Risk Factors Comparison 2024-03-29 to 2023-03-30 Form: 10-K

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The following risks and uncertainties, together with all other information in this Annual Report on Form 10- K, including our consolidated financial statements and related notes, should be considered carefully. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline. Summary of Risk Factors ● There is substantial doubt about our ability to continue as a going concern. ● We may require significant additional financing to sustain our operations and without it we will not be able to continue operations. ● We may need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations. ● We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability. ● We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable. ● We have been, and may continue to be, subject to costly litigation. ● The commercial success of our products, including those we are developing, will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our products. ● If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability. ● We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results. ● ~~We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID- 19, which could significantly disrupt our operations and impact our financial results. ●~~ International expansion of our business could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. ● Unfavorable U. S. or global economic conditions **and conflicts** could adversely affect our business, financial condition or results of operations. ● Global climate change could negatively affect our business. ● We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted. ● We will need to increase the size of our organization, and we may experience difficulties in managing growth. ● We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue. ● Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer. ● Our ability to use net operating loss carryforwards to offset future taxable income for U. S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses. ● The testing, manufacturing and marketing of diagnostics entails an inherent risk of product liability and personal injury claims. ● All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man- made or natural disaster, our operations could be severely impaired. ● An impairment in the carrying value of our intangible assets could negatively affect our results of operations. ~~14~~ ● Governmental payers and health care plans have taken steps to control costs. ● Changes in payer mix could have a material adverse impact on our net sales and profitability. ● Our laboratories require ongoing CLIA certification and we cannot guarantee that our laboratories will pass all future certification inspections. ● Our products that we sell as research use only products and / or that we offer as laboratory developed tests could become subject to government regulations requiring marketing authorization, and the marketing authorization and maintenance process for such products may be expensive, time- consuming and uncertain in both timing and outcome. ● Failure to comply with HIPAA could be costly. ● Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations. ● We may become subject to the Anti- Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws. ● We cannot be certain that measures taken to protect our intellectual property will be effective. ● The price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock. ● The price of our stock may be vulnerable to manipulation. ● If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities. ● Increased costs associated with corporate governance compliance may significantly impact our results of operations. ● We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock. ● If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. ● The sale or issuance of our common stock to Alliance Global Partners may cause significant dilution and the sale of the shares of common stock acquired by Alliance Global Partners, or the perception that such sales may occur, could cause the price of our common stock to fall. ● The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall. Risks Related to Our Business and StrategyThere is substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has issued an opinion on our consolidated financial statements included in this Annual Report on Form 10- K

that states that the consolidated financial statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and ~~have~~ **15have** used cash in our operating activities for the past few years. For the year ended December 31, ~~2022~~ **2023**, the Company had a net loss of $ ~~12~~ **5**. ~~2~~ **8** million and net cash used in operating activities of $ ~~7~~ **3**. ~~7~~ **6** million. As of December 31, ~~2022~~ **2023**, the Company had an accumulated deficit of $ ~~92~~ **98**. ~~3~~ **2** million and working capital of $ ~~1~~ **0**. ~~3~~ **5** million. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot be certain that additional financing, if needed, will be available on ~~15acceptable~~ -- **acceptable** terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations. There remains substantial doubt about the Company' s ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued. To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur net losses through at least ~~2023~~ **2024** as we further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will ~~continue to~~ increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability. Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail. We may require significant additional financing to sustain our operations and without it we will not be able to continue operations. At December 31, ~~2022~~ **2023**, we had working capital of $ ~~1~~ **0**. ~~3~~ **5** million. For the year ended December 31, ~~2022~~ **2023**, we had an operating cash flow deficit of $ ~~7~~ **3**. ~~7~~ **6** million and a net loss of $ ~~12~~ **5**. ~~2~~ **8** million. We do not currently have sufficient financial resources to fund our operations or those of our subsidiaries. Therefore, we need additional funds to continue these operations. Our primary sources of funds to meet our liquidity and capital requirements include cash on hand, funds generated from operations, funding pursuant to a sales agreement with A. G. P. / Alliance Global Partners (" AGP ") and possible sales of certain receivables under our receivable factoring agreement. To facilitate ongoing operations and product development, on April ~~2~~ **14**, ~~2021~~ **2023**, **we** ~~the Company~~ entered into a sales agreement with AGP, pursuant to which we may offer and sell our common stock, par value $ 0. 01 per share (the " Common Stock ") (the " Shares "), having aggregate sales proceeds of up to $ ~~22~~ **5**. ~~0~~ **8** million, to or through AGP, as sales agent (the " AGP **2023** Sales Agreement "), from time to time, in an " at the market offering " (as defined in Rule 415 (a) (4) under the Securities Act of 1933, as amended) of the Shares (the " **2023** ATM Offering "). We are limited in the number of shares we can sell in the **2023** ATM Offering due to the offering limitations currently applicable to us under General Instruction I. B. 6. of Form S- 3 and our public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP **2023** Sales Agreement. The extent we rely on AGP as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from AGP were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $ ~~22~~ **5**. ~~0~~ **8** million under the AGP **2023** Sales Agreement, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects. From April ~~2~~ **14**, ~~2021~~ **2023** through the date the consolidated financial statements were issued, we received approximately $ ~~16.~~ 0 **. 1** ~~million~~ **16million** in gross proceeds through the AGP **2023** Sales Agreement from the sale of ~~5~~ **10**, **192** ~~119, 656~~ shares of common stock **. We have approximately** ~~, leaving us with an additional~~ $ ~~6~~ **3**. ~~0~~ **7** million available for future sales pursuant to the AGP **2023** Sales Agreement **. On January 19, 2024, we filed a prospectus supplement to our prospectus dated April 25, 2023 registering the offer and sales of up to $ 865, 889 of shares of our common stock. We have approximately $ 0. 8 million of remaining availability pursuant to this prospectus supplement**. On March 27, 2023, we entered into **a** receivables factoring agreement **(the " Factoring Agreement ")** with Culain Capital Funding LLC (" Culain "). Under the terms of this agreement, we may offer for sale, and Culain in its sole discretion may purchase eligible ~~16receivables~~ -- **receivables** of the Company (the " Purchased Accounts "). Upon purchase, Culain becomes the absolute owner of the Purchased Accounts, which are payable directly to Culain, subject to certain repurchase obligations of the Company. The willingness of Culain to make advances to us by purchasing eligible accounts receivable is subject to customary conditions for financings of this nature. If we are unable to satisfy those conditions, Culain could refrain from providing financing to us, and we might not have sufficient cash on hand to fund **our ongoing operations. As of the date of this report, we have not used the Factoring Agreement to fund any of** our ongoing operations. We may have to raise significant additional capital or obtain additional credit to fund our operations in the future. The failure to raise significant capital, or obtain credit when needed, on acceptable terms, could have a material adverse effect on our business, prospects, financial condition and results of operations, and we may not be able to continue our business as currently contemplated or may be required to seek protection under United States federal bankruptcy law. Substantially all of our consolidated assets are subject to a security interest in favor of Culain

under our Factoring Agreement. Our obligations under certain accounts receivable financing arrangements are secured by a lien on substantially all our consolidated tangible and intangible assets, including receivables from the operations of our business and outstanding ownership interests in each of our direct and indirect subsidiaries. Pursuant to the Factoring Agreement with Culain, we are advanced funds against future accounts receivable. We remain responsible for collecting the accounts receivable. If we are unable to meet our payment obligations under this arrangement, including as the result of failure to collect accounts receivable, Culain would have the right to liquidate our assets to pay off the amounts owed. If any of our assets were to be liquidated, our business could be materially and adversely affected. As of the date of issuance of this Annual Report on Form 10- K, we did not have any receivables outstanding under these arrangements. We may need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations. As of December 31, ~~2022~~ **2023**, we had cash of $ ~~3~~ **1**. ~~4~~ **5** million and ~~our~~ **we had** working capital ~~was~~ **of** $ ~~1~~ **0**. ~~3~~ **5** million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we may be required to raise additional capital to complete the development and commercialization of our current product candidates and to pay off our obligations. To date, to fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings. In future periods, when we seek additional capital, we may seek to sell additional equity and / or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and / or commercialization of one or more of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unattractive terms. We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability. We have incurred losses since our inception and expect to incur losses in the future. At December 31, ~~2022~~ **2023**, we had working capital of $ ~~1~~ **0**. ~~3~~ **5** million. For the year ended December 31, ~~2022~~ **2023**, we had an operating cash flow deficit of $ ~~7~~ **3**. ~~7~~ **6** million and a net loss of $ ~~12~~ **5**. ~~2~~ **8** million. For the year ended December 31, ~~2022~~ **2023**, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and ~~building~~ **17building** a sales force to market our products and services. We expect to incur substantial net losses through at least ~~2023~~ **2024** as we further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability. ~~17We~~ **We** are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable. We have had several customers who, from time to time, have individually represented 10 % or more of our total revenue, or whose accounts receivable balances individually represented 10 % or more of our total accounts receivable. For the years ended December 31, **2023 and** 2022 ~~and 2021~~, **one and** no ~~customer~~ **customers** individually represented 10 % or more of our total revenue **, respectively**. We expect to maintain ongoing relationships with our customers, however, the loss of, or significant decrease in demand from, any of our top customers could have a material adverse effect on our business, results of operations and financial condition. At **December 31, 2023, one customer accounted for approximately 13 % of our total accounts receivable and at** December 31, 2022, one customer accounted for approximately 12 % of our total accounts receivable ~~and at December 31, 2021, two customers accounted for approximately 33 % of our total accounts receivable~~. The business risks associated with this concentration, including increased credit risks for these and other customers and the possibility of related ~~bad debt~~ **credit loss** write- offs, could negatively affect our margins and profits. Additionally, the loss of any of our top customers, whether through competition or consolidation, or a disruption in sales to such a customer, could result in a decrease of the Company' s future sales, earnings and cash flows. Generally, we do not require collateral or other securities to support our accounts receivable and while we are directly affected by the financial condition of our customers, management does not believe significant credit risks exist at December 31, ~~2022~~ **2023**. We have been, and may continue to be, subject to costly litigation. We have been, and may continue to be, subject to legal proceedings. Due to the nature of our business and our history of insufficient capital resources to pay our obligations on a timely basis, we may be subject to a variety of regulatory investigations, claims, lawsuits and other proceedings in the ordinary course of our business. The results of these legal proceedings cannot be predicted with certainty due to the uncertainty inherent in litigation, including the effects of discovery of new evidence or advancement of new legal theories, the difficulty of predicting decisions of judges and juries and the possibility that decisions may be reversed on appeal. Such litigation has been, and in the future, could be, costly, time-consuming and distracting to management, result in a diversion of resources and could materially adversely affect our business, financial condition and operating results. In addition, we may settle some litigation through the issuance of equity securities which may result in significant dilution to our stockholders. For more information related to this risk factor, see Legal Proceedings under Item 3 in this Annual Report. The commercial success of our diagnostic products, including those we are developing, will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our products. Our products may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our existing and future products will depend on several factors, including: ● our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing diagnostics technology; ● the willingness of physicians and patients to utilize our products; ~~and~~ **and18** ● the agreement by commercial third- party payers and government payers to reimburse our products, the scope and amount of which will affect patients'

willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products. In addition, physicians may rely on guidelines issued by industry groups, such as the NCCN, medical societies, such as the College of American Pathologists ~~,~~(" CAP "), or other key oncology- related organizations before utilizing any diagnostic test. ~~18We~~ **We** believe that publications of scientific and medical results in peer- reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer- review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer- reviewed journals could limit the adoption of our products. Failure to achieve widespread market acceptance of our products would materially harm our business, financial condition, and results of operations. If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability. The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. We face significant competition from competitors ranging in size from diversified global companies with significant research and development resources to small, specialized firms whose narrower product lines may allow them to be more effective in deploying related PCR technology in the genetic diagnostic industry. Our closest competitors fall largely into two groups, consisting of companies that specialize in oncology and offer directly competing services to our diagnostic services, offering their services to oncologists and pathology departments within hospitals, as well as large commercial companies that offer a wide variety of laboratory tests that range from simple chemistry tests to complex genetic testing. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain molecular diagnostics companies have established technologies that may be competitive to our product candidates and any future tests that we develop. Some of these tests may use different approaches or means to obtain diagnostic results, which could be more effective or less expensive than our tests for similar indications. Moreover, these and other future competitors have or may have considerably greater resources than we do in terms of technology, sales, marketing, commercialization and capital resources. These competitors may have substantial advantages over us in terms of research and development expertise, experience in clinical studies, experience in regulatory issues, brand name exposure and expertise in sales and marketing as well as in operating central laboratory services. Many of these organizations have financial, marketing and human resources greater than ours; therefore, there can be no assurance that we can successfully compete with present or potential competitors or that such competition will not have a materially adverse effect on our business, financial position or results of operations. We believe that many of our competitors spend significantly more on research and development- related activities than we do. Our competitors may discover new diagnostic tools or develop existing technologies to compete with our diagnostic technology. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, are more convenient or are less expensive than our product candidates. We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results. Our success depends on our ability to develop new products and applications for our diagnostic technology in existing and new markets, while improving the performance and cost- effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing or future markets for our products, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost- effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will ~~offer~~ **19offer** enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted. Competitors may respond more quickly and effectively than we do to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as ~~19existing~~ -- **existing** companies and competitors develop new or improved products and as new companies enter the market with new technologies ~~. We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID- 19, which could significantly disrupt our operations and impact our financial results. The COVID- 19 pandemic continues to evolve. Despite recent progress in the administration of vaccines, COVID- 19 had an adverse impact on the global economy and to some extent on our business. The COVID- 19 pandemic continues to have a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services may be slow to return to pre- pandemic levels, if they return to pre-pandemic levels. Our laboratory operations resumed to near- normal capacity, but we may continue to experience challenges in procuring materials and supplies in a consistently timely manner due to COVID- 19- related supply chain issues. The demand for COVID- 19 vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, during a public health emergency may make it more difficult to obtain materials or manufacturing. If any of our third- party manufacturers is adversely impacted by the COVID- 19 pandemic or if they divert resources or manufacturing capacity to accommodate the development or manufacture of COVID- 19 coronavirus vaccines, our supply chain may be disrupted, limiting our ability to produce our diagnostic tests. We have been and will continue to be prudent in managing through this economic crisis. Digital connectivity is now fundamental to the continuity of our business operations. The extent to which the COVID- 19 pandemic continues to impact our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new~~

~~information that may emerge concerning the severity and longevity of COVID- 19 and its variants, the resurgence of COVID- 19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID- 19 on economic activity, and the actions to contain its impact on public health and the global economy~~ . International expansion of our business could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. When cleared, authorized or approved, we and our collaborators may market, sell, and distribute our products and services outside of the United States, and our business would be subject to risks associated with doing business outside of the United States, including an increase in our expenses and diversion of our management' s attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: ● multiple, conflicting and changing laws and regulations such as privacy, security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anticorruption laws, regulatory requirements, reimbursement or payer regimes and other governmental; ● approvals, permits and licenses; ● failure by us, our collaborators or our distributors to obtain regulatory clearance, authorization or approval for the use of our products and services in various countries; ● additional potentially relevant third- party patent rights; ● complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property **rights throughout the world** ; ● difficulties in staffing and managing foreign operations, including repatriating foreign earned profits; ● complexities associated with managing multiple payer reimbursement regimes, government payers or patient self- pay systems; ● difficulties in negotiating favorable reimbursement negotiations with governmental authorities; ● logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays; ● limits in our ability to penetrate international markets if we are not able to conduct our clinical diagnostic services locally; ~~20~~ ● financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations; ● international regulations and license requirements that may restrict foreign investment in and operation of the internet, IT infrastructure, data centers and other sectors, and international transfers of data; ● natural disasters, political and economic instability, including wars, terrorism and political unrest, and outbreak of disease; ● boycotts, curtailment of trade and other business restrictions; **and** ● regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, or FCPA, its books and records provisions, or its anti- bribery provisions or laws similar to the FCPA in other jurisdictions in which we may in the future operate, such as the United Kingdom' s, (" UK "), Bribery Act of 2010 and anti- bribery requirements of member states in the European Union, (" EU ") ~~; and ● our products (including HemeScreen ® reagents which are authorized under the previous EU Directive on In- Vitro Diagnostic Devices (98 / 79 / EC)) may not be compliant with the new regulatory framework brought in by the In- Vitro Diagnostic Devices Regulation ((EU) 2017 / 746), and approvals of our products under the new regulatory regime may be delayed and consequently our ability to continue to commercialize them in the EU may be impacted~~ . Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations. ~~The~~ **20The** sales of our products in the EU and the UK are regulated through a process that either requires self- certification or certification by a notified body in order to affix a CE mark. Such processes are uncertain, particularly in light of changes to the regulatory framework in the EU and UK. There may be a risk of delay in placing such products on the market and, once on the market, a risk of review and challenges to certain certified statuses. On May 24, 2022, we received CE- IVD approval for the sale of HemeScreen ® reagents in the UK and the EU in accordance with the requirements of the EU IVDD. However, the new EU **IVDR** ~~In- Vitro Diagnostic Devices Regulation ((EU) 2017 / 746)~~ , came into effect on May 26, 2022 and repealed the IVDD. The transitional provisions under the IVDR allow for devices with a notified body certificate issued under the IVDD and which are placed on the EU market prior to May 26, 2022 to continue to be placed on the market in the EU until May 26, 2025. Our device will need to be re- certified under the IVDR by such date in order to remain on the EU market, which will include evaluation by an EU notified body to confirm whether our device meets the general safety and performance requirements under the IVDR. There is no guarantee that our device will be determined to be compliant with such requirements. It should also be appreciated that there currently is a severe shortage of capacity of the EU notified bodies to assess all devices that will require notified body certification under the IVDR. There can be no assurance that our ability to market HemeScreen ® reagents in the EU in the future will not be interrupted and this could, in turn, have a negative impact on our business and operating results. The regulatory framework for medical devices in the UK is likely to evolve now that the UK is no longer part of the EU. Changes to the UK regulations may require additional review of our devices and there is a risk our devices may not be compliant with any revised UK regulations. Now that the UK has left the EU, the new UKCA mark will replace the EU CE mark in Great Britain, (" GB "). The EU legal framework remains applicable in Northern Ireland (indeed any products placed on the market in Northern Ireland must be compliant with EU law). EU CE marks will continue to be recognized in GB for in- vitro diagnostic devices ~~for the time being, however, from July 2024, transitional arrangements will apply for CE and UKCA marked devices placed on the GB market. These transitional arrangements have not yet been brought into force through the UK medical devices regulations, but the UK Government intends to introduce legislation by Spring 2023~~ that ~~will bring~~ **are compliant with** ~~these~~ -- **the** ~~into force~~ **EI IVDR until June 30, 2030** . In addition, all devices must now be registered with the MHRA in order to be placed on the GB market. These new requirements under the UK medical devices legislation and any other changes that are brought into force could result in delays in our ability to obtain a UKCA mark and to continue to market our product in the UK. The UK' s departure from the EU has also impacted customs regulations as well as timing and ease of shipments into the EU from UK. ~~21Unfavorable~~ -- **Unfavorable** U. S. or global economic conditions could adversely affect our business, financial condition or results of operations ~~. Over the twelve months ended June 2022, the US Bureau of Labor and Statistics reported that inflation increased 9. 1 percent as against prices from June 2021. This represents the largest 12- month advance since 1981~~ . Our results of operations could be adversely affected by

general conditions in the global economy and financial markets. A severe or prolonged economic downturn or increase in inflation rates could result in a variety of risks to our business, including weakened demand for our products and services and our ability to raise additional capital when needed on favorable terms, if at all. A weak declining or inflationary economy could strain our collaborators and suppliers, possibly resulting in supply disruption, or cause delays in their payments to us. In addition, the Company' s operations and access to capital may be impacted by disruptions to the banking system and financial market volatility resulting from bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank **(" SVB ")** and other financial institutions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect the Company' s current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past ~~and~~ **21and** may in the future lead to market- wide liquidity problems. For example, on March 10 **and March 12** , 2023, ~~Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed~~ the Federal Deposit Insurance Corporation **took control and** ~~(" FDIC ") as~~ **was appointed** receiver ~~. Similarly~~ **of SVB** , **and** ~~on March 12, 2023,~~ Signature Bank and Silvergate Capital Corp. ~~were~~ **(" Silvergate Capital "), respectively, after** each ~~swept into receivership~~ **bank was unable to continue their operations** . **Since** ~~Although a statement by the~~ **then** ~~Department of the Treasury~~ , **additional financial institutions** ~~the Federal Reserve and the FDIC indicated that all depositors of SVB would~~ have **experienced similar failures** ~~access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit~~ and **have been** ~~certain other financial instruments with SVB, Signature Bank or any other financial institution that is~~ placed into receivership ~~by the FDIC may be unable to access undrawn amounts thereunder~~ . **It is possible that** ~~If any of our suppliers or~~ other **banks will face** ~~parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar~~ **similar difficulty** ~~impacts have occurred~~ in the ~~past, such as during~~ **future. These events exposed vulnerabilities in** the ~~2008- 2010 financial crisis~~ **banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market prices of regional bank stocks to plummet** . Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with ~~22which~~ -- **which** we have or may enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, 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 could involve financial institutions with which we have or may enter into financial or business relationships, but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: ● Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; ● Delayed or lost access to other working capital sources and / or delays, inability or reductions in our ability to enter into new credit facilities or access other working capital resources; ● Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements; ● Potential or actual breach of financial covenants in any credit agreements or credit arrangements; or ● Potential or actual cross- defaults in other credit agreements, credit arrangements or operating or financing agreements. 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 acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business. Global climate change could negatively affect our business. Increased public awareness and concern regarding global climate change will likely result in more regional and / or national requirements to reduce or mitigate the effects of greenhouse gas emissions. In addition, our

stockholders and customers also expect us to reduce our greenhouse gas emissions. There continues to be a lack of consistent climate legislation, which creates economic and regulatory uncertainty. Any future regulations aimed at mitigating climate change ~~may~~ **22may** negatively impact the prices of raw materials and energy as well as the demand for certain of our customer' s products which could in turn impact demand for our products and impact our results of operations. The costs of compliance and any changes to our operations mandated by new or amended laws, may be significant. We may also face unexpected delays in obtaining permits and approvals required by such laws in connection with our manufacturing facilities, which would hinder our operation of these facilities. Furthermore, any violations of these laws may result in substantial fines and penalties, remediation costs, third party damages, or a suspension or cessation of our operations. We also face physical and transition risks from climate change. The manifestations of climate change, such as extreme weather conditions or more frequent extreme weather events, including wildfires, flooding, water stress and extreme heat, could disrupt our operations, damage our facilities, disrupt our supply chain, impact the availability and cost of materials needed for manufacturing or increase insurance and other operating costs. As a result, severe weather events or natural disasters could result in a prolonged disruption to our operations or operations of our customers or suppliers, which could have a material adverse effect on our operating results, cash flows or financial ~~condition23We----~~ **condition. We may be impacted by economic and supply disruptions associated with events beyond our control, such as war, including the current conflicts between Russia and Ukraine and between Israel and Hamas, acts of terror, political unrest, public health concerns, labor disputes or natural disasters. The operations of our suppliers and customers, could be disrupted by events beyond our control, such as war, acts of terror, political unrest, public health concerns, labor disputes, or severe weather conditions or natural disasters. In addition, our operations could be adversely affected as a result of other disruptions at our facilities due to fire, electrical blackouts, power losses, telecommunications failures or other similar effects. Any such disruption could cause delays in the production and distribution of our products and the loss of sales and customers. We may not be insured against all such potential losses and, if insured, the insurance proceeds that we receive may not adequately compensate us for all of our losses. Such losses could lead to an increase in the deductibles or cost of insurance for those facilities, a reduction of insurance available to us, or the unavailability of insurance on terms that are acceptable to us. We** depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted. Our success is largely dependent upon the continued contributions of our officers and employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire additional personnel with specialized experience in a number of disciplines, including assay development, laboratory and clinical operations, sales and marketing, billing and reimbursement. There is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any future tests could be delayed or negatively impacted. If any of them becomes unable or unwilling to continue in their respective positions, and we are unable to find suitable replacements, our business and financial results could be materially negatively affected. **If we are unable to hire and retain employees capable of performing at a high- level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third- party outsourcing, have unintended negative effects, our business could be adversely affected. A sustained labor shortage, lack of skilled labor, increased turnover or labor cost inflation as a result of general macroeconomic factors could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, which could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business and have other adverse effects on our results of operations and financial condition.** We will need to increase the size of our organization, and we may experience difficulties in managing growth. We are a small company with ~~53~~ **51** full- time employees and ~~3~~ **6** part-time employees as of March ~~15~~ **1** , ~~2023~~ **2024** . Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of diagnostic technology. Our future financial performance and our ability to ~~commercialize~~ **23commercialize** our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to: ● integrate additional management, administrative, manufacturing and regulatory personnel; ● maintain sufficient administrative, accounting and management information systems and controls; and ● hire and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future diagnostic products and product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company. We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results. We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue. We have limited experience in marketing our products and services. We intend to continue to develop our in- house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain marketing and

sales personnel. If we are unable to further grow our internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from ~~24product~~ -- **product** sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer. Cybersecurity refers to the combination of technologies, processes and procedures established to protect information technology systems and data from unauthorized access **, misuse** , attack, or damage. We rely on our information systems to provide security for processing, transmission and storage of confidential information about our patients, customers and personnel, such as names, addresses and other individually identifiable information protected by the Health Insurance Portability and Accountability Act, (" HIPAA "), other privacy laws. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or ~~breaches~~ **incidents** . We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such **cyberattacks** ~~cyber- attacks~~ and any such attacks could result in losses described above, as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to **, misuse of,** or disclosure of such ~~information~~ **24information** could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches **or other incidents** , we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our **business.** ~~businessCyberattacks~~ -------- **Cyberattacks** are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes. We have not experienced any known attacks on our information technology systems that compromised any confidential information. We maintain our information technology systems with ~~safeguard~~ **safeguards designed to** ~~protection~~ --- **protect** against **cyberattacks** ~~cyber- attacks~~ including passive intrusion protection, firewalls and virus detection software. However, these safeguards do not ensure that a significant **cyberattack** ~~cyber- attack~~ could not occur. Although we have taken steps to protect the security of our information systems and the data maintained in those systems, it is possible that our safety and security measures will not prevent the systems' improper functioning or damage or the improper access or disclosure of personally identifiable information such as in the event of **cyberattacks** ~~cyber- attacks~~ . Security ~~breaches~~ **incidents** , including physical or electronic break- ins, computer viruses, attacks by hackers and similar ~~breaches~~ **incidents** can create system disruptions or shutdowns or the unauthorized disclosure **of, access to, or misuse** of confidential information. If personal information or protected health information is improperly accessed, tampered with **, misused** or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security rules under HIPAA or other similar federal or state laws protecting confidential personal information. In addition, a security breach of **or other incident affecting** our information systems could damage our reputation, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations. 25Changes in tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local and non- U. S. taxation are constantly under review by persons involved in the legislative process, the Internal Revenue Service, the U. S. Treasury Department and other taxing authorities. Changes to tax laws or tax rulings, or changes in interpretations of existing laws (which changes may have retroactive application), could adversely affect us or holders of our common stock. These changes could subject us to additional income- based taxes and non- income taxes (such as payroll, sales, use, value- added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. ~~As~~ **For example, under Section 174 of the Internal Revenue Code, as amended, currently, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U. S. will be capitalized and amortized, which may have an adverse effect on our cash flow. More recently, however, there have been proposals to retroactively reinstate deductibility under Code Section 174. Furthermore, as** we expand the scale of our business activities, any changes in the U. S. and non- U. S. taxation of such

activities may increase our effective tax rate and harm our business, financial condition, and results of operations. Our ability to use net operating loss carryforwards to offset future taxable income for U. S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses. As of December 31, ~~2022~~ **2023**, we had approximately $ ~~74~~ **76** million of federal net operating losses, (" NOLs "). Approximately $ 28 million of the federal NOLs will expire at various dates beginning in 2036 through 2037 if not utilized, while the remaining amount will have an indefinite life. As of December 31, ~~2022~~ **2023**, we had approximately $ 2. 4 million of state NOLs. ~~For~~ **The** state NOLs ~~expiration~~ **expire on various** dates ~~, it varies from 2022 to unlimited~~. Under current law, federal NOLs generated in taxable years ending after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80 % of our taxable income annually for tax years beginning after December 31, 2020. NOLs generated prior to December 31, 2017, however, have a 20- year carryforward period, but are not subject to the 80 % limitation. Under U. S. federal income tax law, a corporation' s ability to utilize its NOLs to offset future taxable income may be significantly limited if it experiences an " ownership change " as defined in Section 382 of the Internal Revenue Code, as amended. In general, an ownership change will occur if there is a cumulative change in a corporation' s ownership by " 5- percent shareholders " that exceeds 50 percentage points over a rolling three- year period **, including changes in ownership arising from new issuances of stock**. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre- ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long- term tax- exempt rate (subject to certain adjustments) **. Our ability to use NOLs to reduce future taxable income and liabilities may be subject to annual limitations as a result of ownership changes that may occur in the future**. Furthermore, our ability to utilize NOLs of companies that we have acquired or may acquire in the future may be subject to similar limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the NOLs, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition. The testing, manufacturing and marketing of diagnostics entails an inherent risk of product liability and personal injury claims. To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, our existing insurance may not be renewed by us at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our cash flow and thus potentially a materially adverse effect on our business, financial condition and results of operations. 26All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man- made or natural disaster, our operations could be severely impaired. Laboratory and R & D facilities located in New Haven, Connecticut and Omaha, Nebraska house development teams that collaborate on new products and services. The Company operates CLIA laboratories in both the New Haven, Connecticut and Omaha, Nebraska locations providing essential blood cancer diagnostics to office- based oncologists in many states nationwide. Despite precautions taken by us, any future natural or man- made disaster at these laboratories, such as a fire, earthquake or terrorist activity, could cause substantial delays in our operations, damage or destroy our equipment and testing samples or cause us to incur additional expenses. In addition, we are leasing the facilities where our laboratories operate. We are currently in compliance with all and any lease obligations, but should the leases terminate for any reason, or if at any time either of the laboratories is moved due to conditions outside our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of either laboratory, we may be unable to perform our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could harm our operating results and financial condition. Further, if we have to use a substitute laboratory while our facilities were shut down, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA- certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to certification under CLIA and licensure by various states, which would take a significant amount of time and result in delays in our ability to continue our operations. An impairment in the carrying value of our intangible assets could negatively affect our results of operations. A significant portion of our assets are intangible assets which are reviewed at least annually for impairment. If we do not realize our business plan, our intangible assets may become impaired resulting in an impairment loss in our results of operations. Reimbursement and Regulatory Risks Relating to Our BusinessGovernmental payers and health care plans have taken steps to control costs, which could negatively affect our business. Third- party payers, including private insurers and governmental entities, have implemented and will continue to implement measures to control the cost, utilization, and delivery of healthcare services, including products and services we offer. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals may not use our services if third- party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local, and third- party payer regulations or policies may decrease our revenues and adversely affect our results of operations and our financial condition. Occasionally, legislative pauses and changes impact our products that are reimbursed under the Medicare Physician Fee Schedule (" MPFS "), or the Clinical Laboratory Fee Schedule (" CLFS "). Further, CMS and state Medicaid agencies may adopt regulations and policies that change, limit or exclude coverage for our products and services. We expect that efforts to contain costs will continue and that coverage and reimbursement for our products and services may be impacted. These efforts,

including changes in law or regulations that may occur in the future, may each individually or collectively have a material adverse impact on our business, results of operations, financial condition, and prospects. 27Changes in payer mix could have a material adverse impact on our net sales and profitability. Testing services are billed to physicians, patients, government payers such as Medicare, and insurance companies. Tests may be billed to different payers depending on a particular patient' s medical insurance coverage. Government payers have increased their efforts to control the cost, utilization and delivery of health care services as well as reimbursement for laboratory testing services. Further reductions of reimbursement for Medicare and Medicaid services or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a physician or qualified practitioner' s signature on test requisitions, may be implemented from time to time. Reimbursement for the laboratory services component of our business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates and changes in payment policies of other third party payers may occur as well. Such changes in the past have resulted in reduced payments as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. As a result, increases in the percentage of services billed to government payers could have an adverse impact on our net sales. Our laboratories require ongoing CLIA certification, and we cannot guarantee that our laboratories will pass all future certification inspections. The Clinical Laboratory Improvement Amendments of 1988, (" CLIA "), extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally- approved accreditation agency. The CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories must also undergo proficiency testing and are subject to inspections. The sanctions for failure to comply with the CLIA requirements include suspension, revocation or limitation of a laboratory' s CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory' s approval to receive Medicare and / or Medicaid reimbursement, as well as significant fines and / or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes in the CLIA law or regulations (or interpretation of the law or regulations) could have a material adverse effect on us. We believe that we are in compliance with all applicable laboratory requirements, but no assurances can be given that our laboratories will pass all future certification inspections. Our products that we sell as research use only products and / or that we offer as laboratory developed tests could become subject to government regulations requiring marketing authorization, and the marketing authorization and maintenance process for such products may be expensive, time- consuming and uncertain in both timing and outcome. A number of our products are currently, and in the future will be, labeled and sold as research use only (RUO) products. Even though our products are labeled and sold as RUO products, the United States Food and Drug Administration (FDA) could question whether our products are intended for research use only. For example, in August 2021, we were contacted by the FDA regarding HemeScreen, and we have subsequently revised the labeling for HemeScreen. Should the FDA disagree with our conclusion that our products are intended for research use only or deem our sales, marketing and promotional efforts as being inconsistent with RUO products, our products could be subject to government regulation as diagnostic products. Diagnostic products are regulated as medical devices by the FDA and may require marketing authorization through clearance following the 510 (k) premarket notification process, authorization following a request for de novo classification or premarket approval from the FDA, in each case prior to marketing. Obtaining the requisite marketing authorizations can be expensive and may involve considerable delay. Moreover, if the FDA believed we inappropriately labeled our products as RUO products, it could allege that we had misbranded or adulterated our RUO products. Additionally, our CLIA laboratory offers testing utilizing our laboratory developed tests (LDTs). Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the FDA' s requirements for medical devices, such as the FDA' s requirements pertaining to marketing authorization, establishment registration, device listing, the Quality System Regulation, and other post- market controls. However, the FDA has stated it intends to end its policy of enforcement discretion and to actively regulate LDTs. For example, on October 3, 2014, the FDA issued two draft guidance documents, entitled " Framework for Regulatory 28Oversight of Laboratory Developed Tests (LDTs) " and " FDA Notification and Medical Device Reporting for Regulatory Oversight of Laboratory Developed Tests (LDTs) ", that set forth a proposed risk- based regulatory framework that would apply varying levels of FDA oversight to LDTs. The ~~timing of when, if at all, the~~ draft guidance documents ~~will be~~ **have not been** finalized ~~is unclear~~ . In January 2017, the FDA issued a " Discussion Paper on Laboratory Developed Tests (LDTs), " which includes a possible approach to LDT oversight that is intended to advance public discussion on the topic. Additionally, legislative proposals have been introduced in Congress or have been publicly circulated. Such proposals would implement differing approaches to the regulation of LDTs, including in certain instances to require marketing authorization from the FDA. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business. **On October 3, 2023, the FDA published a proposed rule on LDTs, in which the FDA proposes to end enforcement discretion for virtually all LDTs in five stages over a four- year period from the date the FDA publishes a final rule. In Phase 1 (effective one year post- finalization), laboratories would be required to comply with medical device (adverse event) reporting and correction / removal reporting requirements. In Phase 2 (effective two years post- finalization), laboratories would be required to comply with all other device requirements (e. g., registration / listing, labeling, investigational use), except for quality systems and premarketreview. In Phase 3 (effective three years post- finalization), laboratories would be required to comply with quality systems requirements. In Phase 4 (effective three and a half years post- finalization, but not before October 1, 2027), laboratories would be required to comply with premarket review requirements for high- risk tests (i. e., tests subject to the PMA requirement). Finally, in Phase 5 (effective four years post- finalization, but not before April 1, 2028), laboratories would be required to comply with premarket review requirements for moderate- and low- risk tests (i. e., tests subject to de novo or the 510 (k) requirement). Unlike previous proposals, the proposed rule does not provisions that would allow for " grandfathering " of existing tests. The content and timing of any final rule on LDTs is uncertain at this time.** If the FDA asserts that our

RUO products and / or LDTs are subject to marketing authorization, or that our RUO products and / or LDTs are adulterated or misbranded, our business, financial condition or results of operations could be adversely affected. Failure to comply with HIPAA could be costly. HIPAA and associated regulations protect the privacy and security of certain patient health information and establish standards for electronic health care transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our laboratories are subject to HIPAA and its associated regulations. If we fail to comply with these laws and regulations we could suffer civil and criminal penalties, fines, exclusion from participation in governmental health care programs and the loss of various licenses, certificates and authorizations necessary to operate our patient testing business. We could also incur liabilities from third party claims. Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations. Our research and development and commercial activities involve the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and international laws and regulations governing the use, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. We cannot be certain that accidental contamination or injury will not occur. Any such accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs. We may become subject to the Anti- Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws. There are several federal laws addressing fraud and abuse that apply to businesses that receive reimbursement from a federal health care program. There are also a number of similar state laws covering fraud and abuse with respect ~~to~~ **29to** , for example, private payers, self- pay and insurance. Currently, we receive a substantial percentage of our revenue from private payers and from Medicare. Accordingly, our business is subject to federal fraud and abuse laws, such as the Anti- Kickback Statute, the Stark Law, the False Claims Act, the Civil Monetary Penalties Law and other similar laws. Moreover, we are already subject to similar state laws. We believe we have operated, and intend to continue to operate, our business in compliance with these laws. However, these laws are subject to modification and changes in interpretation, and are enforced by authorities vested with broad discretion. Federal and state enforcement entities have significantly increased their scrutiny of healthcare companies and providers which has led to investigations, prosecutions, convictions and large settlements. We continually monitor developments in this area. If these laws are interpreted in a manner contrary to our interpretation or are reinterpreted or amended, or if new legislation is enacted with respect to healthcare fraud and abuse, illegal remuneration, or similar issues, we may be required to restructure our affected operations to maintain compliance with applicable law. There can be no assurances that any such restructuring will be possible or, if possible, would not have a material adverse effect on our results of operations, financial position, or cash flows. ~~29Anti~~ -- **Anti** - Kickback Statute A federal law commonly referred to as the " Anti- Kickback Statute " prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in return for the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid. The term " remuneration " has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. The PPACA amended the intent requirement of the Anti- Kickback Statute such that a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate the statute. Further, the PPACA now provides that claims submitted in violation of the Anti- Kickback Statute constitute false or fraudulent claims for purposes of the federal False Claims Act (" FCA "), including the failure to timely return an overpayment. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to influence the purchase, lease or ordering of healthcare items and services reimbursed by a governmental health program or state Medicaid program. Some of these state prohibitions apply to remuneration for referrals of healthcare items or services reimbursed by any third- party payer, including commercial payers and self- pay patients. Stark Law Section 1877 of the Social Security Act, or the Stark Law, prohibits a physician from referring a patient to an entity for certain " designated health services " reimbursable by Medicare if the physician (or close family members) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. The designated health services covered by the law include, among others, laboratory and imaging services. Some states have self- referral laws similar to the Stark Law for Medicaid claims and commercial claims. Violation of the Stark Law may result in prohibition of payment for services rendered, a refund of any Medicare payments for services that resulted from an unlawful referral, civil monetary penalties for specified infractions, criminal penalties, and potential exclusion from participation in government healthcare programs, and potential false claims liability. The repayment provisions in the Stark Law are not dependent on the parties having an improper intent; rather, the Stark Law is a strict liability statute and any violation is subject to repayment of all amounts arising out of tainted referrals. If physician self- referral laws are interpreted differently or if other legislative restrictions are issued, we could incur significant sanctions and loss of revenues, or we could have to change our arrangements and operations in a way that could have a material adverse effect on our business, prospects, damage to our reputation, results of operations and financial condition. False Claims Act The FCA prohibits providers from, among other things, (1) knowingly presenting or causing to be presented, claims for payments from the Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; (2) knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government; or (3) knowingly making, using or causing to be made or used, a false record ~~or~~ **30or** statement to avoid, decrease or conceal an obligation to pay money to the federal government **. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims** . The " qui tam " or "

whistleblower ” provisions of the FCA allow private individuals to bring actions under the FCA on behalf of the government. These private parties are entitled to share in any amounts recovered by the government, and, as a result, the number of “ whistleblower ” lawsuits that have been filed against providers has increased significantly in recent years. Defendants found to be liable under the FCA may be required to pay three times the actual damages sustained by the government, plus civil penalties for each separate false claim. There are many potential bases for liability under the FCA. The government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, billing for services not provided, and providing care that is not medically necessary or that is substandard in quality. The PPACA also provides that claims submitted in connection with patient referrals that result from violations of the Anti- Kickback Statute constitute false claims for the purpose of the FCA, and some courts have held that a violation of the Stark law can result in FCA liability, as well. In addition, a number of states have adopted their own false claims and whistleblower provisions whereby a private ~~30party~~ -- **party** may file a civil lawsuit in state court. We are required to provide information to our employees and certain contractors about state and federal false claims laws and whistleblower provisions and protections. Civil Monetary Penalties Law The Civil Monetary Penalties Law prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person or entity knows or should know is likely to influence the beneficiary’ s selection of a particular provider or supplier of items or services reimbursable by a federal or state healthcare program. This broad provision applies to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. This law could affect how we have to structure our operations and activities. Intellectual Property Risks Related to Our BusinessWe cannot be certain that measures taken to protect our intellectual property will be effective. We rely upon patents, trade secrets, copyrights and trademarks, as well as non- disclosure agreements and other contractual confidentiality provisions to protect our confidential and proprietary information for which we are not seeking patent protection for various reasons. Such measures, however, may not provide adequate protection for our trade secrets or other proprietary information. If such measures do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. Our intellectual property portfolio with respect to certain aspects of our technology and product candidates is at an early stage. We have one company- owned, pending **international** patent application directed to our HemeScreen test. This ~~provisional~~ **international** patent application is not eligible to become an issued patent until, among other things, we file ~~a non-provisional patent~~ **national and / or regional stage** ~~application~~ **applications** ~~within 12 months of~~ **in individual countries and / or regions by** the **appropriate deadline** ~~filing date of the applicable provisional patent application~~ . Any failure to file ~~a non-provisional~~ **one or more national and / or regional stage** patent ~~application~~ **applications** within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated ~~provisional~~ **international** patent ~~applications~~ - **application** . If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in ~~a~~ **31a** timely manner. Disruptions at the United States Patent and Trademark Office (USPTO) or other government agencies may also slow the time necessary for patent applications to be reviewed by the USPTO, which could adversely affect our patent portfolio. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or pending patent applications, or that we were the first to file for patent protection of such ~~inventions31We~~ ---- **inventions. We** depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products. **We** ~~On September 1, 2022, we terminated the license agreement with Dana- Farber pursuant to which we previously licensed our ICP technology. For more information regarding this license agreement termination, please see “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations- Recent Developments ”. In the future, we~~ may enter into ~~other~~ license agreements with third parties for certain licensed technologies that are, or may become, relevant to the products we market, or plan to market. In addition, we may elect to license third party intellectual property to further our business objectives and / or as needed for freedom to operate for our products. We **may** ~~do not and will~~ not own the patents, patent applications or other intellectual property rights that are the subject of the ~~Dana- Farber~~ license **agreements we enter into** ~~or these other future licenses~~ . Our rights to use these technologies and employ the inventions claimed in the licensed patents, patent applications and other intellectual property rights are or will be subject to the continuation of and compliance with the terms of those licenses. We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e. g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties,

which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products. In some cases, we do not or may not control the prosecution, maintenance, or filing of the patents or patent applications to which we hold licenses, or the enforcement of these patents against third parties. As a result, we cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed. In addition to the protection afforded by patents, we rely upon trade secret protection, know- how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements may not be self- executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know- how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim ~~against~~ **32against** a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time- consuming and the outcome is unpredictable. Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could purchase our product candidates and 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. ~~32Additionally~~ -- **Additionally** , if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Third- party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business. Our commercial success depends in part on our avoiding infringement, misappropriation and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the diagnostic industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U. S. patent reform, new procedures including inter partes review and post grant review have been implemented. As stated above, this reform will bring uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the diagnostic industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U. S. by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. There may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products or product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, ~~constructs~~ **33constructs**

or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we obtained such a license, it may only be non- exclusive, which would permit third parties to use the same intellectual property and compete with us. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, we may be unable ~~33to~~ **to** commercialize our product candidates or such efforts may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also 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 material adverse effect on the price of shares of our common stock. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market earlier than would otherwise have been the case, which would have a material adverse effect on our business. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement ~~proceeding~~ **34proceeding** , there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have ~~34asserted~~ -- **asserted** trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also 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 material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects. Changes to the patent law in the U. S. and other jurisdictions could

diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other diagnostic companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the diagnostic industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the U. S. has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to DNA molecules are not patentable. In addition, the case Amgen Inc. v. Sanofi affects the way antibody claims are examined and litigated. We cannot predict how future decisions by the courts, the Congress or the USPTO may impact the value of our patents. In addition, a European Unified Patent Court (UPC) ~~is scheduled to come~~ **came** into force ~~during~~ **in June** 2023. The UPC **is** ~~will be~~ a common patent court ~~to~~ **that** ~~hear~~ **hears** patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Although we do not currently own any European patents or applications, if we obtain such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC. ~~Third~~ **35Third** parties may assert ownership or commercial rights to inventions we develop. Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, third parties that have been introduced to or have benefited from our inventions may attempt to replicate or reverse engineer our products and circumvent ownership of our inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial ~~35value~~ -- **value** of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. Although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. **We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world. We have limited intellectual property rights outside the United States and do not have any issued patents in foreign jurisdictions. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. In addition, if we obtain foreign patent protection in the future, competitors may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of any patent rights we may obtain in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce any patent rights we may obtain in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patent rights we may obtain at risk of being invalidated or interpreted narrowly and our patent**

applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. ~~Intellectual~~ **36Intellectual** property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we hold rights to; • we, or our licensors or collaborators, might not have been the first to invent or the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned intellectual property rights; • it is possible that our current or future pending owned patent applications will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in the US; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects ~~36Risks --~~ **Risks** Related to Our Common StockThe price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock. There has been, and continues to be, a limited public market for our common stock, and an active trading market for our common stock has not and may never develop or, if developed, be sustained. The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of our common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management. ~~The~~ **37The** price of our stock may be vulnerable to manipulation. We believe our common stock has been the subject of significant short selling by certain market participants. Short sales are transactions in which a market participant sells a security that it does not own. To complete the transaction, the market participant must borrow the security to make delivery to the buyer. The market participant is then obligated to replace the security borrowed by purchasing the security at the market price at the time of required replacement. If the price at the time of replacement is lower than the price at which the security was originally sold by the market participant, then the market participant will realize a gain on the transaction. Thus, it is in the market participant' s interest for the market price of the underlying security to decline as much as possible during the period prior to the time of replacement. Because our unrestricted public float has been small relative to other issuers, previous short selling efforts have impacted, and may in the future continue to impact, the value of our stock in an extreme and volatile manner to our detriment and the detriment of our stockholders. Efforts by certain market participants to manipulate the price of our common stock for their personal financial gain may cause our stockholders to lose a portion of their investment, may make it more difficult for us to raise equity capital when needed without significantly diluting existing stockholders, and may reduce demand from new investors to purchase shares of our stock. If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities. Although our common stock is listed on The Nasdaq Capital Market (" Nasdaq "), we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy Nasdaq' s criteria for maintaining our listing, our securities could be subject to delisting. ~~On October 28, 2022, we received a letter from The Nasdaq Stock Market LLC, notifying us that the closing bid price per share of our common stock was below the $ 1. 00 minimum bid price requirement for continued listing on Nasdaq, as required by Nasdaq Listing Rule 5550 (a) (2) (" Bid Price Rule "). As a result, Nasdaq notified us that we are not in compliance with the Bid Price Rule. Nasdaq has provided us with 180 calendar days, or until April 26, 2023, to regain compliance with the Bid Price Rule. This notification has no immediate effect on our listing on Nasdaq or on the trading of the our common stock. To regain compliance with the Bid Price Rule, the closing bid price of our common stock must meet or exceed $ 1. 00 per share for a minimum of ten consecutive business days during the 180- calendar day grace period. If our common stock does not regain compliance with the Bid Price Rule during this grace period, we may be eligible for an additional grace period of 180 calendar days provided that we satisfy Nasdaq' s continued listing requirement for market value of 37publicly held shares and all other initial listing standards for listing on Nasdaq, other than the minimum bid price requirement, and provide written notice to Nasdaq of our intention to cure the delinquency during the second grace period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will grant us an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will be subject to delisting.** If Nasdaq were to delist our securities, we could face significant consequences, including: ● a limited availability for market quotations for our securities; ● reduced liquidity with respect to our securities; ● a determination that our common stock is a " penny stock, " which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading; ● activity in the secondary trading market for our common stock; ● **reduced or** limited

amount of news and analyst coverage; and ● a decreased ability to issue additional securities or obtain additional financing in the future. In addition, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards ~~. We intend to monitor the closing bid price of our common stock and may, if appropriate, evaluate various courses of action to regain compliance with the Bid Price rule. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule~~ . Increased costs associated with corporate governance compliance may significantly impact our results of operations. As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes- Oxley Act of 2002, or the Sarbanes- Oxley Act, as well as rules implemented by the SEC, and ~~NASDAQ~~ **Nasdaq** . The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd- Frank Wall Street Reform and Consumer Protection Act, or the Dodd- Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd- Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd- Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will ~~cause~~ **38cause** us to incur significant legal and financial compliance costs and will make some activities more time- consuming and costly. The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes- Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes- Oxley Act, that our ~~38internal --~~ **internal** control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline. We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes- Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective. These developments could make it more difficult for us to retain qualified members of our Board of Directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result. To the extent these costs are significant, our general and administrative expenses are likely to increase.

Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur. The Sarbanes- Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We **are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes- Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes- Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline. We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes- Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an 39annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material**

weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective. These developments could make it more difficult for us to retain qualified members of our Board of Directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result. To the extent these costs are significant, our general and administrative expenses are likely to increaseWe have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock. No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor' s investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income. We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology stocks have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or if they issue other unfavorable commentary or cease publishing reports about us or our business. The sale or issuance of our common stock to, or through, AGP may cause significant dilution and the sale of the shares of common stock acquired by AGP, or the perception that such sales may occur, could cause the price of our common stock to fall. On April ~~2~~ **14** , ~~2021~~ **2023** , we entered into a sales agreement with AGP, pursuant to which we may offer and sell our Common Stock, having aggregate sales proceeds of up to $ ~~22~~ **5** . ~~0~~ **8** million, to or through AGP, from time to time, in the **2023** ATM Offering. We are limited in the number of shares ~~it~~ **we** can sell in the **2023** ATM Offering due to the offering limitations currently applicable to **us** ~~the Company~~ under General Instruction I. B. 6. of Form S- 3 and **our** ~~the Company' s~~ public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP **2023** Sales Agreement. Sales to, or through, AGP by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common ~~39stock --~~ **stock** , or the anticipation of such sales, could make it more difficult for us to sell equity or equity- related securities in the future at a time and at a price that we might otherwise wish to effect sales. From April ~~2~~ **14** , ~~2021~~ **2023** through the date ~~the consolidated financial statements were issued~~ **of issuance of this Report on From 10- K** , we received ~~approximately~~ $ ~~16.~~ 0 **. 1** million in gross proceeds through the AGP **2023** Sales Agreement from the sale of ~~5~~ **10** , **192** ~~119, 656~~ shares of Common Stock ~~, leaving us with~~ **. The Company has** an additional $ ~~6~~ **3** . ~~0~~ **7** million available for future sales pursuant to the AGP **2023** Sales Agreement **. On January 19, 2024, we 40filed a prospectus supplement to our prospectus dated April 25, 2023 registering the offer and sales of up to $ 865, 889 of shares of our common stock. We have approximately $ 0. 8 million of remaining availability pursuant to this prospectus supplement. We have issued a substantial number of warrants and equity awards from our equity plans which are exercisable into shares of our common stock which could result in substantial dilution to the ownership interests of our existing stockholders. As of December 31, 2023, approximately 459, 535 shares of our common stock were reserved for issuance upon exercise or conversion of outstanding warrants. Additionally, 232, 744 shares of our common stock were reserved for issuance upon exercise of outstanding stock options. The exercise or conversion of these securities will result in a significant increase in the number of outstanding shares and substantially dilute the ownership interests of our existing stockholders. The shares underlying the equity awards from our equity plans are registered on a Form S- 8 registration statement. As a result, upon vesting these shares can be freely exercised and sold in the public market upon issuance, subject to volume limitations applicable to affiliates. The exercise of options and the subsequent sale of the underlying common stock could cause a decline in our stock price** . Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our diagnostic technologies or current or future development programs. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization

of one or more of our product candidates, delay our pursuit of potential in- licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves. The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall **.** We may seek to settle outstanding obligations to vendors, debtholders or litigants in any litigation through the issuance of our common stock or other security to such persons. Such issuances may cause significant dilution to our stockholders and cause the price of our common stock to fall. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability ~~, including most recently in connection with the ongoing COVID- 19 pandemic~~ , current macroeconomic conditions, currency exchange rates, and volatile financial markets. 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. If the current equity and credit markets deteriorate, or do not improve, it ~~may~~ **41may** make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. 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, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in- licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and ~~40other~~ -- **other** partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. Our amended and restated bylaws, as amended, designate specific courts in as the exclusive forum for certain litigation that may be initiated by the Company' s stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Pursuant to our amended and restated bylaws, as amended (the " bylaws "), unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee or agent of ours to us or our stockholders or debtholders, (3) any action asserting a claim against us or any director or officer or other employee of ours arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or the bylaws (in each case, as they may be amended from time to time), (4) any action asserting a claim against us or any current or former director or officer or other employee or agent of ours governed by the internal affairs doctrine or (5) any action asserting an " internal corporate claim " as that term is defined in Section 115 of the General Corporation Law of the State of Delaware (the " Delaware Forum Provision "); provided, however, that the Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, that in the event that the Court of Chancery of the State of Delaware lacks jurisdiction over any such action or proceeding, the sole and exclusive forum for such action or proceeding shall be another state or federal court located within the State of Delaware; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other states courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our forum provision. If our forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. Forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be ~~41located~~ **42located** or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and our bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: ● a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; ● a requirement that special meetings of stockholders be called only by the chairman of the board, board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, or our chief executive officer; ● advance notice requirements for stockholder proposals and nominations for election to our board of directors; ● a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than a majority he shares then entitled to vote generally for the election of directors; and ● the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware

General Corporate Law (“ DGCL ”), which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These antitakeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. We are a ~~,~~ **“** smaller reporting company, ” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors. We are a smaller reporting company under Rule 12b- 2 of the Exchange Act. For so long as we remain a smaller reporting company, we are permitted and plan to rely on exemptions from certain disclosure requirements, including reduced disclosure obligations regarding executive compensation. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to audit our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common