on information technology and communications systems. The failure of these systems to operate as anticipated could disrupt our business and result in decreased revenue and increased overhead costs. In addition, we do not have complete redundancy for all of our systems and our disaster recovery planning cannot account for all eventualities. Our information technology and communications systems, including the information technology systems and services that are maintained by third- party vendors, are vulnerable to damage or interruption from natural disasters, fire, terrorist attacks, malicious attacks by computer viruses or hackers, and power loss or failure of computer systems, Internet, telecommunications or data networks. If these systems or services become unavailable or suffer a security breach, we may expend significant resources to address these problems, and our reputation, business, and results of operations could be materially and adversely affected.