Risk Factors Comparison 2024-06-03 to 2023-03-30 Form: 10-K

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The following are significant factors known to us that could materially harm our business, financial condition or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward- looking statement made in this Annual Report. The risks described are not the only risks we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, **may** also ~~may~~ adversely affect our business, financial condition and operating results. If any of these risks actually occur, our business, financial condition, and operating results could suffer significantly. ~~Summary Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks~~ **Risks Related** ~~that we face. We encourage you~~ to **Our Business** ~~carefully review the full risk factors contained in this Annual Report in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky.~~ ~~●~~ We have **only** a ~~history~~ **modest amount** of ~~losses~~ **cash** , ~~and we expect~~ **which is not sufficient** to ~~incur losses~~ **support our plan of operations** for the ~~next several years~~ **long- term** . ~~●~~ We **have obtained short- term financing as a result of the March 2024 Private Placement ; however, such financing provided the Company limited capital and there can be no assurance that additional financing** will **be available** ~~require additional capital~~ to ~~fund~~ **us,** ~~our~~ **or** ~~operations, and~~ if **available, will be on terms satisfactory to us in the longer- term. If** we ~~fail~~ **are unable** to obtain ~~necessary financing~~ **funds when we need them or if we cannot obtain funds on terms favorable to us within the longer- term** , we may not be able to ~~continue~~ **maintain our operations** as a going concern. ~~●~~ We **scaled down operations, will not generate significant revenues unless we complete a business combination with an operating company, and need additional capital to fund our activities. We continue to implement cash management initiatives, included scaled down operations to the core functions of a U. S. Nasdaq listed company with only minimal distribution, marketing, and sales support, allowing the Company to conserve cash and focus on the functions needed to pursue potential strategic alternatives. As we** have **transitioned our business model, unless we complete a business combination with an operating company, we will not generate** significant ~~indebtedness that, if~~ **new revenues in the future and** we ~~are unable~~ **will continue** to ~~repay, would cause a material adverse effect on us~~ **incur expenses related to identifying and acquiring an operating company and compliance with our reporting obligations under applicable federal securities laws** . ~~●~~ We ~~face significant competition from other companies in the life sciences and biotechnology industry, and our business~~ will **need** ~~suffer if we fail~~ to **raise additional funds, and such funds** ~~compete effectively. ● We may never successfully develop new products or~~ may not ~~receive or~~ be **available** ~~able to maintain regulatory clearance or approval for or commercialize our new and existing products. ● Our products and services may never achieve significant commercial market acceptance. ● The COVID- 19 pandemic has impacted and may continue to adversely impact our business, financial condition and results of operations. ● Changes in healthcare laws policies, including legislation reforming the U. S. healthcare system, may have a material adverse effect~~ on ~~our financial condition and operations~~ **commercially acceptable terms, if at all** . ~~● We rely~~ **If we cannot raise funds** on **acceptable terms** ~~collaborations with third parties to develop product and services candidates~~ , **we** ~~including our collaboration with FIND. If these collaborations are not successful, our business could be adversely affected. ● We~~ may not be able to ~~expand~~ **continue to execute** our ~~customer~~ **plan to acquire an operating company and in the extreme** ~~base~~ **case** , ~~which is crucial for our future success. ● If~~ we ~~are unable to protect our intellectual property effectively, our business will be harmed. ● We~~ may **need** ~~suffer from adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due~~ to **liquidate the Company** ~~investor concerns regarding inflation and Russia' s war against Ukraine~~ . ~~Risks Related to Our Business~~ We have a history of losses, and we expect to incur losses for the next several years. The report of our independent registered public accounting firm on our financial statements for the years ended December 31, **2023 and** 2022 ~~and 2021~~ contains explanatory language that substantial doubt exists about our ability to continue as a going concern. We have incurred substantial losses since our inception, and we expect to continue to incur additional losses for the next several years. For the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we had net losses of $ **32. 7 million and $** 37. 3 ~~million and $ 34. 8~~ million, respectively. From our inception through December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~272~~ **305** . ~~8~~ **5** million. The reports of our independent registered public accounting firm on our financial statements for the years ended December 31, **2023 and** 2022 ~~and 2021~~ each contain explanatory language that substantial doubt exists about our ability to continue as a going concern. We completed a number of financings in ~~2021 and~~ 2022 ~~, including~~ **and 2023. We completed** an at- the- market ~~public~~ offering ~~which commenced in June 2022 and a registered direct financing in October 2022. The net proceeds from such financings were approximately $ 52. 0 million. We also completed another registered direct financing in January 2023,~~ which raised net proceeds of approximately $ **0. 99 million in 2022, a registered direct financing in October 2022, which raised net proceeds of approximately $ 3. 04 million, a registered direct financing in January 2023, which raised net proceeds of approximately $** 6. ~~8~~ **9 million, a best- efforts public offering in May 2023, which raised net proceeds of approximately $ 3. 0 million, a preferred stock purchase agreement in October 2023 for up to $ 1. 0 million in proceeds, and a warrant inducement agreement in October 2023, which raised net proceeds of $ 2. 057 million. Additionally, we entered into a securities purchase agreement for the sale of preferred stock in March 2024, which is expected to raise proceeds of approximately $ 3. 0** million. We cannot assure you that we can continue to raise the capital necessary to fund our business. ~~Even~~ **Failure to achieve profitable operations may require us to seek additional financing when none is available or is only available on**

unfavorable terms. We have substantial amount of debt which must be liquidated prior to entering an acquisition of an operating company. We have made significant progress in negotiating our debt with our creditors. As part of the March 2024 Purchase Agreement, the Company entered into settlement agreements (the " Settlement Agreements ") with each of the European Investment Bank (" EIB ") and Curetis GmbH, the Company' s subsidiary (" Curetis "), and Curetis' trustee in insolvency, pursuant to which the parties agreed to settle outstanding liabilities amongst the parties. Pursuant to the settlement agreements and March 2024 Purchase Agreement, following the final closing of the transactions contemplated by the March 2024 Purchase Agreement, the Company will pay $ 2. 0 million of the proceeds to settle all outstanding debt of the Company to each of EIB and Curetis. The settlement agreement with EIB also terminated that certain Guarantee and Indemnity Agreement, dated as of July 9, 2020, by and between the EIB and the Company, pursuant to which the Company had guaranteed all of Curetis' debt to EIB. If we are unable to pay and settle such outstanding liabilities in accordance with the terms of the settlement agreements, the Company will continue to have substantial debt to the EIB, and we will not have capital to pay such debt in accordance with its terms, which would have a material adverse effect and, if **the EIB exercises its rights** ~~we achieve significant revenues, we may not become profitable,~~ and ~~even if we achieve profitability~~ **remedies under our guarantee agreement** , ~~we~~ **would likely force us to seek bankruptcy protection. We** may not be able to **acquire** ~~sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy. We have no committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have~~ an ~~adverse effect on our business, financial condition and results of operations~~ - **operating** . ~~We~~ **company and if we complete such an acquisition, we expect that we will** need to raise additional capital ~~to support~~ **. Assuming we transition** our business **model as expected** ~~. If we cannot do so successfully~~ , ~~we~~ **our sole business objective, following liquidation of our debts,** will ~~not~~ be ~~able~~ to **seek** ~~continue as a going concern. We need~~ to **identify strategic opportunities** ~~raise additional capital to support our business~~ . ~~If we cannot do so successfully~~ **As of the date of this report** , we **have commenced the process of identifying strategic opportunities** ~~will not be able to continue as a going concern. To meet our capital needs, we are considering multiple alternatives, including~~ , but ~~not limited to, ATM offerings, additional equity financings, debt financings and other~~ - **there** ~~funding transactions, licensing and / or partnering arrangements and business combination transactions. We believe that additional equity financings are the most likely source of capital. There~~ can be no assurance that we will be able to complete **such a transaction. In the event we complete such a transaction, we expect that we will need to raise substantial additional capital. We intend to rely on external sources of financing to meet** any **capital requirements and to obtain** such ~~financing transaction on acceptable terms or otherwise~~ **funding through the debt and equity markets** . We **cannot provide any** ~~believe that additional equity or debt financings are the most likely source of capital going forward. There can be no assurance~~ **assurances** that we will be able to ~~complete~~ **obtain additional funding when it is required or that it will be available to us on commercially acceptable terms, if at all. If we fail to obtain such necessary funding,** any such ~~financing~~ transaction ~~on acceptable terms or otherwise. We believe that current cash on hand will be sufficient to fund operations into June 2023, if we are unable to amend the repayment terms of the second tranche of the EIB loan facility due in June 2023. In the event we are unable to amend the repayment terms of the second tranche of the EIB loan facility or successfully raise additional capital during the second quarter of 2023, we will not have sufficient cash flows and liquidity to finance our business operations as currently contemplated. Accordingly, in such circumstances we would be compelled to immediately reduce general and administrative expenses and delay research and development projects, including the purchase of scientific equipment and supplies, until we are able to obtain sufficient financing. We have no additional committed sources of capital and may find it difficult to raise money on terms favorable to us or at all. The failure to obtain sufficient capital to support our operations would have a material adverse effect on our business, financial condition and results of operations. If such sufficient financing is not received timely, we would then need to pursue a plan to license or sell assets, seek to be acquired by another entity, cease operations and / or seek bankruptcy protection. Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our products or services to a third party. We may seek additional funding through a combination of equity offerings, debt financings, collaborations, licensing arrangements, and selling our non- core assets. To the extent that we raise additional capital through the sale of equity or convertible debt securities, stockholders' ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect our existing stockholders' rights as a holder of our common stock. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur additional debt or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, issuance of additional equity securities, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations or licensing arrangements or sell non- core assets in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to our products and services that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms. We may not realize the growth and success that we expected from the combination of the OpGen and Curetis businesses. Although we believe the combination of the OpGen and Curetis businesses provided a significant commercial opportunity for growth, we may not realize all of the synergies that we had anticipated and~~ may not be successful ~~in implementing our commercialization strategy across all products and platforms as well as all geographies~~ . Our **Board** ~~combined business is and continues to be subject to all~~ of ~~the risks~~ **Directors has sole discretion to identify** and **evaluate transaction candidates** ~~uncertainties inherent in the pursuit of growth in our industry~~ and ~~we may~~ **complete transactions**

without the approval of our stockholders. We have not **developed any specific transaction guidelines** ~~be able to successfully sell our products, obtain the regulatory clearances~~ and ~~approvals we apply for or, realize the anticipated benefits from our distribution, collaboration and other commercial partners. If~~ we are not ~~able~~ **obligated** to ~~achieve~~ **follow any particular operating, financial, geographic or** ~~the~~ **other** ~~expected benefits from the combined~~ **criteria in evaluating candidates for potential transactions or** business ~~of OpGen as a commercial enterprise, our~~ **combinations. We will target companies that we believe will provide the best potential long- term** financial ~~condition~~ **return for our stockholders and we** will **determine the purchase price** ~~be negatively impacted. The process to obtain~~ and ~~maintain FDA clearances~~ **other terms and conditions of such transactions without review** or ~~approvals~~ **approval of our stockholders. Accordingly, our stockholders will not have the opportunity to evaluate the relevant economic, financial, and other information that our Board will use and consider in deciding whether or not to enter into a particular transaction. We will not generate any significant revenue or earnings in the near future unless and until we merge with or acquire an operating business. Upon settlement of our debts to EIB, if such an event occurs, we will have limited assets and operations. As a result, we do not expect to generate any significant revenue or realize significant revenue unless and until we successfully complete a strategic transaction. There is competition** for ~~our products~~ **those private companies suitable for a merger transaction of the type being contemplated by management. There** is **currently a very competitive market** ~~complex and time and resource consuming. If we fail to obtain such clearances or~~ **for** ~~approvals, our~~ business **opportunities** ~~and results of operations will be materially adversely impacted. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming~~ , ~~and we may not be able to obtain these clearances or approvals on a timely basis, if at all. We were subject to extended delays for the FDA clearance of our Acuitas AMR Gene Panel test due to the national emergency situation caused by the COVID- 19 pandemic and FDA prioritizing COVID- 19 related product reviews. The FDA has not been able to provide any feedback in the form of pre- submission, or presub, meetings for either the Unyvero UTI or IJI panels and declined to host any presub meetings for the IJI panel in early 2022. In addition, the time and expense needed to prepare future clinical trial data for submission to the FDA and reviewing and responding to the FDA's request for additional information may require significant resources and could impact other research and development project timelines, which may adversely affect our strategy and ability to commercialize our diagnostic tests and bioinformatics products and services. We have significant indebtedness~~ which could **reduce** ~~have a material adverse effect on our financial condition. As of December 31, 2022, we owed indebtedness of approximately $ 13. 5 million (€ 12. 6 million) of principal (including deferred interest of $ 2. 0 million (€ 1. 9 million)) under a loan provided by the EIB with remaining maturities in June 2023 and June 2024. Of the approximately € 13. 4 million of indebtedness due to the EIB in April 2022, we made a lump sum payment of approximately € 5. 0 million and thereafter made eight monthly installments totaling approximately € 5. 6 million. In 2023, the Company will pay the remaining four monthly installments from January through April totaling approximately € 2. 8 million, along with approximately € 4. 0 million due in June 2023 for the second EIB tranche. While we continue evaluating options to restructure the remaining indebtedness, we may not be able to do so, and in such event, OpGen may not be able to generate sufficient cash to service all its indebtedness and may be forced to take other~~ -- **the likelihood of consummating a** ~~actions to satisfy its obligations under indebtedness that may not be~~ successful **business combination** ~~. The inability in the future to repay such indebtedness when due would have a material adverse effect on us and, if the EIB exercises its rights and remedies under our loan agreement, would likely force us to seek bankruptcy protection~~ . We expect ~~our ability~~ to ~~utilize our net operating loss carryforwards will~~ be ~~limited as a result of~~ an **insignificant participant in the business of seeking mergers with, joint ventures with, and acquisitions of small private and public entities. A large number of established and well- financed entities, including small public companies, venture capital firms, and special purpose acquisition companies, or** " **SPACs** ~~ownership change,~~ " ~~as defined in Section 382 of the Internal Revenue Code triggered by consummation of the transaction with Curetis. As of December 31~~ , ~~2022, we had approximately $ 232. 7 million of net operating loss, or NOL, carryforwards for U. S. federal tax purposes. Under U. S. federal income tax law, we generally can use our NOL carryforwards (and certain tax credits) to offset ordinary taxable income, thereby reducing our U. S. federal income tax liability, for up to 20 years from the year in which the losses were generated, after which time they will expire. State NOL carryforwards (and certain tax credits) generally may be used to offset future state taxable income for 20 years from the year in which the losses~~ are **active** ~~generated, depending on the state, after which time they will expire. The rate at which we can utilize our NOL carryforwards is limited (which could result~~ in **mergers** ~~NOL carryforwards expiring prior to their use) each time we experience an~~ **and acquisitions** ~~" ownership change, " as determined under Section 382~~ of **companies** ~~the Internal Revenue Code. A Section 382 ownership change generally occurs if a shareholder or a group of shareholders who are deemed to own at least 5 % of our common stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. If an ownership change occurs, Section 382 generally would impose an annual limit on the amount of post- ownership change taxable income~~ that may be **desirable target candidates** ~~offset with pre- ownership change NOL carryforwards equal to the product of the total value of our outstanding equity immediately prior to the ownership change (reduced by certain items specified in Section 382) and the U. S. federal long- term tax- exempt interest rate in effect at the time of the ownership change. A number of special and complex rules apply in calculating this Section 382 limitation. While the complexity of Section 382 makes it difficult to determine whether and when an ownership change has occurred, and if a portion of our NOLs is subject to an annual limitation under Section 382, we believe that an additional ownership change may have occurred upon the consummation of the transaction with Curetis. In addition, our ability to use our NOL carryforwards will be limited to the extent we fail to generate enough taxable income in the future before they expire. Existing and future Section 382 limitations and our inability to generate enough taxable income in the future could result in a substantial portion of our NOL carryforwards expiring before they are used. In addition, under the 2017 Tax Cut and Jobs Act, effective for losses arising in taxable years beginning after December 31, 2017, the deduction for NOLs is limited to 80 % of taxable income, NOLs can no longer be carried back, and NOLs can be~~

carried forward indefinitely. Our products and services may never achieve significant commercial market acceptance. Our products and services may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. **Nearly all** Our ability to achieve commercial market acceptance for our products will depend on several factors, including: ● our ability to convince the **these entities have significantly greater financial resources** medical community of the clinical utility of our products and services and their potential advantages over existing tests , **technical expertise** including our NGS- based isolate sequencing services offering, despite the lack of reimbursement for such services; ● our ability to successfully develop automated rapid pathogen identification and **managerial capabilities** antibiotic resistance testing products and services, including bioinformatics, and convince hospitals and other healthcare providers of the patient safety, improved patient outcomes and potential cost savings that **than** could **we do. As a** result ; ● our ability to further grow our microbial isolate and antibiotic resistance genes knowledge- bases and bioinformatics offerings; ● the willingness of hospitals and physicians to use our products and services; and ● the ability of hospitals and labs to pay for our products and services. Our future success is dependent upon our ability to expand our customer base. The current customers we are targeting for our Unyvero and Acuitas products and services are hospital systems, acute care hospitals, particularly those with advanced care units, such as intensive care units, community- based hospitals and governmental units, such as public health facilities and other laboratories. We need to provide a compelling case for the savings, patient safety and recovery, reduced length of stay and reduced costs that come from adopting our MDRO diagnosis and antibiotic stewardship products and services. If we are not able to successfully increase our customer base, sales of our products and our margins may not meet expectations. We are subject to similar challenges with respect to customers and partners for our ARESdb based offerings and solutions. Attracting new customers and introducing new products and services requires substantial time and expense. Any failure to expand our existing customer base, or launch new products and services, would adversely affect our ability to improve our operating results. We are developing diagnostic products for the more rapid identification of MDROs and antibiotic resistance genomic information. If we are unable to successfully develop, receive regulatory clearance or approval for or commercialize such products and services, our business will be materially, adversely affected. We are developing products that detect antibiotic resistance markers in under ninety minutes as well as four to five hours — and in the case of our NGS- based ARESasp, ARESid, or ARESiss (Express) solutions several days to weeks- that we believe could help address many of the current issues with the need for more rapid identification of infectious diseases and AMR testing. Development of such diagnostic products is difficult and we cannot assure you that we will be successful in such product development efforts, or, if successful, that we will receive the necessary regulatory clearances to commercialize such products. We have identified dozens of resistance genes to help guide clinicians with their antibiotic therapy decisions. Although we have demonstrated preliminary feasibility, and confirmed genotype / phenotype predictive algorithms, such product development efforts will require us to work collaboratively with other companies, academic and government laboratories, and healthcare providers to access sufficient numbers of microbial isolates, develop the diagnostic tests, successfully conduct the necessary clinical trials and apply for and receive regulatory clearances or approvals for the intended use of such diagnostic tests. In addition, we would need to successfully commercialize such products. Such product development, clearance or approval and commercialization activities are time- consuming, expensive and we are not assured that we will have sufficient funds to successfully complete such efforts. Any significant delays or failures in this process could have a material adverse effect on our business and financial condition. We offer some of these products in development to the RUO market and for other non- clinical research uses prior to receiving clearance or approval to commercialize these products in development for use in the clinical setting. We need to comply with the applicable laws and regulations regarding such other uses. Failure to comply with such laws and regulations may have a significant impact on the Company. We may enter into agreements with U. S. or other international government agencies or non- government organizations (NGO), which could be subject to uncertain future funding. The presence of MDROs and the need for antibiotic stewardship activities have prompted state, federal and international government agencies to develop programs to combat the effects of MDROs. From 2018 through September 30, 2021, we were party to a collaboration, called the New York State Infectious Disease Digital Health Initiative, with the New York State DOH and ILÚM (now IDC) to develop a research program to detect, track, and manage antimicrobial- resistant infections at healthcare institutions in New York State. In September 2022, we entered into a research and development collaboration agreement with FIND, a NGO focused on innovative new diagnostics, for the potential use of the Unyvero A30 RQ platform in low- and middle- income countries (LMICs). In the future, we may seek to enter into additional agreements with governmental funding sources or contract with government healthcare organizations or NGOs to sell our products and services, such as our collaboration agreement with FIND. Under such agreements, we rely on the continued performance by these government agencies and NGOs of their responsibilities under these agreements, including adequate continued funding of the agencies and NGOs and their programs. We have no control over the resources and funding that government agencies may devote to these agreements, which may be subject to annual renewal. Government agencies or NGOs may fail to perform their responsibilities under these agreements, which may cause them to be terminated by the government agencies or NGOs. In addition, we may fail to perform our responsibilities under these agreements. Any government or NGO agreements would be subject to audits, which may occur several years after the period to which the audit relates. If an audit identified significant unallowable costs, we could incur a material charge to our earnings or reduction in our cash position. As a result, we may be unsuccessful entering, or ineligible to enter, into future government and NGO agreements. If the utility of our current products and products in development is not supported by studies published in peer- reviewed medical publications, the rate of adoption of our current and future products and services by clinicians and healthcare facilities may be negatively affected. The results of several of our clinical and economic validation studies involving our products have been presented at major infectious disease and infection control society meetings and some have been published in peer reviewed scientific journals. We need to maintain and grow a continued presence in peer- reviewed publications to promote clinician adoption of our products. We believe that peer- reviewed journal articles that provide evidence of the utility of our current and future products and services, and adoption

by key opinion leaders in the infectious disease market are very important to our commercial success. Clinicians typically take a significant amount of time to adopt new products and testing practices, partly because of perceived liability risks and the uncertainty of a favorable cost / benefit analysis. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about our products and demonstrate their clinical benefits. Clinicians may not adopt our current and future products and services unless they determine, based on published peer- reviewed journal articles and the experience of other clinicians, that our products provide accurate, reliable, useful and cost- effective information that is useful in pathogen identification as well as AMR marker detection and possibly MDRO diagnosis and outbreak prevention. If our current and future products and services or the technology underlying our products and services or our future product offerings do not receive sufficient favorable exposure in peer- reviewed publications, the rate of clinician adoption could be negatively affected. The publication of clinical data in peer- reviewed journals is a crucial step in commercializing our products, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study. Our sales cycle for our marketed products and services is lengthy and variable, which makes it difficult for us to forecast revenue and other operating results. The sales cycles for our products are lengthy, which will make it difficult for us to accurately forecast revenues in a given period, and may cause revenue and operating results to vary significantly from period to period. Potential customers for our products typically need to commit significant time and resources to evaluate our products, and their decision to purchase our products may be further limited by budgetary constraints and numerous layers of internal review and approval, which are beyond our control. We spend substantial time and effort assisting potential customers in evaluating our products. Even after initial approval by appropriate decision makers, the negotiation and documentation processes for the actual adoption of our products on a facility- wide basis can be lengthy. As a result of these factors, based on our experience to date, our sales cycle, the time from initial contact with a prospective customer to routine commercial use of our products, has varied and could be 12 months or longer, which has made it difficult for us to accurately project revenues and operating results. In addition, the revenue generated from sales of our products may fluctuate from time to time due to changes in the testing volumes of our customers. As a result, our results may fluctuate on a quarterly basis, which may adversely affect the price of our common stock. We are currently party to, and may enter into additional collaborations with third parties to develop product and services candidates. If these collaborations are not successful, our business could be adversely affected. We are currently party to several collaborations, such as our agreement with FIND, and anticipate that we will enter into additional collaborations related to our platforms and product offerings, including our bioinformatics products and services. Such collaborations are and may be with microbiology and IVD companies, pharmaceutical and biotech companies, CROs and CLIA labs, NGS platform companies or other participants in our industry. We have limited control over the amount and timing of resources that any such collaborators could dedicate to the development or commercialization of the subject matter of any such collaboration. Our ability to generate revenues from these arrangements would depend on our and our collaborator' s abilities to successfully perform the functions assigned to each of us in these arrangements. Our relationships with collaborators may pose several risks, including the following: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● we may not achieve any milestones, or receive any milestone payments, under our collaborations, including milestones and / or payments that we expect to achieve or receive; ● the clinical trials, if any, conducted as part of these collaborations may not be successful; ● a collaborator might elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors, such as an acquisition, that diverts resources or creates competing priorities; ● we may not have access to, or may be restricted from disclosing, certain information regarding the identity of the partner, financial details as well as details on product or services candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product or services candidates; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; ● product or services candidates developed in collaboration with us may be viewed by our collaborators as competitive with their own product or services, which may cause collaborators to cease to devote resources to the commercialization of our product or services candidates; ● a collaborator with marketing and distribution rights to one or more of our product or services candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product or services candidates, may cause delays or termination of the research, development or commercialization of such product or services candidates, may lead to additional responsibilities for us with respect to such product or services candidates or may result in litigation or arbitration, any of which would be time- consuming and expensive; ● collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; ● disputes may arise with respect to the ownership of intellectual property developed pursuant to a collaboration; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and ● collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product or services candidates. If our collaborations do not result in the successful development and commercialization of products or services, we may not receive any future research funding or milestone or royalty payments under the collaborations. If we do not receive the funding we would expect under these agreements, our development of product and services candidates could be delayed, and we may need additional resources to develop our product candidates. We may not be successful in finding strategic collaborators for continuing development of certain of our product or services candidates or

successfully commercializing or competing in the market for certain indications. We may seek to develop strategic partnerships for developing certain of our product or services candidates, due to capital costs required to develop the product or services candidates or manufacturing constraints. We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our product or services candidates because our research and development pipeline may be insufficient, our product or services candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product or services candidates as having the requisite potential to demonstrate commercial success. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product or service candidate, reduce or delay our development program, delay our potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates and our business, financial condition, results of operations and prospects may be materially and adversely affected. We are an early commercial stage company and may never be profitable. We rely principally on the commercialization of our Unyvero, ARESdb based, and Acuitas products and services to generate future revenue growth. To date, our products have delivered only limited revenue. We believe that our commercialization success is dependent upon our ability to significantly increase the number of hospitals, labs, long- term care facilities and other inpatient healthcare settings that use our products. If demand for products does not increase as quickly as we have planned , we may be unable to **effectively compete** increase our revenue levels as expected. We are currently not profitable. Even if we succeed in increasing adoption of our products by our target markets, maintaining and creating relationships with our existing and new customers and developing and commercializing additional molecular testing products, we may not be able to generate sufficient revenue to achieve or sustain profitability. We have limited experience in marketing and selling our products, and if we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability. We sell our products through our own direct sales force, which sells our products in the U. S., and via distribution partners in all other territories. All our products and services may be offered and sold to different potential customers or involve discussions with multiple stakeholders in inpatient facilities. Our future sales will depend in large part on our ability to increase our marketing efforts and adequately address our customers' needs. The inpatient healthcare industry is a large and diverse market. We will need to attract and develop sales and marketing personnel with industry expertise, including internally and at our distribution partners. Competition for such **entities in identifying possible business opportunities** personnel is intense. We may not be able to attract and retain sufficient personnel to maintain an **and** effective sales and marketing force. In addition, we will likely have less control over sales and marketing personnel of our distribution partners. The personnel at our distribution partners may therefore not be adequately trained with respect to our products or may not be sufficiently incentivized to sell our products. If we are unable to successfully **completing a** market our products and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability. If our manufacturing facilities become inoperable, our products, and our business **combination** will be harmed . We manufacture our Unyvero cartridges and consumables and SARS- CoV- 2 test kits in our facility in Bodelshausen, Germany and until 2022, we manufactured our Acuitas products in our facility in Rockville, Maryland. As of December 31, 2022, we were in the process of transferring the Acuitas production to our Bodelshausen facility, and the transfer was successfully completed in early 2023. We do not have redundant facilities for these **These** products. Our facilities and the equipment we use to manufacture our products would be costly to replace and could require substantial lead time to repair or replace, if damaged or destroyed. The facilities may be harmed or rendered inoperable by natural or man- made disasters, including flooding and power outages or fire, which may render it difficult or impossible for us manufacture our products for some period of time. The inability to manufacture our products may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we carry insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all. In order to establish redundant facilities, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees, and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new manufacturing facility opened by us would be subject to FDA inspection and certification. If we fail to maintain our FDA certification or if our FDA certification is suspended, limited or revoked, we would not be able manufacture our products. If demand for these products increase beyond our current forecasts or, regulatory requirements arise, we may not be able to meet our obligations to manufacture these products, and backlog or reduced demand for such products could occur. If any of these issues occur, it could have a material adverse effect on our financial condition and results of operations. We rely on a limited number of suppliers or, in some cases, sole suppliers, for some of our materials and may not be able to find replacements or immediately transition to alternative suppliers. We rely on several sole suppliers and manufacturers, including Zollner, Contexo, Scholz, Thermo Fisher Scientific and Qiagen, for supplying instrument systems and certain reagents, raw materials, supplies and substances which we use to manufacture our products. An interruption in our operations could occur if we encounter delays or difficulties in securing these items or manufacturing our products, and if we cannot, then obtain an acceptable substitute. Any such interruption or damage to third party suppliers or manufacturers for any reason, such as fire or other events beyond our control, including as a result of natural disasters, terrorist attacks, or the occurrence of a contagious disease or illness, such as the COVID- 19 pandemic, could significantly affect our business, financial condition, results of operations and reputation. Our distributors, collaboration partner, and service providers may be impacted and could be delayed

or suspended as a result of the military action by Russia in Ukraine. We have distribution relationships with partners for the distribution of certain of our products in Russia and Ukraine as well as other neighboring territories. We also have relationships with other parties and service providers that may operate in or be impacted by conditions in Russia and Ukraine. In February 2022, Russia commenced a military invasion of Ukraine. Russia' s invasion and the ensuing response by Ukraine may continue to disrupt our and our distribution partner' s distribution efforts in such jurisdictions, impact the ability of certain service providers to perform and could increase our costs and disrupt future planned activities. For example, we believe our distribution partner will not be able to successfully distribute products in Ukraine or Russia during the conflict and Curetis has suspended its business support to our distributors and will not accept any purchase orders until the geopolitical situation has been resolved. Such disruption would significantly impact our ability to market, sell and distribute in such territories and could impact our ability to do so in nearby territories, which would increase our costs and slow down and jeopardize our commercialization efforts. If we cannot compete successfully with our competitors, we may be unable to increase or sustain our revenue or achieve and sustain profitability. Our competitors include rapid diagnostic testing and traditional microbiology companies, commercial laboratories, information technology companies, and hospital laboratories who may internally develop testing capabilities. Principal competitive factors in our target market include organizational size, scale, and breadth of product offerings; rapidity of test results; quality and strength of clinical and analytical validation data and confidence in diagnostic results; cost effectiveness; ease of use; and regulatory approval status. Our principal competition comes from traditional methods used by healthcare providers to diagnose and screen for MDROs and from other molecular diagnostic companies creating screening and diagnostic products such as Bosch, Cepheid (a Danaher company), Becton- Dickinson, bioMérieux, Accelerate Diagnostics, T2 Biosystems, GenMark (a subsidiary of Roche), Qiagen, Mobidiag (a Hologic company) and Luminex (a DiaSorin company). We also face competition from commercial laboratories, such as Bio- Reference Laboratories, Inc., Laboratory Corporation of America Holdings, Quest Diagnostics, Pathnostics, and EuroFins, which have strong infrastructure to support the commercialization of diagnostic laboratory services. Competitors may develop **reduce** their -- **the likelihood** own versions of competing products in countries where we do not have patents or where our intellectual property rights are not recognized or using their own technologies that do not infringe on our intellectual property rights. Many of our potential competitors have widespread brand recognition and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. Others may develop products with prices lower than ours that could be viewed by hospitals, physicians and payers as functionally equivalent to our product and service offering or offer products at prices designed to promote market penetration, which could force us **identifying** to lower the list prices of our product and **consummating** service offerings and affect our ability to achieve profitability. If we are unable to change clinical practice in a meaningful way or compete successfully -- **successful** against current and future competitors, we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline. Our products and services are not covered by reimbursement by the Centers for Medicare & Medicaid Services (CMS) and other governmental and third- party payors. If we cannot convince our customers that the savings from use of our products and services will increase their overall reimbursement, our business **combination** could suffer. Our products and services do not currently receive reimbursement from Medicare, Medicaid, other governmental payors or commercial third- party payors. Policy and rule changes in reimbursement announced by CMS, including potential financial incentives for reductions in healthcare-associated infections (HAI), and penalties and decreased Medicare reimbursement for patients with HAIs provide us with an opportunity to establish a business case for the purchase and use of our screening and diagnostic products and services. If we cannot convince our customers that the savings from use of our products and services will increase or stabilize their overall profitability and improve clinical outcomes, our business will suffer. Failure in our information technology, storage systems or our AREScloud services could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenues, as well as our research, development and commercialization efforts. Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology systems, which support our operations and our research and development efforts, as well as our storage systems and our analyzers. Due to the sophisticated nature of the technology we use in our products and service offerings, including our ARESdb and AREScloud services, we are substantially dependent on our information technology systems. Information technology systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses, ransomware attacks and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our ARESdb, could adversely affect our ability to operate our business. Any interruption in the operation of our ARESdb, due to information technology system failures, part failures or potential disruptions in the event we are required to relocate our instruments within our facility or to another facility, could have an adverse effect on our operations. Security breaches, loss of data and other disruptions 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 our reputation. In the ordinary course of our business, we collect and store sensitive data, which may include legally protected health information and personally identifiable information about our customers and their patients. We also store sensitive intellectual property and other proprietary business information, including that of our customers. We manage and maintain our applications and data utilizing a combination of on- site systems and cloud- based data center systems. These applications and data encompass a wide variety of business- critical information, including research and development information, commercial information and business and financial information. We face four primary risks relative to protecting this critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. We are highly

dependent on information technology networks and systems, including the Internet, to securely process, transmit and store this critical information. Security breaches of this infrastructure, including physical or electronic break- ins, computer viruses, phishing attempts, ransomware attacks or other attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance, and transmission of this critical information is 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 breached due to employee error, malfeasance or other disruptions. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm **, as** ~~of the type~~ described above. Any such breach or interruption could compromise our networks, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal Health Insurance Portability and Accountability Act, or HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to **collect** ~~perform tests, provide test results, bill facilities or patients~~ , process ~~claims and appeals~~ , ~~provide customer assistance services, conduct research and development activities, collect, process~~ and prepare Company financial information **as well as** ~~, provide information about our current and future solutions and other patient and clinician education and outreach efforts through our website, and~~ manage the administrative aspects of our business ~~and damage our reputation~~ , ~~any~~ **all** of which could adversely affect our business ~~. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position~~ . In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the United States and elsewhere 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 and compliance procedures in a manner adverse to our business. **We are subject to risks with respect to counterparties** ~~Data collection is governed by restrictive regulations governing the use~~ , ~~processing,~~ and ~~cross- border transfer of personal information. Our actual or perceived~~ failure **of** ~~to comply with~~ such **counterparties to meet their** obligations could ~~harm~~ **cause us to suffer losses or negatively impact our results of operations and cash flows. We have entered into various contracts that are material to the operation of** our business **that subject us to counterparty risks** . ~~We~~ **The ability** and **willingness of** our ~~collaborators~~ **counterparties to perform their obligations under any contract will depend on a number of factors that** are ~~subject to laws~~ **beyond our control** and **may include** ~~regulations related to~~ , among other things, ~~privacy~~ **general economic conditions** , ~~data protection, information security and consumer protection across different markets where we conduct our business. Such laws and regulations govern~~ the **condition** ~~collection, processing, storage, transfer and use~~ of ~~data and are constantly evolving and changing. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data, and as~~ such **counterparty' s industry** ~~, are likely to remain uncertain for the foreseeable future. Our actual or perceived failure to comply with such obligations could have an~~ **and** ~~adverse effect on our business, operating results and financial operations. Complying with these~~ -- **the overall** ~~numerous, complex, and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the potential or actual misappropriation, loss or other unauthorized processing, use or disclosure of sensitive or confidential patient, consumer or other personal information, whether by us, one of our collaborators or another third party, could adversely affect our business,~~ financial condition ~~, and results~~ of ~~operations, including but not limited to investigation costs, material fines and penalties, compensatory, special, punitive, and statutory damages, litigation, consent orders regarding our privacy and security practices, requirements that we provide notices, credit monitoring services, and / or credit restoration services or other~~ -- **the counterparty** ~~relevant services to impacted individuals, adverse actions against our licenses to do business, reputational damage and injunctive relief~~ . ~~In addition, these and other requirements~~ **A prolonged period of difficult industry conditions** could **lead** ~~limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability~~ to **changes in a counterparty** ~~use, store, transfer, and process data, impact our or our collaborators~~ ' ~~ability to process~~ **s liquidity and increase** ~~or~~ **our exposure** ~~use data in order~~ to **counterparty** ~~support the provision of our products, affect our or our collaborators' ability to offer our products in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities. We cannot provide assurance that future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal information, either of which may prevent us from undertaking or publishing essential research. These burdens or risks~~ - **risk** ~~may prove too great for us to reasonably bear and may adversely affect our ability to achieve profitability or maintain profitably in the future~~ . If ~~we~~ **our counterparties** are unable ~~to develop products to keep pace with rapid technological, medical and scientific change, our~~ - **or** ~~operating~~ **unwilling to perform, it could negatively impact our** results ~~and competitive position could be harmed. New test development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize~~

our diagnostic products and services. The further development and commercialization of additional diagnostic product and service offering are key to our growth strategy. A key element of our strategy is to discover, develop, validate and commercialize a portfolio of additional diagnostic products and services to rapidly diagnose pathogens and AMR and effectively treat MDRO infections and reduce the associated costs to patients, inpatient facilities and the healthcare industry. We cannot assure you that we will be able to successfully complete development of or commercialize any of our planned future products and services, or that they will be clinically usable. The product development process involves a high degree of risk and may take up to several years or longer. Our new product development efforts may fail for many reasons, including: ● failure of the tests at the research or development stage; ● lack of clinical validation data to support the effectiveness of the tests; ● delays resulting from the failure of third- party suppliers or contractors to meet their obligations in a timely and cost- effective manner; ● failure to obtain or maintain necessary certifications, licenses, clearances or approvals to market or perform the test; or ● lack of commercial acceptance by inpatient healthcare facilities and commercial partners. Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new products, or we may be required to expend considerable resources repeating clinical studies or trials, which would adversely impact the timing for generating potential revenues from those new products. In addition, as we develop new products, we will have to make additional investments in our sales and marketing operations , which may be prematurely or unnecessarily incurred if the commercial launch of a product is abandoned or delayed. If we use hazardous materials in a manner that causes injury, we could be liable for damages. Our activities currently require the use of hazardous materials and the handling of patient samples. 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, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an **and** ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We are, or may be in the future, subject to compliance with additional laws and regulations relating to the protection of the environment and human health and safety, and including those relating to the handling, transportation and disposal of medical specimens, infectious and hazardous waste and Occupational Safety and Health Administration, or OSHA, requirements as well as their international equivalents. The requirements of these laws and regulations are complex, change frequently and could become more stringent in the future. Failure to comply with current or future environmental laws and regulations could result in the imposition of substantial fines, suspension of production, alteration of our production processes, cessation of operations or other actions, which could severely harm our business. 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 could lead to product liability claims if someone were to allege that a product failed to perform as it was 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. For example, if we diagnosed a patient as having an MDRO but such result was a false positive, the patient could be unnecessarily isolated in an inpatient setting or receive inappropriate treatment. We may also be subject to similar types of claims related to products we may develop in the future. 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 assure you 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 any 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 services. The occurrence of any of these events could have an adverse effect on our business and results of operations. If our acquired in- process research and development costs or finite- lived tangible and intangible assets or any future goodwill become impaired in the future, we may be required to record non- cash charges to earnings, which could be material and could reduce stockholders' equity or otherwise adversely affect the Company' s financial condition. We review long- lived assets, including property and equipment and identifiable amortizing intangible assets, for impairment whenever changes in circumstances or events may indicate that the carrying amounts are not recoverable. If the fair value is less than the carrying amount of the asset, an impairment is recognized for the difference. Factors which may cause an impairment of long- lived assets include significant changes in the manner of use of these assets, negative industry or market trends, a significant underperformance relative to historical or projected future operating results, extended period of idleness or a likely sale or disposal of the asset before the end of its estimated useful life. For example, in 2021, the Company had determined that the right- of- use asset associated with the Company' s San Diego, California office lease may not be recoverable, and, as a result, the Company recorded an impairment charge of $ 171 thousand during the six months ended June 30, 2021. There can be no assurance that our other long- lived assets and intangible assets will not be further impaired. If our property and equipment and identifiable amortizing intangible assets are determined to be impaired in the future, we may be required to record non- cash charges to earnings during the period in which the impairment is determined, which could be material and have an adverse effect on our financial position and results of operations. In addition, we review and test goodwill for impairment at least annually and whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. The impairment test for goodwill consists of comparing the fair value of the reporting unit and acquired in- process research and development projects (IPR & D), which is estimated using both the income and market approach, to its carrying value. The process of impairment testing for our goodwill involves a number of judgments and estimates made by management including future cash flows , revenue growth rates, profitability assumptions, terminal growth rates and discount rates with regards to our reporting unit. Our internally generated long- range plan includes assumptions regarding pricing and operating forecasts for our products and technologies. For instance, based on the goodwill impairment assessment performed during the quarter ended

~~September 30, 2022, and primarily due to recent changes in the Company' s stock price and market capitalization, it was determined that goodwill was impaired. As a result, the Company recorded a one- time non- cash goodwill impairment charge in the full amount of $ 6, 940, 549 for the year ended December 31, 2022. In addition, during the Company' s annual impairment test for its IPR & D intangible asset, it was determined that the infinite- lived intangible asset was impaired because although the Company has an ongoing collaboration utilizing the intangible asset, the current contracted cash flow associated with this collaboration and projected future cash flows did not support the carrying amount. As a result, the Company recorded an impairment charge in the amount of $ 5, 407, 699 for the year ended December 31, 2022. Accordingly, if the judgments and estimates used in such analyses are not realized or are affected by external factors, our actual results may not be consistent with such judgments and estimates, and we may be required to record further impairment of the Company' s assets in the future, which could be material, could reduce stockholders' equity and have an adverse effect on our financial position and results of operations~~ . Risks Related to Our Securities and Public Company Status If we are unable to maintain effective internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our reported financial information and the market price of our common stock may be negatively affected. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes- Oxley Act of 2002 requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. If we have a material weakness in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. When we are no longer a smaller reporting company, our independent registered public accounting firm will be required to issue an attestation report on the effectiveness of our internal control over financial reporting. Even if our management concludes that our internal control over financial reporting is effective, our independent registered public accounting firm may conclude that there are material weaknesses with respect to our internal controls or the level at which our internal controls are documented, designed, implemented **,** or reviewed. When we are no longer a smaller reporting company, if our auditors were to express an adverse opinion on the effectiveness of our internal control over financial reporting because we had one or more material weaknesses, investors could lose confidence in the accuracy and completeness of our financial disclosures, which could cause the price of our common stock to decline. Internal control deficiencies could also result in a restatement of our financial results in the future. We cannot assure you that we will be able to continue to comply with the Nasdaq Minimum Bid Price Rule **, the Periodic Filing Rule,** or other continued listing standards of the Nasdaq Capital Market. If we are unable to maintain compliance with such standards, we could be subject to delisting or other adverse action, which could negatively impact the trading of our common stock. **As previously disclosed, we requested a hearing by the Nasdaq Hearings Panel of The Nasdaq Stock Market LLC to appeal the Nasdaq listing staff' s determination to delist the Company' s securities as a result of the failure of the Company' s common stock to comply with the minimum bid price requirement of Nasdaq Listing Rule 5550 (a) (2).** In ~~January 2023~~ **response to the Company' s request** , ~~we effected a one- on -~~ **February 9, 2024, the Company received written notification from Nasdaq notifying the Company that the Panel had granted the Company' s request** for **an additional period, during which** ~~- twenty reverse stock split of our common stock (~~ the **Company will remain listed on Nasdaq,** ~~" 2023 Reverse Stock Split ") in order~~ to regain compliance with the **Bid Price Rule. Pursuant to the Notice, the Panel granted the Company an additional period until June 3, 2024 to regain compliance. The extension is subject to certain conditions specified by the Panel in the Notice. Thereafter, Nasdaq notified the Company that it failed to comply with** Nasdaq Listing Rule **5250 (c) (** ~~requiring a minimum closing bid price of at least $~~ 1 ~~. 00 per share. Although~~ **) for failing to timely file this Annual Report and the Company' s Quarterly Report on Form 10- Q for the** ~~the~~ **three - month period ended March 31,** ~~2023~~ **2024** ~~Reverse Stock Split allowed us~~ **. The Panel again granted the Company' s request for additional time** to ~~regain compliance~~ **cure such delinquencies, provided that the Company file this Annual Report by June 3, 2024 and the Quarterly Report on Form 10- Q by July 8, 2024. While the Company intends to comply** with **such conditions and** ~~the minimum bid price rule~~ **rules** , there can be no assurance that the **Company** ~~market price of our common stock following the 2023 Reverse Stock Split~~ will **be able to regain or** remain **in** ~~at the level required for continuing~~ compliance with **the applicable Nasdaq listing requirements on an ongoing basis or** that ~~requirement. It is not uncommon for~~ the ~~market price of a~~ **Panel will afford the** ~~company~~ **Company additional time** ~~' s common stock~~ to **achieve** ~~decline in the period following a reverse stock split and, in some cases, at a rate greater than would occur in the absence of a reverse stock split. In any event, other factors unrelated to the number of shares of our common stock outstanding, such as negative financial or operational results, could adversely affect the market price of our common stock and jeopardize our ability to meet or maintain~~ compliance ~~with Nasdaq' s minimum bid price rule requirements or other listing standards~~ . If we are unable to satisfy these requirements or standards, we could be subject to delisting, which would have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. The ~~2023~~ **2024** Reverse Stock Split may decrease the liquidity of the shares of our common stock. The liquidity of the shares of our common stock may be affected adversely by the ~~2023~~ **2024** Reverse Stock Split given the reduced number of shares outstanding after the ~~2023~~ **2024** Reverse Stock Split, especially if the market price of our common stock does not increase as a result of the ~~2023~~ **2024** Reverse Stock Split. In addition, the ~~2023~~ **2024** Reverse Stock Split may increase the number of stockholders who own odd lots (less than 100 shares) of our common stock, creating the potential for such stockholders to experience an increase in the cost of selling their shares and greater difficulty effecting such sales. Following the ~~2023~~ **2024** Reverse Stock Split, the resulting market price of our common stock may not attract new investors, including institutional investors, and may not satisfy the investing requirements of those investors. Consequently, the trading liquidity of our common stock may not improve. There can be no assurance that the ~~2023~~ **2024** Reverse Stock Split will result in a share price that will attract new investors, including institutional investors. In addition, there can be no assurance that the market price of our common stock will satisfy the investing requirements of those investors. As a result, the trading liquidity of our common

stock may not necessarily improve. The market price of our common stock and the trading volume of our common stock has been, and may continue to be, highly volatile, and such volatility could cause the market price of our common stock to decrease. During ~~2022~~ **2023**, the market price of our common stock fluctuated from a low of $ ~~2~~ **1**. ~~40~~ **70** per share to a high of $ ~~22~~ **34**. ~~20~~ **60** per share, and our stock price continues to fluctuate. The market price and trading volume of our common stock may continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as: ● our ability to **consummate a strategic transaction** ~~grow our revenue and customer base~~; ● the ~~announcement or the market introduction of new products or product enhancements by us or our competitors; ● the~~ trading volume of our common stock ~~; ● developments concerning regulatory oversight and approvals~~; ● variations in our and our competitors' results of operations; ● changes in earnings estimates or recommendations by securities analysts, if our common stock is covered by analysts; ● successes or challenges in our collaborative arrangements or alternative funding sources; ● ~~developments in the health care and life science industries; ● the results of product liability or intellectual property lawsuits; ●~~ adverse effects on our business condition and results of operations from general economic and market conditions and overall fluctuations in the United States and international markets, including deteriorating market conditions due to investor concerns regarding inflation ~~and Russia' s war on Ukraine~~; ● adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions that could adversely affect our business, financial condition or results of ~~operations; ● the continued impact of the COVID- 19 pandemic on our business and~~ operations; ● future issuances of common stock or other securities; ● the addition or departure of key personnel; ● announcements by us or our competitors of acquisitions, investments or strategic alliances; and ● general market conditions and other factors, including factors unrelated to our operating performance. Further, the stock market in general, and the market for health care and life sciences companies in particular, has recently experienced extreme price and volume fluctuations. The volatility of our common stock is further exacerbated due to its low trading volume. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock and the loss of some or all of your investment. Trading of our common stock is limited, and trading restrictions imposed on us by applicable regulations may further reduce trading in our common stock, making it difficult for our stockholders to sell their shares; and future sales of common stock could reduce our stock price. Trading of our common stock is currently conducted on the NASDAQ Capital Market. The liquidity of our common stock is limited, including in terms of the number of shares that can be bought and sold at a given price and reduction in security analysts' and the media' s coverage of us, if any. These factors may result in different prices for our common stock than might otherwise be obtained in a more liquid market and could also result in a larger spread between the bid and ~~asked~~ -- **ask** prices for our common stock. In addition, in the absence of a large market capitalization, our common stock is less liquid than the stock of companies with broader public ownership, and, as a result, the trading prices of our common stock may be more volatile. In the absence of an active public trading market, an investor may be unable to liquidate his **or her** investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock. We cannot predict the prices at which our common stock will trade in the future, if at all. The exercise of outstanding common stock purchase warrants and stock options will have a dilutive effect on the percentage ownership of our capital stock by existing stockholders. As of December 31, ~~2022~~ **2023**, we had outstanding warrants to acquire 1, ~~291~~ **095**, ~~213~~ **517** shares of our common stock, and stock options to purchase ~~107~~ **9**, ~~597~~ **624** shares of our common stock. A significant number of such warrants have exercise prices above our common stock' s recent trading prices, but the holders have the right to effect a cashless exercise of such warrants. If a significant number of such warrants and stock options are exercised by the holders, the percentage of our common stock owned by our existing stockholders will be diluted. We have never paid dividends on our capital stock, and we do not anticipate paying dividends in the foreseeable future. We have never paid dividends on any of our capital stock and currently intend to retain any future earnings to fund the growth of our business. We may also enter into credit agreements or other borrowing arrangements in the future that will restrict our ability to declare or pay cash dividends on our common stock. ~~For example, our loan agreement with the European Investment Bank (EIB) restricts our ability to declare or pay dividends.~~ Any determination to pay dividends in the future will be at the discretion of our ~~board~~ **Board** of ~~directors~~ **Directors** and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our ~~board~~ **Board** of ~~directors~~ **Directors** may deem relevant. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for the foreseeable future. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, instability in inflation in U. S. and foreign markets, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ~~conflict~~ **conflicts** between Russia and Ukraine **and Israel and Hamas**, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts ~~, including Russia' s war on Ukraine,~~ may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, including instability in inflation. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance **,** and stock price ~~and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, distributors, manufacturers, and other partners may not survive an economic downturn or could be adversely affected by geopolitical events, such as the war in~~

Ukraine, which could directly affect our ability to attain our operating goals on schedule and on budget. A large base of individual stockholders may make it difficult for us to take action on certain corporate transactions and matters, which may limit the ability of the Company to enter into certain transaction. We believe that we currently have a large base of individual stockholders instead of institutional investors. Procuring the vote of such stockholders in connection with certain corporate transactions and matters is difficult, time consuming and expensive. For example, in connection with the Company' s 2021 and 2022 Annual Meetings of stockholders, despite extensive efforts by the Company, we were unable to receive votes from a sufficient portion of our outstanding shares of common stock required to approve certain proposals submitted at such meeting. We expect that we may continue to need stockholder approval of additional matters in the future, including, in connection with, amendments to the Company' s amended and restated certificate of incorporation, as amended, and for certain other corporate transactions. If we are unable to obtain the requisite vote due to stockholder disinterest and apathy for engaging in corporate governance of the Company, we may be unable to take certain actions, which could prevent or limit our ability to further finance the Company in the future or enter into certain transactions. Short sellers of our stock may be manipulative and may drive down the market price of our common stock. Short selling is the practice of selling securities that a seller does not own but rather has borrowed, or intends to borrow, from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller' s interest for the price of the stock to decline, some short sellers publish, or arrange for the publication of, opinions or characterizations regarding the relevant issuer, its business prospects and similar matters calculated to or which may create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the securities short. The use of the Internet, social media, and blogging have allowed short sellers to publicly attack a company' s credibility, strategy and veracity by means of so- called " research reports " that mimic the type of investment analysis performed by legitimate securities research analysts. Issuers with substantial retail stockholder bases can be particularly susceptible to higher volatility levels, and can be particularly vulnerable to such short attacks. While we intend to strongly defend our public filings against any such short seller attacks, in many situations we could be constrained, for example, by principles of freedom of speech, applicable state law or issues of commercial confidentiality, in the manner in which we are able to proceed against the relevant short seller. Such short- seller attacks may cause, temporary or possibly long term, declines in the market price of our common stock . We may be subject to litigation or government investigations for a variety of claims, which could adversely affect our operating results, harm our reputation , or otherwise negatively impact our business. We may be subject to litigation or government investigations. These may include claims, lawsuits, and proceedings involving securities laws, fraud and abuse, healthcare compliance, product liability, labor and employment, wage and hour, commercial and other matters. Any such litigation or investigations could result in substantial costs and a diversion of management' s resources and attention. In addition, any adverse determination could expose us to significant liabilities, which could have a material adverse effect on our business, financial condition, and results of operations. Risks Related to Regulation of Our Business There is no guarantee that the FDA will grant De Novo classification requests, 510 (k) clearance or PMA approval of our products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business. We have received 510 (k) clearance from the FDA for our Acuitas AMR Gene Panel test as well as FDA clearances for Unyvero LRT and LRT- BAL in the past. We have plans to submit additional De Novo classification requests for our Unyvero UTI test and our Unyvero IJI test in the future. Such process is complex, time consuming and expensive. For any filed 510 (k) or De Novo submission, the FDA may not clear or grant these products for the indications that are necessary or desirable for successful commercialization. Failure to receive, or a significant delay in receiving, a required clearance or granted request for our products would have a material adverse effect on our ability to expand our business. We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or " off- label " uses. We are currently offering for sale some RUO products to labs, CROs, diagnostics, pharmaceutical and biotech companies, hospitals and other healthcare facilities. We believe that our promotional activities for these products falls within the scope of the FDA' s enforcement discretion and applicable premarket exemptions. However, the FDA could disagree and require us to stop promoting our products for unapproved or " off- label " uses unless and until we obtain FDA clearance or approval for those uses. We could be subject to regulatory or enforcement actions for any violations, including, but not limited to, the issuance of an untitled letter, a Form 483 letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged, and adoption of the products would be impaired. A number of our rapid diagnostic products are regulated by the FDA and non- U. S. regulatory authorities. If we or our suppliers fail to comply with ongoing FDA, or other foreign regulatory authority, requirements, or if we experience unanticipated problems with the products, these products could be subject to restrictions or withdrawal from the market. We have limited experience in complying with the rules and regulations of the FDA and foreign regulatory authorities. The rapid diagnostic products regulated as medical devices, and the manufacturing processes, reporting requirements, post- approval clinical data and promotional activities for such products, are subject to continued regulatory review, oversight and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA' s Quality System Regulations (QSR) for the manufacture, labeling, distribution and promotion of products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval, and with ISO regulations. The FDA enforces the QSR and similarly, other regulatory bodies with similar regulations enforce those regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory

bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions against us: (1) untitled letters, Form 483 observations, warning letters, fines, injunctions, consent decrees and civil penalties; (2) unanticipated expenditures to address or defend such actions; (3) customer notifications for repair, replacement and refunds; (4) recall, detention or seizure of our products; (5) operating restrictions or partial suspension or total shutdown of production; (6) refusing or delaying our requests for De Novo classification, 510 (k) clearance or premarket approval (PMA) of new products or modified products; (7) operating restrictions; (8) withdrawing granted De Novo classifications, 510 (k) clearances or PMAs that have already been granted; (9) refusal to grant export approval for our products; or (10) criminal prosecution. If any of these actions were to occur, it could harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, if any of our key component suppliers are not in compliance with all applicable regulatory requirements, we may be unable to produce our products on a timely basis and in the required quantities, if at all. We and our suppliers are also subject to periodic inspections by the FDA to determine compliance with the FDA' s requirements, including primarily the QSR and medical device reporting regulations. The results of these inspections can include inspectional observations on FDA' s Form 483, untitled letters, warning letters, or other forms of enforcement. Since 2009, the FDA has significantly increased its oversight of companies subject to its regulations, by hiring new investigators and stepping up inspections of manufacturing facilities. The FDA has recently also significantly increased the number of warning letters issued to companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our FDA- cleared products are ineffective or pose an unreasonable health risk, the FDA could take a number of regulatory actions, including but not limited to, preventing us from manufacturing any or all of our devices or performing laboratory testing on human specimens, which could materially adversely affect our business. Some of the clearances obtained are subject to limitations on the intended uses for which the product may be marketed, which can reduce our potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In addition, we may be required to conduct costly post- market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects. If we were to lose, or have restrictions imposed on, FDA clearances received to date, or clearances we may receive in the future, our business, operations, financial condition and results of operations would likely be significantly adversely affected. Modifications to our marketed products may require new 510 (k) clearances, De Novo classifications or PMAs or, in the future, new CE- IVD markings that comply with the EU Regulation on In Vitro Diagnostic Medical Devices (IVDR), or may require us to cease marketing or recall the modified products until clearances or approvals are obtained. If we modify any of our CE- IVD marked or FDA- cleared products, such modifications may require additional future approvals and filings, e. g., notified body authorization or FDA clearance. Modifications to a CE- IVD marked or 510 (k)- cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, may require additional approvals or filings or a new or revised 510 (k) submission, or possibly, a PMA or new IVDR compliant product authorization. The FDA and other regulatory authorities, including notified bodies, require every medical device manufacturer to make this determination, with the potential for the regulatory authorities to impose additional requirements. The applicable regulatory authority nevertheless maintains the right to disagree with a company' s decisions regarding whether new clearances or approvals are necessary. If the FDA or any other relevant regulatory authority requires us to submit additional filings, such as a technical file review and CE- marking under new IVDR, 510 (k) submission, or file a De Novo classification request or a PMA, for any modification to a previously cleared product, we may be required to cease marketing and distributing, or to recall the modified product until we obtain such clearance or approval, and we may be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to recall if the FDA or any other relevant regulatory authority determines, for any reason, that our products are not safe or effective. A mandate for a recall or correction, or where new or revised regulatory submissions are required, could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA or other relevant regulatory agencies in other territories. New or revised regulatory requirements may require us to cease marketing or recall the modified products until clearances or approvals are obtained. In 2017, the EU Regulation on In Vitro Diagnostic Medical Devices (Regulation (EU) 2017 / 746) was adopted. The IVDR became effective in May 2022, subject to certain extended transition periods for existing CE- IVD- marked products until the 2025 to 2027 time frame, and is, among other things, intended to establish a uniform, transparent, predictable and sustainable regulatory framework across European Economic Area. The IVDR introduced new classification rules for in vitro diagnostic medical devices and new regulatory requirements. Moreover, the scrutiny imposed by notified bodies for the technical documentation related to these devices will increase considerably. Complying with the requirements of this regulation may result in the reclassification of existing CE- IVD- marked products and will require filings with and recognition by the notified body or competent authority latest by the time the applicable extended transition period has

expired. Additional filings and or modifications to products to comply with the IVDR could result in significant delays, increased costs associated with modification of a product, loss of revenue and other significant expenditures. Our products may in the future be subject to product recalls that could harm our reputation, business and financial results. The FDA and similar foreign governmental authorities have the authority to require the recall of regulated products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. If our products cause or contribute to a death or a serious injury, or malfunction in certain ways, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Under the FDA and international medical device reporting regulations, medical device manufacturers are required to report to the applicable regulatory authority information that a device has, or may have, caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to death or serious injury if the malfunction of the device or one of our similar devices were to recur. If we fail to report these events within the required timeframes, or at all, the regulatory authorities could take enforcement action against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. We may generate a larger portion of our future revenue internationally and would then be subject to increased risks relating to international activities, which could adversely affect our operating results. A significant portion of our current revenue and anticipated future revenue growth will come from international sources as we implement and expand overseas operations. Engaging in international business involves a number of difficulties and risks, including: ● required compliance with existing and changing foreign health care and other regulatory requirements and laws, such as those relating to patient privacy; ● required compliance with anti- bribery laws, such as the U. S. Foreign Corrupt Practices Act, or FCPA, data privacy requirements, labor laws and anti- competition regulations; ● export or import restrictions; ● various reimbursement and insurance regimes; ● laws and business practices favoring local companies; ● longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; ● political and economic instability; ● potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers; ● foreign exchange controls; ● difficulties and costs of staffing and managing foreign operations; and ● difficulties protecting or procuring intellectual property rights. As we expand internationally, our results of operations and cash flows would become increasingly subject to fluctuations due to changes in foreign currency exchange rates. Our expenses are generally denominated in the currencies in which our operations are located, which is in the United States, Germany, and Austria. If the value of the U. S. dollar increases relative to foreign currencies in the future, in the absence of a corresponding change in local currency prices, our future revenue could be adversely affected as we convert future revenue from local currencies to U. S. dollars. Conversely, a weakening of the value of the U. S. dollar relative to foreign currencies would make our operations in Germany and Austria which operate in euros relatively more expensive. If we dedicate resources to our international operations and are unable to manage these risks effectively, our business, operating results and prospects will suffer. We face the risk of potential liability under the FCPA for past international distributions of products and to the extent we distribute products or otherwise operate internationally in the future. In the past, we have distributed certain of our products internationally, and in the future, we will distribute our products internationally and possibly engage in additional international operations. The FCPA prohibits companies such as us from engaging, directly or indirectly, in making payments to foreign government and political officials for the purpose of obtaining or retaining business or securing any other improper advantage, including, among other things, the distribution of products and other international business operations. We currently dedicate certain resources to comply with the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. Like other U. S. companies operating abroad, we may face liability under the FCPA if we, or third parties we have used to distribute our products or otherwise advance our international business, have violated the FCPA or any of the relevant international equivalents. Any violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition or results of operations. We could also suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures. Risks Related to Compliance with Healthcare and Regulations Changes in healthcare policy, including legislation reforming the U. S. healthcare system, may have a material adverse effect on our financial condition and operations. In March 2010, both the Patient Protection and Affordable Care Act, or Affordable Care Act, and the reconciliation law known as Health Care and Education Reconciliation Act, with the Affordable Care Act, the 2010 Health Care Reform Legislation, were enacted. The constitutionality of the 2010 Health Care Reform Legislation was confirmed twice by the Supreme Court of the United States. The 2010 Health Care Reform

Legislation has changed the existing state of the health care system by expanding coverage through voluntary state Medicaid expansion, attracting previously uninsured persons through the health care insurance exchanges and by modifying the methodology for reimbursing medical services, drugs and devices. The U. S. Congress is seeking to replace the 2010 Health Care Reform Legislation. At this time, the Company is not certain as to the impact of federal health care legislation on its business. The 2010 Health Care Reform Legislation includes the Open Payments Act (formerly referred to as the Physician Payments Sunshine Act), which, in conjunction with its implementing regulations, requires manufacturers of certain drugs, biologies, and devices that are reimbursed by Medicare, Medicaid and the Children' s Health Insurance Program to report annually certain payments or " transfers of value " provided to physicians and teaching hospitals and to report annually ownership and investment interests held by physicians and their immediate family members during the preceding calendar year. Recent amendments to the Open Payments Act expand the categories of health care providers for which reporting is required. The failure to report appropriate data accurately, timely, and completely could subject us to significant financial penalties. Other countries and several states currently have similar laws and more may enact similar legislation. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any changes in government regulation of the United States healthcare industry may result in decreased profits to us, which may adversely affect our business, financial condition and results of operations. We are subject to potential enforcement actions involving false claims, kickbacks, physician self- referral or other federal or state fraud and abuse laws, and we could incur significant civil and criminal sanctions, which would hurt our business. The government has made enforcement of the false claims, anti- kickback, physician self- referral and various other fraud and abuse laws a major priority. In many instances, private whistleblowers also are authorized to enforce these laws even if government authorities choose not to do so. In most of these cases, private whistleblowers brought the allegations to the attention of federal enforcement agencies. The risk of our being found in violation of these laws and regulations is increased by the fact that some of the laws and regulations have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We could be subject to enforcement actions under the following laws: ● the federal Anti- Kickback Statute, which constrains certain marketing practices, educational programs, pricing policies and relationships with healthcare providers or other entities by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; ● federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third- party payors that are false or fraudulent; ● federal physician self- referral laws, such as the Stark Law, which prohibit a physician from making a referral to a provider of certain health services with which the physician or the physician' s family member has a financial interest, and prohibit submission of a claim for reimbursement pursuant to a prohibited referral; and ● state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. If we or our operations are found to be in violation of any of these laws and regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U. S. federal or state healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We will monitor changes in government enforcement as we grow and expand our business. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management' s attention from the operation of our business and hurt our reputation. If we were excluded from participation in U. S. federal healthcare programs, we would not be able to receive, or to sell our tests to other parties who receive reimbursement from Medicare, Medicaid and other federal programs, and that could have a material adverse effect on our business. Risks Related to Our Intellectual Property If we cannot license rights to use technologies on reasonable terms, we may not be able to commercialize new products in the future. In the future, we may license third- party technology to develop or commercialize new products. In return for the use of a third party' s technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of cost of services and affect the margins on our products. We may also need to negotiate licenses to patents and patent applications after introducing a commercial product. Our business may suffer if we are unable to enter into the necessary licenses on acceptable terms, or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the license or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable. If we are unable to protect our intellectual property effectively, our business would be harmed. We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us and we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate, however 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 potentially relevant jurisdictions. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable products, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our current or future patented technologies. We may not be successful in defending any challenges made against our patents or patent applications. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. The outcome of patent litigation can

be uncertain and any attempt by us to enforce our patent rights against others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business. The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the biotechnology field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA. In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests, like ours, are particularly uncertain. Various courts, including the U. S. Supreme Court, have recently rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests and related methods. These decisions state, among other things, that patent claims that recite laws of nature (for example, the relationship between blood levels of certain metabolites and the likelihood that a dosage of a specific drug will be ineffective or cause harm) are not themselves patentable. What constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third- party challenges to any owned and licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. We may not develop additional proprietary products, methods and technologies that are patentable. In addition to pursuing patents on our technology, we take steps to protect our intellectual property and proprietary technology by entering into agreements, including confidentiality agreements, non- disclosure agreements and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. We may also be subject to claims that our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of third parties, or to claims that we have improperly used or obtained such trade secrets. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and face increased competition to our business. A loss of key research personnel work product could hamper or prevent our ability to commercialize potential products, which could harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Further, competitors could attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. Others may independently develop similar or alternative products and technologies or replicate any of our products and technologies. 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. We have not yet registered certain of our trademarks in all of our potential markets. If we apply to register these trademarks, our applications may not be allowed for registration in a timely fashion or at all, and our registered trademarks may not be maintained or enforced. In addition, opposition or cancellation proceedings may be filed against our trademark applications and registrations, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. 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 direct competition. If our intellectual property does not provide adequate coverage of our competitors' products, our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time consuming and expensive. We may be involved in litigation related to intellectual property, which could be time- intensive and costly and may adversely affect our business, operating results or financial condition. We may receive notices of claims of direct or indirect infringement or misappropriation or misuse of other parties' proprietary rights from time to time. Some of these claims may lead to litigation. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third- party trade secrets, infringement by us of third- party patents and trademarks or other rights, or the validity of our patents, trademarks or other rights, will not be asserted or prosecuted against us. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we may have to participate in interference proceedings, derivation proceedings, or other post- grant proceedings declared by the United States Patent and Trademark Office that could result in substantial cost to us. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, recent changes to the patent laws of the United States allow for various post- grant opposition proceedings that have not been extensively tested, and

their outcome is therefore uncertain. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction. Litigation may be necessary for us to enforce our patent 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. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In addition, if we resort to legal proceedings to enforce our intellectual property rights or to determine the validity, scope and coverage of the intellectual property or other proprietary rights of others, the proceedings could be burdensome and expensive, even if we were to prevail. 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, operating results or financial condition. As we move into new markets and applications for our products, incumbent participants in such markets may assert their patents and other proprietary rights against us as a means of slowing our entry into such markets or as a means to extract substantial license and royalty payments from us. Our competitors and others may now and, in the future, have significantly larger and more mature patent portfolios than we currently have. In addition, future litigation may involve patent holding companies or other adverse patent owners who have no relevant product revenue and against whom our own patents may provide little or no deterrence or protection. Therefore, our commercial success may depend in part on our non- infringement of the patents or proprietary rights of third parties. Numerous significant intellectual property issues have been litigated, and will likely continue to be litigated, between existing and new participants in our existing and targeted markets and competitors may assert that our products infringe their intellectual property rights as part of a business strategy to impede our successful entry into or growth in those markets. Third parties may assert that we are employing their proprietary technology without authorization. In addition, our competitors and others may have patents or may in the future obtain patents and claim that making, having made, using, selling, offering to sell or importing our products infringes these patents. We could incur substantial costs and divert the attention of our management and technical personnel in defending against any of these claims. Parties making claims against us may be able to obtain injunctive or other relief, which could block our ability to develop, commercialize and sell products, and could result in the award of substantial damages against us. In the event of a successful claim of infringement against us, we may be required to pay damages and ongoing royalties, and obtain one or more licenses from third parties, or be prohibited from selling certain products. We may not be able to obtain these licenses on acceptable terms, if at all. We could incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our financial results. In addition, we could encounter delays in product introductions while we attempt to develop alternative methods or products to avoid infringing third- party patents or proprietary rights. Defense of any lawsuit or failure to obtain any of these licenses could prevent us from commercializing products, and the prohibition of sale of any of our products could materially affect our business and our ability to gain market acceptance for our products. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. In addition, our agreements with some of our customers, suppliers or other entities with whom we do business require us to defend or indemnify these parties to the extent they become involved in infringement claims, including the types of claims described above. We could also voluntarily agree to defend or indemnify third parties in instances where we are not obligated to do so if we determine it would be important to our business relationships. If we are required or agree to defend or indemnify third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, operating results, or financial condition. The COVID- 19 pandemic has, and other similar pandemic events may, adversely impact our business, financial condition and results of operations. The COVID- 19 pandemic and more recently possible endemic has continued to impact the global economy and has impacted our operations in the United States and abroad (including, in particular, China), including by negatively impacting our sales and revenue. As a result, we have implemented certain operational changes in order to address the evolving challenges presented by the global pandemic. We have experienced significant reductions in the demand for certain of our products, particularly due to the decline in elective medical procedures and medical treatment unrelated to COVID- 19, which negatively impacted our revenues in fiscal years 2020 and 2021 as well as into 2022. As the COVID- 19 pandemic or endemic continues, we expect to continue to experience weakened demand for these products as a result of the reduction in elective and nonessential procedures, lower utilization of routine testing and related specimen collection, reduced spending by customers due to funding diverted to fight COVID- 19 and reduced demand from research laboratories and staffing shortages with many hospitals and labs as well as our own personnel. Healthcare providers, including our strategic partners worldwide, spend significant time dealing with COVID- 19, and may be unable to initiate or continue to participate in our clinical activities. For example, some clinical trial sites, most notably in China, have imposed and continue to maintain restrictions on site visits by sponsors and CROs, the initiation of new or execution of ongoing trials, and new patient enrollment to protect both site staff and patients from possible COVID- 19 exposure and to focus medical resources on patients suffering from COVID- 19. The COVID- 19 pandemic may therefore delay initiation enrollment in and completion of our clinical trials due to prioritization of hospital resources toward the outbreak, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Moreover, due to site and participant availability during the COVID- 19 pandemic and in the interest of patient safety, many of our partners had paused new subject enrollment for most clinical trials during the earlier phase of the COVID- 19 pandemic and might do so again. For ongoing and / or planned future trials, we have seen an increasing number of clinical trial sites imposing restrictions on patient visits to limit risks of possible COVID- 19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines,

travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID- 19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies, such as the supplemental clinical study in China. Further, health regulatory agencies globally may also experience disruptions in their operations as a result of the COVID- 19 pandemic. The FDA and comparable foreign regulatory agencies have had and may continue to have slower response times or be under- resourced, which could significantly delay the FDA' s ability to timely review and process any submissions we or our partners have filed or may file. The FDA in 2021 notified us that the agency would continue prioritizing emergency use authorization requests for diagnostic products intended to address the COVID- 19 pandemic during 2021. Due to delays from such prioritization, we only received a clearance decision on our Acuitas AMR Gene Panel on September 30, 2021, which was originally targeted for a decision by mid- 2020, and, more recently, we did not receive responses to our requests for pre- submission meetings for our other products. As a result of the outbreak, we and certain of our suppliers may also be affected and could experience closures and labor shortages, which could disrupt activities. We could therefore face difficulty sourcing key components necessary to produce our product candidates, which may negatively affect our clinical development activities. Even if we are able to find alternate sources for some of these components, they may cost more, which could affect our results of operations and financial position. At this point in time, there remains significant uncertainty relating to the potential effect of the coronavirus on our business and results of operations. As coronavirus and its mutations become endemic, it could have a continued negative impact on our ability to operate our business, financial condition and results of operations as well as virtual marketing, sales and customer service interactions not being as effective as in- person interactions. While several vaccines have been approved for use, and with vaccination programs successfully implemented in many countries, the limited acceptance of vaccination by many individuals in the United States as well as in Europe and globally, and potential failure to be effective for all known mutations of the SARS- CoV- 2 virus still makes it hard to predict if and when the COVID- 19 pandemic will subside and remain endemic. Moreover, we have continued to have a subset of our office- based employee population in a remote work environment in an effort to mitigate the spread of COVID- 19, which may exacerbate certain risks to our business, including cybersecurity attacks and risk of phishing due to an increase in the number of points of potential attack, such as laptops and mobile devices (both of which are now being used in increased numbers). Customer demand for and our ability to sell and market our products may be adversely affected by the COVID- 19 pandemic and the legislative and regulatory responses thereto. U. S. state and local governments as well as many governments around the world had imposed orders, restrictions and recommendations resulting in closures of businesses, work stoppages, travel restrictions, quarantine orders, social distancing practices and cancellations of gatherings and events. Such orders, restrictions and recommendations, combined with fears of the spreading of COVID- 19, had and may continue to cause certain of our customers to delay, cancel or reduce orders of our products and makes it difficult to facilitate meetings with current and potential customers, as our sales personnel often rely on in- person meetings and interaction with our customers. COVID- 19 related restrictions have thus harmed our sales efforts, and continued restrictions could continue to have a negative impact on our sales and results of operations. We are unable to accurately predict how these factors will reduce our sales going forward and when these orders, restrictions and recommendations will be relaxed or lifted. There can be no assurances that our customers and distributors will resume purchases of our products upon termination of these governmental orders, restrictions and recommendations, particularly if there remains any continued community outbreak of COVID- 19. A prolonged economic contraction or recession may also result in our customers seeking to reduce their costs and expenditures, which could result in lower demand for our products. If our sales decline, or if such lost sales are not recoverable in the future, our revenues, business and results of operations will be significantly adversely affected. General Risk Factors We are dependent on the services of our management and other key personnel and members of our board of directors, and if we are not able to retain these individuals or recruit additional management, our business will suffer. Our success depends in part on our continued ability to attract, retain, manage and motivate highly qualified management and other key personnel. We are highly dependent upon our senior management and other members of our management team. The loss of services of any of these individuals could cause the loss of critical Company knowledge and information, delay or prevent the successful development of our products, initiation or completion of our preclinical studies and clinical trials or the commercialization of our products. Although we have executed employment agreements or offer letters with each member of our senior management team, we may not be able to retain their services as expected. We do not currently maintain " key person " life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. Adverse developments affecting the financial services industry, including events or concerns involving liquidity, defaults or non- performance by financial institutions, could adversely affect our business, financial condition or results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future adversely affect our liquidity. For example, on March 10, 2023, the Federal Deposit Insurance Corporation (" FDIC ") announced that Silicon Valley Bank had been closed by the California Department of Financial Protection and Innovation. At that time, most of our cash and cash equivalents were held at Silicon

Valley Bank and our access to such funds was limited until the United States Department of the Treasury announced in a joint statement with the Federal Reserve and FDIC that depositors of Silicon Valley Bank would have access to all of their money starting March 13, 2023. While we have regained access to our funds at Silicon Valley Bank and are evaluating our banking relationships, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by events such as liquidity constraints or failures, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors may also adversely affect our ability to access our cash and cash equivalents at affected financial institutions. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on terms favorable to us, or at all. Any decline in available funding or access to our cash and liquidity resources could, among other things, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our business, financial condition or results of operations. Fluctuations in exchange rates could result in foreign currency exchange losses, which may adversely affect our financial condition, results of operations and cash flows. We incur portions of our expenses and derive portions of our revenues in currencies other than U. S. dollars, in particular, the Euro. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. For example, while our U. S. operations use U. S. dollars, our foreign operations use Euros. In addition, depending on the jurisdiction, we may pay suppliers in either U. S. dollars or Euros. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U. S. dollar. An increase in the value of the U. S. dollar against currencies in countries in which we conduct business could have a negative impact on our operating and research and development costs. The value of the Euro against the U. S. dollar and other currencies may fluctuate and is affected by, among other things, changes in political and economic conditions. Generally, to the extent that we need to convert U. S. dollars into Euro for our operations, appreciation of the Euro against the U. S. dollar would have an adverse effect on the Euro amount we would receive. Conversely, if we decide to convert our Euro into U. S. dollars for other business purposes, appreciation of the U. S. dollar against the Euro would have a negative effect on the U. S. dollar amount we would receive. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows. Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employee benefits liability, property, umbrella, business interruption, workers' compensation, product liability, errors and omissions, cybersecurity, and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. While we currently qualify as a smaller reporting company under SEC regulations, we cannot be certain whether taking advantage of the reduced disclosure requirements applicable to these companies will not make our common stock less attractive to investors. Once we lose smaller reporting company status, the costs and demands placed upon our management are expected to increase. The SEC' s rules permit smaller reporting companies to take advantage of certain exemptions from various reporting requirements applicable to other public companies. As long as we qualify as a smaller reporting company, based on our public float, and report less than $ 100 million in annual revenues in a fiscal year we are permitted, and we intend to, omit the auditor' s attestation on internal control over financial reporting that would otherwise be required by the Sarbanes- Oxley Act. We lost our status as an emerging growth company as of December 31, 2020. While we expect to remain a smaller reporting company and non- accelerated filer, we now face increased disclosure requirements as a non- emerging growth company, such as stockholder advisory votes on executive compensation (" say- on- pay "). Until such time that we lose smaller reporting company status, it is unclear if investors will find our common stock less attractive because we may rely on certain disclosure exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and could cause our stock price to decline. As a result of the loss of our emerging growth company status, we expect the costs and demands placed upon our management to increase, as we now have to comply with additional disclosure and accounting requirements. In addition, even if we remain a smaller reporting company, if our public float exceeds $ 75 million and we report $ 100 million or more in annual revenues in a fiscal year, we will become subject to the provisions of Section 404 (b) of the Sarbanes- Oxley Act requiring an independent registered public accounting firm to provide an attestation report on the effectiveness of our internal control over financial reporting, making the public reporting process more costly. We incur increased costs and demands on management as a result of compliance with laws and regulations applicable to public companies, which could harm our operating results. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. In addition, the Sarbanes- Oxley Act of 2002 and the Dodd- Frank Act of 2010, as well as rules implemented by the SEC and the Nasdaq Stock Market, impose a number of requirements on public companies, including with respect to corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance and disclosure obligations. Moreover, compliance with these rules and regulations has increased our legal, accounting and financial compliance costs and has made some activities more time- consuming and costly. It is also more expensive for us to obtain director and officer liability insurance. We may be adversely affected by the current economic environment and future adverse economic environments. Our ability to attract and retain

customers, invest in and grow our business and meet our financial obligations depends on our operating and financial performance, which, in turn, is subject to numerous factors, including the prevailing economic conditions and financial, business and other factors beyond our control, such as the rate of unemployment, the number of uninsured persons in the United States and continued high inflationary pressures. We cannot anticipate all the ways in which the current economic climate and financial market conditions, and those in the future, could adversely impact our business. We are exposed to risks associated with reduced profitability and the potential financial instability of our customers, many of which may be adversely affected by volatile conditions in the financial markets. For example, unemployment and underemployment, and the resultant loss of insurance, may decrease the demand for healthcare services and diagnostic testing. If fewer patients are seeking medical care because they do not have insurance coverage, we may experience reductions in revenues, profitability and / or cash flow. In addition, if economic challenges in the United States result in widespread and prolonged unemployment, either regionally or on a national basis, a substantial number of people may become uninsured or underinsured. To the extent such economic challenges result in less demand for our proprietary tests, our business, results of operations, financial condition and cash flows could be adversely affected. Also, inflationary pressures remain high, we are experiencing increases in operating costs, materials, and shipping expenses. If we are unable to pass these increased costs through to our customers, we may experience reductions in margin. The Company' s certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between the Company and its stockholders, which could limit its stockholders' ability to obtain a favorable judicial forum for disputes with the Company or its directors, officers or other employees. The Company' s Amended and Restated Certificate of Incorporation, as amended (the " Certificate "), provides that, unless the Company consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Company or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or the Company' s Certificate or Bylaws, or (iv) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision is intended to apply to claims arising under Delaware state law and would not apply to claims brought pursuant to the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction. The exclusive forum provision in the Company' s Certificate will not relieve the Company of its duties to comply with the federal securities laws and the rules and regulations thereunder, and stockholders of the Company will not be deemed to have waived the Company' s compliance with these laws, rules and regulations. This exclusive forum provision may limit a stockholder' s ability to bring a claim in a judicial forum of its choosing for disputes with the Company or its directors, officers or other employees, which may discourage lawsuits against the Company and its directors, officers and other employees. In addition, stockholders who do bring a claim in the Court of Chancery of the State of Delaware could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near Delaware. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder would otherwise choose to bring the action, and such judgments or results may be more favorable to the Company than to its stockholders. However, the enforceability of similar exclusive forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings. If a court were to find the exclusive forum provision contained in the Company' s Certificate to be inapplicable or unenforceable in an action, the Company might incur additional costs associated with resolving such action in other jurisdictions.