Risk Factors Comparison 2024-02-29 to 2023-03-06 Form: 10-K

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The following risk factors and other information included in this Annual Report on Form 10- K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see page ii of this Annual Report on Form 10- K for a discussion of some of the forward- looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. Risk Factor Summary Our business is subject to numerous risks and uncertainties. The following summary highlights some of the risks to be considered with respect to our business and prospects. This summary is not complete and the risks summarized below are not the only risks we face. Readers should review and carefully consider the risks and uncertainties described in more detail below, which includes a more complete discussion of these risks. ● **Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to fluctuate, which could cause the value of our common stock to fluctuate or decline significantly.** ● We have incurred annual losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability. ● **Failure** ~~Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue~~ to ~~fluctuate~~ **remediate material weaknesses in** , ~~which~~ **or inherent limitations associated with, our internal control over financial reporting** could **result in material misstatements in** ~~cause the value of our common stock to fluctuate or our decline significantly~~ **financial statements** . ● If our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected. ● Sales of our assays for neurological indications have become increasingly important to our business, and any significant decrease in sales of such assays could have a material adverse effect on our business. ● We may ~~fail to achieve the intended cost savings, revenue improvement, and related benefits from our Restructuring Plan. ● We may~~ not be **successful** ~~able to obtain the anticipated product and quality- related benefits from our assay improvement program. ● Failure to remediate a material weakness~~ in **penetrating the diagnostics market** ~~, or inherent limitations associated with, our internal accounting controls could result in material misstatements in our financial statements~~ . ● Because a significant portion of our revenue comes from a few large customers, any significant decrease in sales to these customers, due to industry consolidation or otherwise, could harm our operating results. ● Our long- term results depend upon our ability to improve existing products, develop or acquire new technology, and develop, introduce and market new products successfully. ● ~~If defects~~ **Defects** ~~are discovered~~ **or other quality issues** in our products **could lead to** ~~, we may incur additional~~ unforeseen costs, **product recalls, adverse regulatory actions, negative publicity, and litigation, including product liability claims, any of which could cause customers to decide not to purchase** our products ~~may be subject to recalls~~ , **harm** ~~customers may not purchase our products,~~ our reputation ~~may suffer~~ , and ~~ultimately~~ **negatively affect** our sales ~~and~~ **,** operating **results** ~~earnings could be negatively affected. ● We may seek to enter into strategic collaborations~~ and **financial condition** ~~licensing arrangements with third parties, but we may not be successful in establishing or maintaining such arrangements~~ . ● We generate a substantial portion of our revenue internationally and we expect this will continue in the future; as a result, our business is subject to various risks relating to our international activities, which could adversely affect our business, operating results and financial condition. ● We rely on a single contract manufacturer to manufacture and supply our Simoa HD- X instrument and rely on a different single contract manufacturer to manufacture and supply our Simoa SR- X. If either of these manufacturers should fail to perform, or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected. ● We rely on a limited number of suppliers or, in some cases, one supplier, for some of our materials and components used in our consumable products and our SP- X instrument, and we may not be able to find replacements or immediately transition to alternative suppliers if any of these suppliers fail to perform, which could have a material adverse effect on our business, financial condition, results of operations and reputation. ● **We face significant competition in** ~~Epidemic diseases, such as COVID- 19 and its variants, and other~~ -- **the life sciences research** ~~events could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers~~ and **diagnostic markets** ~~/ or result in reduced demand from our customers, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows~~ . ● If the FDA determines that our products are subject to regulation as medical devices **, if the FDA modifies its regulations to require that our LDTs are subject to regulation as devices,** or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance (s) or approval (s) and may be required to cease or limit sales of our then- marketed products, which could materially and adversely affect our business, financial condition and results of operations. Any such regulatory process would be expensive, time- consuming and uncertain both in timing and in outcome **. ● If we do not comply with governmental regulations applicable to our CLIA- certified laboratory, we may not be able to continue our operations or continue offering our LDTs** . ● Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation ~~. 38 ● If we do not comply with governmental regulations applicable to our CLIA- certified laboratory, we may not be able to continue our operations or continue offering our LDTs~~ . ● If we are unable to protect our intellectual property, our ability to maintain any technological or competitive advantage over our competitors and potential competitors may be reduced and our business may be harmed. ● If we or any of our partners are sued for infringing intellectual property rights of third parties, the resulting litigation would be costly and time- consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business. ● ~~We may not be able to protect our~~

~~intellectual property rights throughout the world, which could have a materially adverse effect on our business. ●~~ Our stock price may fluctuate significantly. Risks Related to Our Financial Condition **Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue to** fluctuate,which could cause the value of our common stock to fluctuate or decline significantly.Numerous factors,many of which are outside of our control,may cause or contribute to significant fluctuations in our quarterly and annual operating results.These fluctuations may make financial planning and forecasting difficult.In addition, ~~these fluctuations may result in unanticipated decreases in our available cash,which could negatively affect our business and prospects.In addition,~~ one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others ~~.As a result~~ , **and** comparing our operating results on a period- to- period basis might not be meaningful.Investors should not rely on our past results as indicative of our future performance.Moreover,our stock price might be based on expectations of future performance that are unrealistic or that we might not meet and,if our revenue or operating results fall below the expectations of investors or securities analysts,the **price of our common stock could decline significantly.** We have incurred annual losses since we were formed and expect to incur losses in the future. We cannot be certain that we will achieve or sustain profitability. We incurred net losses of $ **32. 3 million, $** 96. 7 million ~~,~~ **and** $ 57. 7 ~~million and $ 31. 5~~ million for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~402~~ **434** . ~~2 5~~ million. We cannot predict if or when we will achieve profitability or if or when we will be able to sustain ~~such~~ profitability once achieved. We expect that our losses will continue at least through the next 24 months as we ~~continue to invest funds for technology development, including our assay redevelopment program designed to improve our ability to manufacture and deliver high- quality assays at scale and~~ execute our strategy for our entry into translational pharma and clinical **diagnostic** markets. We may incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Annual Report on Form 10- K, the market acceptance of our products, competitive products, future product development and our market penetration and margins. **Failure** ~~Our quarterly and annual operating results and cash flows have fluctuated in the past and might continue~~ to **remediate** fluctuate, which could cause the value..... Any of these factors could have a material ~~adverse effect on our financial condition, operating results and business. Failure to remediate a material weakness~~ **weaknesses** in, or inherent limitations associated with, ~~internal accounting controls could result in material misstatements in our financial statements. Our management has identified material weaknesses in our~~ internal control over financial reporting ~~related~~ **could result in material misstatements in our financial statements. In our Annual Report on Form 10- K for the year ended December 31, 2022, we identified four material weaknesses in our internal control over financial reporting, relating** to the operating effectiveness of our internal controls associated with **:** (i) the accounting for inventory, including excess and obsolescence reserves **(the " Inventory MW ")** , (ii) the accounting for ~~salary~~ **salaries** and commissions expense **(the " Compensation MW ")** , (iii) the financial statement close process, including financial reporting, share- based compensation and non- recurring transactions such as impairment of assets and accounting for leases **(the " Financial Statement Close Process MW ")** , and (iv) the accounting for property and equipment, net ~~. See~~ **(the** " **Property** ~~Item 9A. Controls~~ and ~~Procedures~~ **Equipment MW** " **)** . **20During 2023** ~~A material weakness is a deficiency~~ , **we took a number of actions designed to improve or our** ~~a combination of deficiencies, in~~ internal control over financial reporting **to remediate** ~~, such that there~~ **these** ~~is a reasonable possibility that a~~ material **weaknesses. Based** ~~misstatement of the Company' s annual or interim financial statements will not be prevented or detected~~ on **these efforts, and after demonstrating the operating effectiveness of the related internal controls for** a **sufficient period of** ~~timely~~ -- **time** ~~basis. As a result~~ , **our** management has concluded that **the Financial Statement Close Process MW and Compensation MW were remediated as of December 31** , ~~due to such~~ **2023. However, management also concluded that control deficiencies did exist as of December 31, 2023, and that these control deficiencies constituted** material weaknesses ~~,~~ **in** our ~~disclosure~~ **internal control over financial reporting. Specifically, management concluded that a portion of the Inventory MW related to the valuation of our inventory, including excess and obsolescence reserves (the " Inventory Valuation MW ") and the Property and Equipment MW continued to exist as of December 31, 2023. The primary cause of the Inventory Valuation MW is our reliance on manual processes to verify the completeness and accuracy of information used in our inventory valuation outputs, and the adequacy and documentation of reviews over these outputs. For the Property and Equipment MW, while the related internal** controls **were implemented** and ~~procedures~~ **effective as of December 31, 2023, they** were not **in all cases in place for a sufficient period of time to demonstrate operating** ~~effective~~ **effectiveness** as of December 31, ~~2022~~ **2023 . For a discussion of these material weaknesses and our efforts to remediate them, please see " Item 9A. Controls and Procedures "** . Our efforts to ~~improve our~~ **remediate the outstanding material weaknesses, and to maintain effective** internal ~~controls~~ - **control over financial reporting,** are ongoing; however, there are inherent limitations in all control systems and no evaluation of controls can provide absolute assurance that all deficiencies have been detected. ~~If we are unable to maintain effective~~ **We cannot assure you that additional material weaknesses in our** internal control over financial reporting ~~,~~ **will not arise** or **be identified in the future. If** after having remediated ~~such~~ **the remaining** material weaknesses ~~, fail~~ **we are unable** to maintain the effectiveness of our internal control over financial reporting or our disclosure controls and procedures, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline **,** and we could be subject to regulatory scrutiny, civil or criminal penalties or litigation. Continued or future failure to maintain effective internal control over financial reporting could also result in financial statements that do not accurately reflect our financial condition or results of operations, may result in material misstatements in our financial statements and may also restrict our future access to the capital markets. **During the year** ~~40We are currently implementing a plan intended~~ --- **ended December 31, 2023, we incurred significant expense and dedicated significant internal resources** to ~~remediate~~ **address** the material weaknesses described above ~~. The implementation~~ **, and we expect that the continued execution** of ~~this~~ **the** plan ~~could~~ **to remediate the remaining material weaknesses will** be costly and **will** distract management from other activities.

There can be no assurance that we will ~~not~~ conclude in the future that we have ~~not~~ effectively remediated ~~these~~ -- **the remaining** material weaknesses ~~and they continue to exist~~ or that we will not identify any significant deficiencies or other material weaknesses that will impair our ability to report our financial condition and results of operations accurately or on a timely basis. Our ability to use net operating losses to offset future income may be subject to certain limitations. As of December 31, ~~2022~~ **2023** , we had federal net operating loss (**“** NOLs **”**) carryforwards to offset future taxable income of approximately $ ~~309~~ **313** . ~~7~~ **4** million, which begin to expire in 2026. A lack of future taxable income would adversely affect our ability to utilize these NOLs. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended (the **“** Code **”**), a corporation that undergoes an “ ownership change ” is subject to limitations on its ability to utilize its NOLs to offset future taxable income. We have already experienced ownership changes as defined under Section 382 of the Code. Depending on the timing of any future utilization of our NOLs, the amount that can be utilized each year may be limited as a result of such previous ownership changes. In addition, future changes in our stock ownership, including changes that may be outside of our control, could result in additional ownership changes under Section 382 of the Code. Our NOLs may also be impaired under similar provisions of state law. We have recorded a full valuation allowance related to our NOLs and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. Risks Related to Our BusinessIf our products fail to achieve and sustain sufficient market acceptance, our revenue will be adversely affected. Our success depends on our ability to develop and market products that are recognized and accepted by our customers and potential customers as reliable, enabling and cost-effective. Continued market acceptance of our Simoa ~~technology~~ **21technology** platform and products and other platforms and products we may develop in the future will depend on many factors, including our ability to convince potential customers that our technology is an attractive alternative to other available technologies. ~~Historically, a significant part of our sales and marketing efforts has been directed at demonstrating the advantages of our technology to industry leaders and encouraging such leaders to publish or present their evaluation of our system. We also need to demonstrate to current and prospective customers that our products can help them accomplish their objectives in a cost- effective and efficient manner.~~ If we are unable to continue to motivate **customers** ~~leading researchers~~ to use Simoa technology or other technologies we may develop, ~~or if such researchers are unable to achieve or unwilling to publish or present significant experimental results using our systems, acceptance and~~ adoption of our ~~systems~~ **technology** may be slowed and our ability to retain and grow our customer base and increase our revenue would be adversely affected ~~. Our future success is dependent upon our ability to retain and further penetrate our existing customer base and attract new customers. Our success will depend upon our ability to successfully retain, respond to the evolving needs of, and increase our market share among, existing customers and add new customers. Identifying, cultivating, engaging and marketing to customers requires substantial time, expertise and expense and involves a number of risks, including that: ● we may not have the ability to attract, retain and manage the sales, marketing and service personnel necessary to expand market acceptance for our Simoa technology or other platforms we may develop in the future; ● the time and cost of maintaining and growing a specialized sales, marketing and service force may be better spent elsewhere; and ● our sales, marketing and service force may be unable to accomplish their goals. 41We have utilized third parties to assist with sales, distribution and customer support in certain regions of the world. When we enter into such arrangements, there is no guarantee that we will be successful in attracting desirable sales and distribution partners. There is also no guarantee that we will be able to enter into such arrangements on favorable terms. Any failure of our sales and marketing efforts, or those of any third- party sales and distribution partners, would adversely affect our business~~ . Sales of our assays for neurological indications have become increasingly important to our business, and any significant decrease in sales of such assays could have a material adverse effect on our business. Neurology has been one of our primary focus areas for commercialization of our Simoa technology and the services that we provide to our customers. Sales from neurological- related biomarkers have become an increasingly important part of our business. There can be no assurance that we will continue to derive meaningful revenues from the sale of our neurological products, from services related to neurodegenerative conditions or from sales of instruments driven by customers desiring access to our technology for work relating to neurological conditions. The adoption by our customers of competitive technologies for detecting biomarkers of neurodegenerative conditions could negatively impact our revenues and have a material adverse effect on our business. We may ~~fail to achieve the intended cost savings, revenue improvement, and related benefits from our Restructuring Plan. In August 2022, we announced a plan of restructuring and strategic re- alignment, which included the elimination of 119 positions, or 25 % of our workforce at the time, and other cost- savings measures (the Restructuring Plan). We incurred expenses of approximately $ 3. 8 million related to the Restructuring Plan in the third and fourth quarter of 2022, substantially all of which were cash expenditures for severance and other costs relating to the Restructuring Plan. Overall, as a result of the Restructuring Plan we expect to realize estimated annualized operating expense savings of approximately $ 25 million. However, these estimates are subject to a number of assumptions, and actual results may differ. There is no guarantee that the Restructuring Plan will achieve its intended benefits. For example, our cost restructuring and business re- alignment efforts may~~ not ~~result~~ **be successful** in **penetrating** ~~the anticipated savings or other~~ -- **the diagnostics market** ~~economic benefits and could result in total costs and expenses that are greater than expected, each of which could have an adverse effect on our business. As part of the Restructuring Plan, we do not currently, nor do we intend to in the future, occupy the additional space acquired under the Bedford facilities lease agreement. We are reviewing our alternatives with respect to this space. These alternatives may include sub- leasing all, or a portion, of the Bedford facilities~~ . We believe **our Simoa technology has the capability to enable the development of a new category of less- invasive diagnostic tests** that ~~the Billerica office~~ **could replace current invasive** , ~~laboratory~~ **expensive,** and **inconvenient diagnostic methods. Accordingly, we have begun to expand into the diagnostics market. Transitioning from research use only to also serving the diagnostics market entails significant risks, including: ● significant investments in product development, scaling** manufacturing ~~space will be sufficient~~ **processes, marketing and sales activities, regulatory compliance, reimbursement and billing activities and infrastructure** to ~~meet~~ **support the foregoing; ● navigating complex regulatory frameworks,**

including but not limited to FDA regulations and equivalent agencies internationally; ● competition from products that may offer superior performance, pricing, ~~our~~ **or** ~~needs for~~ **convenience, and prevent us from penetrating target markets effectively; and ● challenges associated with obtaining adequate reimbursement from government healthcare programs and private insurers. Further, our progress in penetrating the diagnostics market may be slower than we intend and may require a substantially larger investment than we expect. If we are unable to manage** ~~the~~ **these** ~~foreseeable future. Refer~~ **risks effectively, our efforts** to **penetrate** ~~Note 12 to~~ the ~~consolidated~~ **diagnostics market may be unsuccessful, and our business, operating results and** financial **condition** ~~statements for further details related to the Bedford lease. The Restructuring Plan may cause disruption to our business operations, and we may fail to effectively execute on the Restructuring. We may not be able to obtain the anticipated product and quality- related benefits from our assay improvement program. In connection with the Restructuring Plan, we have implemented an assay improvement program designed to improve our ability to manufacture and deliver high- quality assays at scale. We made initial progress toward this initiative in 2022, and we expect that the program will be completed in 2023. We may not be able to obtain the anticipated product and quality- related benefits from these efforts. Further, we may be delayed in completing this program. Delays in completing the assay improvement program or our inability to fully realize the anticipated product and quality- related benefits~~ could **suffer** ~~materially and adversely affect our revenue and cash flows and could undermine customer confidence in our products and adversely affect our business~~. The sales cycle for our Simoa instruments can be lengthy and variable, which makes it difficult for us to forecast revenue and other operating results. The sales process for our Simoa instruments generally involves numerous interactions with multiple individuals within an organization, and often includes in- depth analysis by potential customers of our technology and products and a lengthy review process. Our customers' evaluation processes often involve a number of factors, many of which are ~~42beyond~~ -- **beyond** our control. As a result of these factors, the capital investment required to purchase our systems, and the budget cycles of our customers, the time from initial contact with a customer to our receipt of a purchase order can vary significantly **. In 2023, these factors resulted in softness in sales of our instruments** . Given the length and uncertainty of our sales cycle, we have in the past experienced, and expect in the future to experience, fluctuations in our sales on a period- to- period basis. In addition, any failure to meet customer expectations could result in customers choosing to retain their existing systems, using existing assays not requiring capital equipment, or purchasing systems other than ours. ~~Because~~ **22Because** a significant portion of our revenue comes from a few large customers, any significant decrease in sales to these customers, due to industry consolidation or otherwise, could harm our operating results. One customer accounted for ~~13~~ **greater than 10** % of our total revenue for the year ended December 31, ~~2022~~ **2023** , and several other customers accounted for a significant portion of our total revenue. The loss of a significant amount of business from one or more of our major customers would have a material adverse effect on our business. There can be no assurance that there will not be a loss or reduction in business from one or more of our major customers. In addition, we cannot assure that net sales from customers that have accounted for significant net sales in the past, either individually or as a group, will reach or exceed historical levels in any future period. Our long- term results depend upon our ability to improve existing products and introduce and market new products successfully. We generally sell our products in industries that are characterized by rapid technological changes, frequent new product introductions and changing industry standards. Accordingly, our business is dependent on the continued improvement of our existing Simoa products and our development of new products utilizing Simoa or other technology we develop or acquire. As we introduce new products or refine, improve or upgrade versions of existing products, we cannot predict the level of market acceptance or the amount of market share these products will achieve, if any. We cannot guarantee that we will not experience material delays in the introduction of new products in the future. In addition, ~~introducing~~ - **introduction of** new products could result in a decrease in revenues from ~~our~~ existing products. Consistent with our strategy of offering new products and product refinements, we have invested substantial capital on research and development, and we expect to continue to use a substantial amount of capital for product research and development. Our research and development initiatives can be costly and time- consuming, and they may fail to achieve the intended benefits ~~. We may need more capital for product research and development than is available on terms favorable to us, if at all~~ . If we do not develop new products and product enhancements based on technological innovation on a timely basis, our products may become obsolete over time and our revenues, cash flow, profitability and competitive position will suffer. ~~If defects~~ **Defects** ~~are discovered~~ **or other quality issues** in our products **could lead to** ~~, we may incur additional~~ unforeseen costs, **product recalls, adverse regulatory actions, negative publicity, and litigation, including product liability claims, any of which could cause customers to decide not to purchase** our products ~~may be subject to recalls~~ , **harm** ~~customers may not purchase our products,~~ our reputation ~~may suffer~~ , and ~~ultimately~~ **negatively affect** our sales ~~and~~ **,** operating **results and financial condition** ~~earnings could be negatively affected~~ . Our Simoa products are complex and may contain undetected errors or defects, especially when first introduced or as new versions or new products are released. ~~New products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment.~~ We **have in the past devoted, and will** continue to ~~invest funds for~~ **devote, funding and resources to** technology development ~~and~~ **,** quality assurance ~~, including~~ **and manufacturing initiatives designed to ensure** ~~our~~ - **or improve quality, such as the** assay redevelopment program **initiated in 2022** ~~, which is designed to improve our ability to manufacture and deliver high- quality assays at scale~~ . However, there can be no assurance that we will be successful in our efforts **to manufacture products at a level of quality necessary for our customers or** to avoid our products containing undiscovered defects **or quality issues** . Defects ~~or~~ **,** errors **or quality issues** in our products may discourage customers from purchasing our products ~~. Disruptions affecting the introduction or release of, or other performance problems with, our products may damage our customers' businesses~~ and could harm ~~their and~~ our reputation ~~. If that occurs, we may incur significant costs, the attention of our key personnel could be diverted or other significant customer relations problems may arise~~ . We may also be subject to warranty **claims** and ~~liability~~ **litigation involving** claims for damages ~~related~~ **or incur additional costs, in each case due** to errors or defects in our products. In addition, if we do not meet industry or quality standards, if applicable, our products

may be subject to recall **, and products subject to the FDA' s medical device regulations could be required to be recalled under such regulations** . A material liability claim, recall or other occurrence that harms our reputation or decreases market acceptance of our products could harm our business and operating results. ~~43Use~~ -- **Use** of our products or services by us or a customer for diagnostic purposes could result in a product liability claim alleging that one of our products contained a design or manufacturing defect that resulted in the failure to adequately perform, leading to death or injury. A product liability claim could result in substantial damages and be costly and time- consuming to defend, either of which could materially harm our business or financial condition. We cannot guarantee that our product liability insurance would adequately protect our assets from the financial impact of defending a product liability claim. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing insurance coverage in the future. ~~We may seek to enter into additional strategic collaborations and licensing arrangements with third parties, but we may not be successful in establishing or maintaining such arrangements. We may seek to enter into additional strategic collaborations and licensing agreements with third parties to develop products based on our Simoa technology, such as for certain IVD purposes. However, we may not be successful in doing so. Establishing collaborations and licensing arrangements is difficult and time- consuming, and discussions may not lead to collaborations or licenses on favorable terms, if at all. Even if we establish such relationships, if our partners do not prioritize and commit sufficient resources to develop and sell products based on our Simoa technology, such relationships may never result in the successful development or commercialization of products based on our Simoa technology. Our~~ **23Our** reliance on distributors for sales of our products outside of the United States could ~~limit or prevent us from selling our products and could~~ impact our revenue. We have established ~~exclusive~~ distribution agreements for our Simoa instruments and related consumable products ~~within~~ -- **with distributors in** certain foreign countries, including Australia, Brazil, China, the Czech Republic, India, Hong Kong, Israel, Japan, New Zealand, Qatar, Saudi Arabia, Singapore, South Africa, South Korea, Taiwan and the UAE. We intend to continue to grow our business internationally, and to do so we must attract additional distributors and retain existing distributors to maximize the commercial opportunity for our products. There is no guarantee that we will be successful in attracting or retaining desirable sales and distribution partners or that we will be able to enter into such arrangements on favorable terms. Distributors may not commit the necessary resources to market and sell our products to the level of our expectations or may choose to favor marketing the products of our competitors. If current or future distributors do not perform adequately, or if we are unable to enter into effective arrangements with distributors in particular geographic areas, we may not realize long- term international revenue growth. In addition, if our distributors fail to comply with applicable laws and ethical standards, including anti- bribery laws, this could damage our reputation and could have a significant adverse effect on our business and our revenues. We generate a substantial portion of our revenue internationally and we expect this will continue in the future; as a result, our business is subject to various risks relating to our international activities, which could adversely affect our business, operating results and financial condition. For the years ended December 31, **2023,** 2022, **and** 2021, ~~and 2020,~~ approximately **37 %,** 38 % ~~,~~ **and** 36 ~~% and 31~~ %, respectively, of our total revenue was generated from customers located outside of North America. We believe that a substantial percentage of our future revenue will continue to come from international sources as we expand our overseas operations and develop opportunities in additional areas. Engaging in international business involves a number of difficulties and risks, including: ● **difficulties and costs of staffing and managing foreign operations;** ● required compliance with existing and changing U. S. or foreign regulatory requirements and laws ~~; ● difficulties and costs of staffing and managing foreign operations~~ ; ● a shortage of high- quality salespeople and distributors; ● pricing pressure that we may experience internationally ~~; 44 ● difficulties in maintaining consistency with our internal guidelines~~ ; ● difficulties in enforcing our intellectual property rights and in defending against third- party threats and intellectual property enforcement actions against us or any of our distributors, suppliers or collaborators; ● reduced or varied protection for intellectual property rights in some countries; ● required compliance with anti- bribery laws, such as the U. S. Foreign Corrupt Practices Act, data privacy requirements, such as the GDPR, labor laws and anti- competition regulations; ● export or import restrictions and supply chain disruptions; ● laws and business practices favoring local companies; ● longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; ● the imposition of restrictions on the activities of foreign agents, representatives and distributors; ● foreign currency exchange rate fluctuations; ● the imposition of U. S. or international sanctions against a country, company, person or entity with whom we do business that would restrict or prohibit continued business with the sanctioned country, company, person or entity; ● the impact of political and economic instability and conflict, which could lead to uncertainty and instability in global financial markets; ● scrutiny of foreign tax authorities which could result in significant fines, penalties and additional taxes being imposed on us; ● the imposition of new trade restrictions; and ● potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers. **24If** ~~Historically, most of our revenue has been denominated in U. S. dollars. In the future,~~ we ~~may sell our products and services in local currency outside of the United States. As our operations in countries outside of the United States grow, our results of operations and cash flows may be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. For example, if the value of the U. S. dollar increases relative to foreign currencies, in the absence of a corresponding change in local currency prices, our revenue could be adversely affected as we convert revenue from local currencies to U. S. dollars. If we dedicate significant resources to our international operations and~~ are unable to manage these risks effectively, our business, operating results and financial condition will suffer . We could be adversely affected by..... penalties, disgorgement and other remedial measures . We rely on a single contract manufacturer to manufacture and supply our Simoa HD- X instrument and rely on a different single contract manufacturer to manufacture and supply our Simoa SR- X instrument. If either of these manufacturers should fail to perform, or not perform satisfactorily, our ability to supply these instruments would be negatively and adversely affected. We currently rely on a single contract manufacturer, STRATEC, an analytical and diagnostic systems manufacturer located in Germany, to manufacture and supply all of our Simoa HD- X instruments. In addition, we currently rely on a single contract manufacturer,

Paramit, a contract manufacturer located in California, to manufacture and supply all of our SR- X instruments. Since our contract with STRATEC does not commit them to supply quantities beyond the amounts included in our forecasts and our contract with Paramit does not commit them to carry inventory or make available any particular quantities, ~~these contract manufacturers may give other customers' needs higher priority than ours, and~~ we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If either of these manufacturers were not able to supply instruments, our business would be harmed. In the event it becomes necessary to utilize a different contract manufacturer for the HD- X instrument or the SR- X instrument, we would experience additional costs, delays and difficulties in doing so as a result of needing to identify and enter into an agreement with a new supplier as well as needing to prepare such new supplier to meet the logistical requirements associated with manufacturing our instruments, and our business would suffer. We may also experience additional costs and delays in the event we need access to or rights under any intellectual property of STRATEC. In addition, certain of the components used in our instruments are sourced by these manufacturers from limited or sole suppliers. If they were to lose such suppliers, there can be no assurance that they would be able to identify or enter into agreements with alternative suppliers on a timely basis on acceptable terms, if at all. An interruption in our ability to sell and deliver instruments to customers could occur if our manufacturers encounter delays or difficulties in securing these components, or if the quality of the components supplied do not meet specifications, or if they cannot then obtain an acceptable substitute. If any of these events occur, our business and operating results could be harmed. We rely on a limited number of suppliers or, in some cases, one supplier, for some of our materials and components used in our consumable products and services and our SP- X instrument, and we may not be able to find replacements or immediately transition to alternative suppliers if any of these suppliers fail to perform, which could have a material adverse effect on our business, financial condition, results of operations and reputation. We rely on limited or sole suppliers for certain reagents and other materials and components that are used in our consumable products and services and in our SP- X instrument. While we have long- term contracts with some critical suppliers, we do not have contracts with all suppliers and instead rely on periodically forecasting our needs for such materials and entering into standard purchase orders with our suppliers. In addition, our use of many of the materials used in our consumable products is limited to research use only. As we expand into diagnostic applications for our products, we will need to secure diagnostic rights to such materials. If we were to lose suppliers or were unable to secure required rights for materials from suppliers, there can be no assurance that we will be able to identify or enter into ~~46agreements~~ -- **agreements** with alternative suppliers on a timely basis and on acceptable terms, if at all. An interruption in our operations could occur if we encounter delays or difficulties in securing these materials or any required rights to these materials, if the quality of the materials supplied do not meet our requirements, or if we cannot then obtain an acceptable substitute. The time and effort required to qualify a new supplier and ensure that the new materials provide the same or better quality results could result in significant additional costs. Any such interruption could significantly affect our business, financial condition, results of operations and reputation. **25We** ~~Increased demand may cause us to experience delays in production or backlogs in deliveries that could limit the growth of our revenue or increase our losses. A significant unforecasted increase in demand for our products may result in delays or shortfalls in our production and backlogs in deliveries. If we are unable to keep up with demand for our products, our revenue could be impaired, market acceptance for our products~~ could be adversely affected **by violations of the U. S. Foreign Corrupt Practices Act** and **other worldwide anti- bribery laws by us** ~~our~~ **or** ~~customers might instead purchase~~ **our agents. We are subject to the U. S. Foreign Corrupt Practices Act (the " FCPA "), which prohibits companies and individuals from corruptly making payments, directly** ~~our~~ **or** ~~competitors~~ **indirectly through third parties, to non- U. S. government officials for the purpose of obtaining or retaining business or securing any other improper advantage. We are also subject to the FCPA ' s accounting provisions, which require us to keep accurate books and records and to maintain a system of internal accounting controls sufficient to assure management' s control, authority and responsibility over our assets. Our reliance on independent distributors to sell our** products ~~. Our inability to successfully manufacture~~ **internationally demands a high degree of vigilance in maintaining** our ~~products~~ **policy against participation in corrupt activity, because there are circumstances under which we** ~~would~~ **could be held responsible for their actions. Other U. S. companies in the medical device and pharmaceutical fields** have faced criminal penalties under the FCPA for allowing their distributors and other third parties to deviate from appropriate practices in doing business with these individuals.We are also subject to similar anti- bribery laws in the jurisdictions in which we operate,including the United Kingdom' s Bribery Act of 2010,which also prohibits commercial bribery and makes it a crime for companies to fail to prevent bribery.These laws are complex and far- reaching in nature,and **any violations** ~~,as a result,we cannot guarantee that we would not be required in the future to alter one or more~~ of ~~our practices to be in compliance with~~ these laws **,** or ~~any changes~~ **allegations of such violations,could disrupt our operations,involve significant management distraction,involve significant costs and expenses,including legal fees,and could result** in a material adverse effect on our ~~operating~~ **business, prospects, financial condition, or** results **of operations. We could also incur severe penalties, including criminal and civil penalties, disgorgement and other remedial measures** . The life sciences research and diagnostic markets are highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer. We face significant competition in the life sciences research and diagnostic markets. We currently compete with both established and early- stage companies that design, manufacture and market systems and consumable supplies. Many of our current competitors have competitive advantages over us, including: ● greater name and brand recognition; ● substantially greater financial and human resources; ● broader product lines; ● larger sales forces and more established distributor networks; ● more substantial intellectual property portfolios; ● larger and more established customer bases and relationships; and ● better established, larger scale and lower cost manufacturing capabilities. We cannot guarantee that our products will compete favorably or that we will be successful in the face of increasing competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot guarantee that our competitors do not have or will not develop products or technologies that currently or in the future will enable

them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results. Integrating any business, product or technology we acquire can be expensive and time- consuming and can disrupt and adversely affect our ongoing business, including product sales, and distract our management. We may acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses ~~, such as our 2018 acquisition of Aushon and our 2019 47acquisition of Uman~~ . Our ability to successfully integrate any business, product or technology we acquire depends on a number of factors, including, but not limited to, our ability to: ● minimize the disruption and distraction of our management and other employees ~~, including our sales force,~~ in connection with the integration of any acquired business, product or technology ~~; ● minimize disruption in relationships with customers, distributors or suppliers as a result of such a transaction~~ ; ● avoid acquisition of unanticipated liabilities related to acquired companies; ● maintain and increase sales of our existing products; **26** ● establish or manage the transition of the manufacture and supply of any acquired product; ● identify and add the necessary sales, marketing, manufacturing, regulatory and other related personnel, capabilities and infrastructure that are required to successfully integrate any acquired business, product or technology; ● manage the transition and migration of acquired personnel and all commercial, financial, legal, regulatory and other pertinent information relating to any acquired business, product or technology; ● comply with legal, regulatory and contractual requirements applicable to any acquired business, product or technology; and ● maintain and extend intellectual property protection for any acquired product or technology. If we are unable to perform the above functions or otherwise effectively integrate any acquired businesses, products or technologies, our business, financial condition and operating results will suffer. ~~Foreign acquisitions (such as our acquisition of Uman) involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.~~ Also, the anticipated benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. ~~Epidemic diseases, such as COVID- 19 and its variants, and other events could negatively affect various aspects of our business, make it more difficult to meet our obligations to our customers and / or result in reduced demand from our customers, each of which could have a material adverse effect on our business, financial condition, results of operations or cash flows. Our business could be adversely affected by the effects of a widespread outbreak of contagious disease, such as COVID- 19 and its variants, or as a result of natural disasters or other catastrophic events. Potential impacts to our business include disruptions to or restrictions on our employees' and customers' ability to travel, temporary closures of the facilities of our suppliers or customers, delays in installation of instruments and delays in shipments to and from affected countries. Any such travel restrictions and business closures could adversely impact our operations locally and worldwide, including our ability to manufacture, sell or distribute our products, as well as cause temporary closures of our foreign distributors, or the facilities of suppliers or customers. Any material disruption of our employees, distributors, suppliers or customers in impacted countries could impact our global sales and operating results. In addition, if any of these events adversely 48affect the economies and financial markets of countries in which we sell our products and services, resulting in an economic downturn, demand for our products could be affected and could adversely impact our operating results.~~ Risks Related to Government Regulation and Diagnostic Product ~~ReimbursementIf~~ -- **Reimbursement If** the FDA determines that our products are subject to regulation as medical devices **, if the FDA modifies its regulations to require that our LDTs are subject to regulation as devices,** or if we seek to market our products for clinical diagnostic or health screening use, we will be required to obtain regulatory clearance (s) or approval (s) ~~and may be required to cease or limit sales of our then marketed products, which could materially and adversely affect our business, financial condition and results of operations~~ . Any such regulatory process would be expensive, time- consuming and uncertain both in timing and in outcome. We focused initially on the life sciences research market. This includes offering products for use by laboratories associated with academic and governmental research institutions, as well as pharmaceutical, biotechnology and contract research companies. Accordingly, the majority of our products are labeled as " Research Use Only ". While we focused initially on the life sciences research market and RUO products only, our strategy includes expanding our product line to encompass products that are intended to be used for the diagnosis of disease, including LDTs and IVD devices, either alone or in collaboration with third parties. ~~Other than our LDTs, such~~ IVD products **are** ~~, once developed and offered, will be~~ subject to regulation by the FDA, or comparable international agencies, as medical devices including requirements for regulatory clearance or approval of such products before they can be marketed. The process of obtaining regulatory clearances to market a medical device can be costly and time consuming, and we or our collaborators may not be able to obtain these clearances or approvals on a timely basis, if at all. In general, the FDA permits commercial distribution of a new medical device only after the device has received clearance under Section 510 (k) of the Federal Food, Drug and Cosmetic Act **(" FDCA ")** , or is the subject of an approved PMA, unless the device is specifically exempt from those requirements. The FDA will clear marketing of a lower risk medical device through the 510 (k) process if the manufacturer demonstrates that the new product is substantially equivalent to ~~other~~ **a legally marketed predicate device, which can include** pre- amendment, 510 (k)- exempt, 510 (k) cleared products, or PMA- approved products that have subsequently been down- classified. If the FDA determines that the device is not " substantially equivalent " to a predicate device, or if the device is novel, it is automatically classified into Class III, and the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek ~~reclassification~~ -- **classification** of the device through the de novo classification process ~~. Pursuant to amendments to the statute in 2012, a manufacturer can also submit a petition for a direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. Class III devices, which are high risk devices deemed to pose the~~

~~greatest risk, such as life- sustaining, life- supporting, or implantable devices, require the approval of a PMA~~ . The PMA process is more costly, lengthy and uncertain than the 510 (k) clearance process. A PMA application must be supported by extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA' s satisfaction the safety and efficacy of the device for its intended use. **If any** ~~Foreign governmental authorities that regulate the manufacture and sale~~ of **our products are subject to** medical ~~devices~~ **device** ~~have become increasingly stringent and, to the extent we market and sell our products internationally for such uses, we may be subject to rigorous international~~ regulation ~~in the future. In these circumstances~~ , we ~~may rely significantly on our foreign independent distributors or collaborators to comply with the varying regulations, and any failures on their part could result in restrictions on the sale of our products in foreign countries. If we or our collaborators are required to obtain a PMA or 510 (k) clearance for products based on our technology, we or they~~ would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, QSRs — which cover the design, testing, production, control, quality assurance, labeling, packaging, servicing, sterilization (if required), and storage and shipping of medical devices (among other activities) — product labeling, advertising, recordkeeping, ~~post~~ **27post** - market surveillance, post- approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we ~~or a collaborator~~ may develop using our technology may also require clinical trials in order to generate the data required for a PMA, de novo classification request or 510 (k) premarket notification. Complying with these requirements may be time- consuming and ~~49expensive~~ - **expensive** . We ~~or our collaborators~~ may be required to expend significant resources to ensure ongoing compliance with the FDA regulations ~~and / or take satisfactory corrective action in response to enforcement action, which may have a material adverse effect on the ability to design, develop, and commercialize products using our technology as planned~~ . Failure to comply with these requirements may subject us ~~or a collaborator~~ to a range of enforcement actions, such as warning letters, injunctions, civil monetary penalties, criminal prosecution, recall and / or seizure of products, and revocation of marketing authorization, as well as significant adverse publicity. If we ~~or our collaborators~~ fail to obtain, or experience significant delays in obtaining, regulatory approvals for IVD products, such products may not be able to be launched or successfully commercialized in a timely manner, or at all. LDTs are a subset of IVD tests that are offered as services by **CLIA- certified** high complexity clinical laboratories and designed, manufactured and used within a single laboratory. In July 2022, we launched an LDT to quantitatively measure ~~pTau~~ **p** - **Tau** 181 in plasma as an aid in diagnostic evaluation of Alzheimer' s disease, and in January 2023, we launched an LDT to quantitatively measure NfL in serum as an aid in the evaluation of individuals for possible neurodegenerative conditions or other causes of neuronal or central nervous system damage. The FDA maintains that LDTs are medical devices and has **,** for the most part **,** exercised enforcement discretion for most LDTs, meaning that the FDA has not required LDTs to obtain premarket approval or clearance or comply with post- market medical device requirements. A significant change in the way that the FDA regulates ~~any~~ **LDTs could affect our business. Most recently, in September 2023, FDA announced a proposed rule regarding** LDTs that ~~we, our collaborators or our customers develop using our technology could~~ **would** ~~affect our business~~ **make explicit that in vitro diagnostic products are devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer is a laboratory** . The **proposed rule also describes a policy under which** FDA ~~has considered the appropriate way to regulate such tests, but after publishing several draft guidances in 2014 and holding a number of public hearings and workshops, no final guidance has been issued, as the FDA indicated the agency~~ would ~~defer to a legislative~~ **provide greater oversight of LDTs by phasing out its general enforcement discretion** approach ~~. Congress~~ **, and** ~~has~~ **phase in medical** ~~considered several bills that would have imposed a new FDA regulatory framework (with many similarities to the current~~ device ~~framework)~~ **regulation,** for LDTs **over a period of four years. FDA requested comment on several aspects of its proposal** and ~~IVD devices~~ **approach, including whether certain types of LDTs should remain under enforcement discretion. Currently FDA' s target date for final action on this rule is April 2024** , but ~~to date~~ **we cannot predict the ultimate timing or form of FDA guidance or regulation** , **legislative action or their potential impact. Any new regulatory approach for LDTs by the FDA, including** ~~has~~ **as described in the September 2023 proposed rule, would likely lead to an increased regulatory burden, including additional costs and delays in introducing new tests, and potentially a requirement for our current LDTs to receive premarket clearance or approval from FDA to continue offering them after the enforcement discretion phaseout is complete. Any new regulatory approach could also result in our tests being removed from the market if we are** not **able to secure regulatory clearance** ~~passed such legislation. However, if Congress~~ or ~~the~~ **approval from** FDA ~~requires~~ **. FDA' s rule could also have impacts on our business more broadly, given that many of our customers would be subject to additional regulation and delays, which could potentially affect the development of new diagnostics that incorporate our instruments or consumables. This also may increase costs and regulatory burdens on** laboratories **that develop** ~~to undergo premarket review and comply with other applicable FDA requirements in the future, the cost and time required to commercialize an LDT~~ **LDTs** ~~will increase substantially~~ , **thereby reducing** ~~and may reduce~~ the financial incentive for laboratories to develop **new** LDTs **or invest in instruments** , which could reduce demand for our instruments and our other products ~~. The FDA could also take enforcement action against us if it determines the tests we have currently launched as LDTs do not fall within the agency' s definition of an LDT and therefore do not fall within the scope of the agency' s enforcement discretion for LDTs~~ . Foreign jurisdictions have laws and regulations similar to those described above, which may adversely affect our ability to market our products as planned in such countries. The number and scope of these requirements are increasing. As in the United States, the cost and time required to comply with regulatory requirements may be substantial, and there is no guarantee that we will obtain the necessary authorization (s) required to make our products commercially viable. In addition, the imposition of foreign requirements may also have a material adverse effect on the commercial viability of our operations. Our products may in the future be subject to product recalls that could harm our reputation, business and financial results. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products, including RUO products, in the event of material deficiencies or defects in design or

manufacture. In the case of the FDA, the authority to require a recall **of a medical device** must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government- mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. **28U** ~~The FDA requires that certain recalls (including field corrections and removals) be reported to the FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted. 50U~~ . S. legislative, FDA or global regulatory reforms may make it more difficult and costly for us to obtain any required regulatory approval of our product candidates and to manufacture, market and distribute our products after approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory approval, manufacture and marketing of regulated products or the reimbursement thereof. For example, in December 2022, Congress enacted the Food and Drug Omnibus Reform Act of 2022 (**"** FDORA **"**). FDORA reauthorized the FDA to collect device user fees and contained substantive amendments to the device provisions of the FDCA, including imposing new cybersecurity and clinical trial requirements for devices. Congress has also considered, but not yet passed, legislation to impose a new FDA regulatory framework for **all diagnostics, including** IVD devices and LDTs. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. **For example, in September 2023, the FDA issued a proposed rule to change the FDA' s regulatory approach to LDTs. Under the proposed rule, FDA would phase out its current enforcement discretion approach for LDTs, and phase in medical device regulation, over a period of four years.** It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be ~~. Moreover, leadership, personnel and structural changes within the FDA as well as recent and future federal election outcomes could result in significant legislative and regulatory reforms impacting the FDA' s regulation of our products~~ . Any change in the laws or regulations that govern the clearance and approval processes relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. Significant delays in receiving clearance or approval, or the failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business. In addition, in the E. U. new regulations recently entered into force that result in greater regulation of medical devices and IVDs. The IVD Regulation is significantly different from the IVD Directive that it replaces in that it ensures that the new requirements apply uniformly and on the same schedule across the member states, includes a risk- based classification system and increases the requirements for conformity assessment. The CE registration for Uman' s ~~Nf~~ **NfL** ~~- L~~ ELISA assay kit for cerebral spinal fluid was approved in March 2014 under the IVD Directive. Under the IVD Directive the assay is classified as a general IVD product, ~~class I~~ and required self- certification with no involvement of a notified body / authority. The IVD Regulation introduces a new classification system for IVDs and assessment by a notified body is required for class B, C and D products. Uman' s ~~Nf~~ **NfL** ~~- L~~ ELISA assay kit for CSF is classified as a class B product and must fully comply with (and have a CE mark issued under) the IVD Regulation by May 2027 **(subject to proposed extension of the transitional periods in the IVD Regulation)** . The new requirements include an ISO 13485 certification of the quality system (which Uman received **in** July 2018) and increased technical evidence and follow- up of performance of the specific product (e. g. clinical evidence and post-market activities). The work to evaluate and to meet the new technical requirements is on- going. ~~In order to continue to sell our products in the E. U., we must maintain our CE marks and comply with the IVD Regulation.~~ Our failure to continue to comply with applicable foreign regulatory requirements, including those administered by authorities of the European Economic Area (**"** EEA **"**) countries, could result in enforcement actions against us, including refusal, suspension or withdrawal of our CE Certificates of Conformity by our notified body, which could impair our ability to market products in the EEA in the future ~~. Any changes to the membership of the E. U., such as the departure of the United Kingdom, may impact the regulatory requirements for the impacted countries and impair our business operations and our ability to market products in such countries~~ . If we do not comply with governmental regulations applicable to our CLIA- certified laboratory, we may not be able to continue our Accelerator laboratory operations or continue offering our LDTs ~~. The operation of our CLIA- certified laboratory is subject to regulation by numerous federal, state and local governmental authorities in the United States. This laboratory holds a CLIA certificate of compliance and is licensed by the Commonwealth of Massachusetts and the State of Maryland, and we may obtain other state licenses if required in the future. Failure to comply with federal or state regulations or changes in those regulatory requirements could result in a substantial curtailment or even prohibition of the operations of our laboratory and could have an adverse effect on our business~~ . CLIA is a federal law that regulates clinical laboratories that perform ~~testing on~~ **examination of** human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the ~~51assessment --~~ **assessment** of health of, human beings **. The operation of our CLIA- certified laboratory is subject to regulation by numerous federal, state and local governmental authorities in the United States. This laboratory holds a CLIA certificate of compliance for high- complexity testing and is licensed by California, Maryland, Massachusetts, Pennsylvania and Rhode Island, and we may obtain other state licenses if required in the future. Failure to comply with federal or state regulations or changes in those regulatory requirements could result in a substantial curtailment or even prohibition of the operations of our laboratory and could have an adverse effect on our**

business . To maintain CLIA certification, laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make unannounced ~~inspections~~ **29inspections** of these laboratories. If we were to lose our CLIA certification or any required state licenses, whether as a result of a revocation, suspension or limitation, it could have a material adverse effect on our business. We expect to rely on third parties in conducting any required future studies of diagnostic products that may be required by the FDA or other regulatory authorities, and those third parties may not perform satisfactorily. We do not have the ability to independently conduct clinical trials or other studies that may be required to obtain FDA and other regulatory clearance or approval for future diagnostic products. Accordingly, we expect that we would rely on third parties, such as clinical investigators, contract research organizations, consultants, and collaborators to conduct such studies if needed. For example, we are currently working with the Alzheimer' s Drug Discovery Foundation and the Global Alzheimer' s Platform Foundation on prospective clinical trials for our assays. Our reliance on these third parties for clinical and other development activities would reduce our control over these activities. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised, we may not be able to obtain regulatory clearance or approval. If diagnostic procedures that are enabled by our technology are subject to unfavorable pricing regulations or third- party coverage and reimbursement policies, our business could be harmed. The ability of us, our customers or our collaborators to commercialize diagnostic tests based on our technology, including our recently launched LDTs, will depend in part on the extent to which coverage and reimbursement for these tests will be available from government health **care** programs, private health insurers and other third- party payors. In the United States, the principal decisions about reimbursement for new technologies are often made by CMS. Private payors often follow CMS' s reimbursement policies to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of payments for particular products and procedures. We cannot be sure that coverage will be available for any diagnostic tests based on our technology, and, if coverage is available, the level of reimbursement. Payor coverage and reimbursement decisions may impact the demand for those tests. If coverage is not available or the reimbursement amount is inadequate, any tests for which marketing authorization is received may not be able to be successfully commercialized. ~~Current and future legislation may increase the difficulty and cost to obtain marketing approval of and to commercialize any products based on our technology and affect the prices that may be obtained. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the ACA), is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. As a result, certain sections of the ACA have not been fully implemented or were effectively repealed. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels and the number of insured individuals, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively affect our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we or our collaborators will receive for any cleared or approved product. Any reduction in payments from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare 52reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any of our products for which we receive marketing approval. In addition, sales of our tests outside of the United States will subject us to foreign regulatory requirements, which may also change over time. We cannot predict whether future healthcare initiatives will be implemented at the federal or state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us. Any such initiatives may result in decreased profits to us, lower reimbursements by payors for our products or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.** Risks Related to Our OperationsWe depend on our information technology systems, and any failure of these systems could harm our business. We depend on information technology and telecommunications systems to operate our business. Our enterprise software systems affect a broad range of business processes and functional areas, including, for example, systems handling human resources, accounting, manufacturing, inventory control, financial controls and reporting, sales administration, and other infrastructure operations. We maintain preventative and detective security controls and seek to enhance such controls by, for example, augmenting the monitoring and alerting functions, network design, and automatic countermeasure operations of our technical systems. We also periodically assess the adequacy of our hardware and systems and are planning to upgrade hardware and systems where appropriate. These information technology and telecommunications systems support a variety of functions, including manufacturing operations, quality control, customer service support, finance **,** and other general administrative activities. Information technology and telecommunications systems are vulnerable to damage from a variety of sources, including telecommunications, systems or network failures, malicious human acts **,** and natural disasters. Moreover, despite network security and back- up measures, some of our servers are potentially vulnerable to physical or electronic break- ins, computer viruses, and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology and telecommunications systems, those measures may be inadequate and failures or significant downtime of our information technology or telecommunications systems or those used by our third- party suppliers could prevent us from operating our business and managing the administrative aspects of our business. Loss of data or a material delay in our access to our data due to a security breach ~~or~~ **30or** other interruption could also prevent us from operating our

business. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business. Cybersecurity breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. In the ordinary course of our business, we collect and store sensitive data, and intellectual property and proprietary business information owned or controlled by ourselves or our customers. This data encompasses a wide variety of business- critical information including research and development information, operational information, commercial information, and business and financial information. We face four primary risks relative to protecting this critical information: loss of access; inappropriate disclosure; inappropriate modification; and inadequate monitoring of our controls over the first three risks. The secure processing, storage, maintenance, and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses, breaches, interruptions due to employee error, malfeasance, faulty password management, lapses in compliance with privacy and security mandates, or other ~~53disruptions~~ **disruptions** . The risk of a security breach or disruption, particularly through cyber- attack or cyber intrusion, including by computer hackers, foreign governments **,** and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Our IT networks and related systems are essential to the operation of our business and our ability to perform day- to- day operations. Although we make efforts to maintain the security and integrity of these types of IT networks and related systems, and we have implemented various measures to manage the risk of a security breach or disruption, **no security measure is infallible and** there can be no assurance that our security efforts and measures will be effective or that attempted security breaches or disruptions ~~would~~ **will** not be successful or damaging. Our information technology systems may have vulnerabilities, and we may not have the resources or technical sophistication to anticipate or prevent rapidly evolving types of cyberattacks, such as ransomware attacks. **Although we have experienced cybersecurity incidents from time to time that have not had a material adverse effect on our business, financial condition, or results of operations, there can be no assurance that a cyber- attack, security breach, or other cybersecurity incident will not have a material adverse effect on us in the future.** A significant cyber incident, including system failure, security breach, disruption by malware or other damage, could interrupt or delay our operations, result in a violation of applicable cybersecurity and privacy and other laws, damage our reputation, cause a loss of customers **,** or expose sensitive customer data, or give rise to monetary fines and other penalties, which could be significant ~~. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost, or stolen~~ . Third parties may attempt to fraudulently induce employees or other persons into disclosing usernames, passwords **,** or other sensitive information, which may in turn be used to access our information systems, commit identity theft or carry out other unauthorized or illegal activities. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost **,** or stolen. We engage third- party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, malicious software, phishing schemes, and fraud. Our ability to monitor our vendors and service providers' data security is limited, and ~~, in any event,~~ third parties may be able to circumvent ~~those~~ **any** security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third- party service providers' systems. We and our third- party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third- party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third- party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management' s attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. ~~Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing- attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant additional expenses. Any~~ **31Any** ~~such~~ security breach or interruption, as well as any action by us or our employees or contractors that might be inconsistent with the rapidly evolving data privacy and security laws and regulations applicable within the United States and elsewhere where we conduct business, could result in enforcement actions by ~~U. S. states~~ **state or** ~~, the U. S.~~ federal ~~government~~ **governments** or foreign governments, liability or sanctions under data privacy laws that protect personally identifiable information, regulatory penalties, other legal proceedings such as but not limited to private litigation, the incurrence of significant remediation costs, disruptions to our development programs, business operations and collaborations, diversion of management efforts and damage to our reputation ~~, which could harm our business and operations~~ . Because of the rapidly moving nature of technology and the increasing sophistication of cybersecurity threats, our measures to prevent, respond to and minimize such risks may be unsuccessful. In addition, our insurance may be insufficient to cover our losses resulting from cyber- attacks, breaches, or other interruptions, and any incidents may result in loss of, or increased costs of, such insurance. The successful assertion of one or more large claims against us that exceed available insurance coverage, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation. ~~54We~~ **We** are currently subject to, and may in the future become subject to additional, U. S. federal and state **and international** laws and regulations imposing obligations on how we collect, store and process personal information. Our

actual or perceived failure to comply with such obligations could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our future customer base, and thereby decrease our revenue. In the ordinary course of our business ~~,~~ we ~~currently, and in the future will,~~ collect, store, transfer, use or process sensitive data, including personally identifiable information of employees, and intellectual property and proprietary business information owned or controlled by ourselves and other parties. The secure processing, storage, maintenance, and transmission of this critical information are vital to our operations and business strategy. We are, and may increasingly become, subject to various laws and regulations, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws and regulations may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that may have a material adverse effect on our business, financial condition, results of operations and prospects. In the United States, various federal and state regulators, including governmental agencies like the Federal Trade Commission, have adopted, or are considering adopting, laws and regulations concerning personal information and data security. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to personal information than federal, international **,** or other state laws, and such laws may differ from each other, all of which may complicate compliance efforts. For example, the California Consumer Privacy Act (the **“** CCPA **”**), which increases privacy rights for California residents and imposes obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide ~~new~~ disclosures to California consumers ~~and provide such consumers new~~ **regarding the processing of their personal data, as well as** data protection and privacy rights, including the ability to opt- out of certain sales **or sharing** of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. In November 2020, California also passed the California Privacy Rights Act (the **“** CPRA **”**), which **became effective on January 1, 2023 and** significantly expands the CCPA, including by introducing additional obligations such as data minimization and storage limitations and granting additional rights to consumers. ~~In 2021~~ **More recently** , **other states, including Connecticut, Colorado, Utah and** Virginia **have** ~~and Colorado both~~ passed comprehensive state data privacy **laws, and states like Washington and Nevada have enacted consumer health privacy laws. Most of these laws are enforced by state attorneys general, but there is the potential for private actions by plaintiffs in some circumstances under certain** laws. In addition, laws in all 50 U. S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U. S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. These and future laws and regulations may increase our compliance costs and potential liability. ~~Furthermore~~ **32Furthermore** , regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information (known as “ protected health information ”) and require the implementation of administrative, physical **,** and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can require complex factual and statistical analyses and may be subject to changing interpretation. Although we take measures to protect sensitive data from unauthorized access, use or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost **,** or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, HITECH **,** and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media. Such a notice could harm our reputation and our ability to compete. **Outside** ~~In addition, the European Parliament and the Council~~ of the ~~E. U. adopted~~ **United States, many countries have privacy and data security laws and regulations concerning the collection and use of personal data, including but not limited to** the GDPR **and China’ s Personal Information** ~~in 2016 to replace the European Union Data~~ Protection **Law (“ PIPL ”)** ~~Directive and related country- specific legislation~~ . The GDPR **, which** ~~took effect in May 2018~~ ~~55and~~ governs the collection and use of personal data in the E. U. **and** ~~The GDPR, which~~ is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third- party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the E. U. to the United States, enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to € 20 million or 4 % of the annual global revenues of the infringer, whichever is greater. While we have taken steps to comply with the GDPR, including reviewing our security procedures and entering into data processing agreements with relevant contractors, we cannot guarantee that our compliance efforts will be fully successful ~~. Further, unauthorized access, loss or dissemination of sensitive information could also disrupt our operations, including our ability to conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business, any of which could adversely affect our reputation and our business. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our products could be delayed. We face risks~~

~~related to handling of hazardous materials and other regulations governing environmental, health and safety. Our operations are subject to complex and stringent federal, state and local environmental, health, safety and other laws and regulations that both public officials and in some circumstances private individuals may seek to enforce. Our activities that are subject to these laws and regulations include, among other things, our use of hazardous materials and the generation, transportation, disposal and storage of waste. Although we have secured clearance from the EPA historically, and currently are operating in compliance with applicable EPA rules and regulations, our business could be adversely affected if we discover that we or an acquired business is not in material compliance with these rules and regulations. In the future, we may pursue the use of other surfactant substances that will require clearance from the EPA, and we may fail to obtain such clearance. Existing laws and regulations may also be revised or reinterpreted, or new laws and regulations may become applicable to us, whether retroactively or prospectively, that may have a negative effect on our business and results of operations. It is also impossible to eliminate completely the risk of accidental environmental contamination or injury to individuals. In such an event, we could be liable for any damages that result, which could adversely affect our business~~ . Risks Related to Intellectual PropertyIf we are unable to protect our intellectual property, our ability to maintain any technological or competitive advantage over our competitors and potential competitors may be reduced, and our business may be harmed. We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection and contractual restrictions to protect our proprietary technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. Our currently pending or future patent applications may not result in granted patents, and we cannot predict how long it will take for such patents to be granted. It is possible that, for any of our patents that have granted or that may grant in the future, others will design around our patented technologies. Further, other parties may challenge any patents granted to us and courts or regulatory agencies could hold our patents to be invalid or unenforceable. We may not be successful in defending challenges made against our patents and patent applications. Any successful third- party challenge to our patents could result in the unenforceability or invalidity of such patents, or to such patents being interpreted narrowly or otherwise in a manner adverse to our interests. Our ability to establish or maintain a technological or competitive advantage over our competitors may be diminished because of these uncertainties. For ~~56these~~ -- **these** and other reasons, our intellectual property may not provide us with any competitive advantage. To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition. If our intellectual property does not provide adequate coverage over our products and protection against our competitors' products, our competitive position could be adversely affected, as could our business. ~~In~~ **33In** addition to pursuing patents on our technology, we also rely upon trademarks, trade secrets, copyrights and unfair competition laws, as well as license agreements and other contractual provisions, to protect our intellectual property and other proprietary rights. Despite these measures, any of our intellectual property rights could be challenged, invalidated, circumvented or misappropriated. In addition, we take steps to protect our intellectual property and proprietary technology by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, when needed, our advisors. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. Moreover, if a party having an agreement with us has an overlapping or conflicting obligation to a third party, our rights in and to certain intellectual property could be undermined. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time- consuming, the outcome would be unpredictable, and any remedy may be inadequate. In addition, courts outside of the United States may be less willing to protect trade secrets. Some of our owned and in- licensed intellectual property has been discovered through government- funded programs and thus is subject to federal regulations such as " march- in " rights, certain reporting requirements, and a preference for U. S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non- U. S. manufacturers. Some of the intellectual property rights we own and have in- licensed have been generated through the use of U. S. government funding and are therefore subject to certain federal regulations. For example, some of the issued U. S. patents we own and all of the intellectual property rights licensed to us under our license agreement with Tufts have been generated using U. S. government funds. As a result, the U. S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh- Dole Act of 1980 ~~(the Bayh- Dole Act)~~ . These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as " march- in rights "). The U. S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U. S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U. S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference

requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances. ~~If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh- Dole Act. To the extent any of our current or future intellectual property is generated through the use of U. S. government funding, the provisions of the Bayh- Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects. 57Our~~ -- **Our** Simoa bead- based technology is licensed to us by Tufts University. Any loss of our rights to this technology **or other technologies we license** could prevent us from selling our products. Our Simoa bead- based technology is licensed exclusively to us from Tufts University (**“** Tufts **”**). We do not own the patents that underlie this license. Our rights to use this technology and employ the inventions claimed in the licensed patents are subject to the continuation of and compliance with the terms of the license. Our principal obligations under our license agreement with Tufts are as follows: ● making royalty payments; **34** ● making milestone payments; ● paying annual maintenance fees for the underlying patents; ● using commercially reasonable efforts to develop and sell a product using the licensed technology and developing a market for such product; ● paying and / or reimbursing fees related to prosecution, maintenance and enforcement of patent rights; and ● providing certain reports. If we breach any of these obligations, Tufts may have the right to terminate the license, which could result in our being unable to develop, manufacture and sell products using our Simoa bead- based technology or a competitor gaining access to the Simoa technology. Termination of our license agreement with Tufts would have a material adverse effect on our business. In addition, we are a party to a number of other agreements that include licenses to intellectual property, including non- exclusive licenses. We expect that we may need to enter into additional license agreements in the future. Our business could suffer materially and adversely, for example, if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. ~~We may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future products, and we cannot provide any assurances that we would be able to do so. We may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our current or future products, and we cannot provide any assurances that third- party patents do not exist that might be enforced against our current or future products in the absence of such a license. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we could not obtain a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation. Licensing of intellectual property involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain the licensing arrangements on acceptable terms, 58we may be unable to successfully develop and commercialize the affected product, or the dispute may have an adverse effect on our results of operation. In addition to agreements pursuant to which we in- license intellectual property, we have in the past and expect in the future to grant licenses under our intellectual property. Like in- licenses, out- licenses are complex, and disputes may arise between us and our licensees. Moreover, our licensees may breach their obligations, or we may be exposed to liability due to our failure or alleged failure to satisfy our obligations. Any such occurrence could have an adverse effect on our business.~~ If we or any of our partners are sued for infringing intellectual property rights of third parties, the resulting litigation would be costly and time- consuming, and an unfavorable outcome in that litigation could have a material adverse effect on our business. Our success also depends on our ability to develop, manufacture, market and sell our products and perform our services without infringing upon the proprietary rights of third parties. ~~Numerous U. S.- and foreign- issued patents and pending patent applications owned by third parties exist in the fields in which we are developing products and services.~~ As part of a business strategy to impede our successful commercialization and entry into new markets, competitors have claimed, and may claim in the future, that our products and / or services infringe their intellectual property rights and have suggested, and may suggest in the future, that we enter into license agreements. ~~Any~~ **We believe any** such claims made to date are ~~, we believe,~~ without merit. **However,** ~~Even~~ **even** if such claims are without merit, we could incur substantial costs and divert the attention of our management and technical personnel in defending ourselves against claims of infringement made by third parties or settling such claims. Any adverse ruling by a court or administrative body, or perception of an adverse ruling, may have a material adverse impact on our ability to conduct our business and our finances. Moreover, third parties making claims against us may be able to obtain injunctive relief against us, which could block our ability to offer one or more products or services and could result in a substantial award of damages against us. In addition, since we sometimes indemnify customers, collaborators or licensees, we may have additional liability in connection with any infringement or alleged infringement of third ~~-~~party intellectual property. Because patent applications can take many years to issue, there may be pending applications, some of which are unknown to us, that may result in issued patents upon which our products or proprietary technologies may infringe. Moreover, we may fail to identify issued patents of relevance or incorrectly conclude that an issued patent is invalid or not infringed by our technology or any of our products. There is a substantial amount of litigation involving patent and other intellectual property rights in our industry. If a third party claims that we or any of our licensors, customers or collaboration partners infringe upon a third party’ s intellectual property rights, we may have to: ● seek to obtain licenses that may not be

available on commercially reasonable terms, if at all; ● abandon any infringing product or redesign our products or processes to avoid infringement; ● pay substantial damages **,** including, in ~~an~~ exceptional ~~case~~ **cases** , treble damages and attorneys' fees ~~, which we may have to pay if a court decides that the product or proprietary technology at issue infringes upon or violates the third- party' s rights~~ ; ● pay substantial royalties or fees or grant cross- licenses to our technology; or ● defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. ~~59We~~ **35We** may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents that we license. In the event of infringement or unauthorized use, we may file one or more infringement lawsuits ~~, which~~ **. Patent litigation** can be ~~expensive~~ **very costly** and time- consuming ~~. An adverse result in any such litigation proceedings could put one or more of our patents at risk of being invalidated , found to be unenforceable or interpreted narrowly,~~ and ~~it could put our patent applications at risk of not issuing. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there~~ -- **the outcome** is **uncertain** ~~a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Many of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could~~ . In addition, ~~the uncertainties associated with litigation could have a material adverse effect on our ability to raise any funds necessary to continue our operations, continue our internal research programs, in- license needed technology, or enter into development partnerships that would help us bring our products to market. In addition, patent litigation can be very costly and time- consuming. An adverse outcome in such litigation or proceedings may expose us or any of our future development partners to loss of our proprietary position, expose us to significant liabilities, or require us to seek licenses that may not be available on commercially acceptable terms,~~ if ~~at all. Our issued patents could be found invalid or unenforceable if challenged in court, which could have a material adverse impact on our business. If~~ we or any of our partners were to initiate legal proceedings against a third party to enforce a patent covering one of our products or services, the defendant in such litigation could counterclaim that our patent is invalid and / or unenforceable. In patent litigation ~~in the United States~~ , defendant counterclaims alleging invalidity and / or unenforceability are commonplace ~~. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement, or failure to claim patent eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO even outside of the context of litigation~~ . The outcome following legal assertions of invalidity and unenforceability is unpredictable. ~~With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution.~~ If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the challenged patent. Such a loss of patent protection ~~would~~ **could** have a material adverse impact on our business. We may not be able to protect our intellectual property rights throughout the world, which could have a material adverse effect on our business. Filing, prosecuting and defending patents on current and future products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside of 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 that federal and state laws do in the United States. Consequently, regardless of whether we are able to prevent third parties from practicing our inventions in the United States, we may not be able to prevent third parties from practicing our inventions in all countries outside of the United States, or from selling or importing products made by using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not pursued and obtained patent protection to develop their own products, and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as it is in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from competing. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time ~~-~~consuming process with uncertain outcomes. ~~60Accordingly~~ -- **Accordingly** , we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China and certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and 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 and may adversely impact our business. In addition, we and our partners also face the risk that our products are imported or reimported into markets with relatively higher prices from markets with relatively lower prices, which would result in a decrease of sales and any payments we receive from the affected market. Recent developments in U. S. patent law have made it more difficult to stop these and related practices based on theories of patent infringement. **36We** ~~Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products. Under the America Invents Act (the AIA), as of March 16, 2013, the United States transitioned to a " first- to- file "~~

~~system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to the filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions. Among some of the other changes introduced by the AIA are changes that limit where a patent holder may file a patent infringement suit and provide additional opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our owned and in- licensed U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings, compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Additionally, the U. S. Supreme Court has ruled on several patent cases in recent years, such as Impression Products, Inc. v. Lexmark International, Inc., Association for Molecular Pathology v. Myriad Genetics, Inc., Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Alice Corporation Pty. Ltd. v. CLS Bank International, either narrowing the scope of patent protection available in certain circumstances or weakening 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 U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. 61If 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, 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 by potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks. 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. We~~ use third- party software that may be difficult to replace or may cause errors or failures of our products that could lead to lost customers or harm to our reputation. We use software licensed from third parties in our products. In the future, this software may not be available to us on commercially reasonable terms, or at all. Any loss of the right to use any of this software could result in delays in the production of our products until equivalent technology is either developed by us, or, if available, is identified, obtained and integrated, which could harm our business. In addition, any errors or defects in third- party software or other third- party software failures could result in errors, defects or cause our products to fail, which could harm our business and be costly to correct. Many of these providers attempt to impose limitations on their liability for such errors, defects or failures, and if enforceable, we may have additional liability to our customers or third- party providers that could harm our reputation and increase our operating costs. ~~We will need to maintain our relationships with third- party software providers and to obtain software from such providers that does not contain any errors or defects. Any failure to do so could adversely impact our ability to deliver reliable products to our customers and could harm our reputation and results of operations.~~ Risks Related to Our Common Stock and Being a Public CompanyOur stock price has fluctuated significantly and may continue to fluctuate significantly. The market price of shares of our common stock has been and could continue to be subject to wide fluctuations in response to many factors listed in this section, and others beyond our control, including: ● actual or anticipated fluctuations in our financial condition and operating results; ● announcements by us, our partners or our competitors of new products, significant contracts, restructuring plans, strategic partnerships, joint ventures, collaborations, acquisitions, commercial relationships or capital commitments; ● competition from existing products or new products that may emerge; ● failure to meet or exceed financial estimates and projections of the investment community or that we may provide to the public; ● issuance of new or updated research or reports by securities analysts or recommendations with respect to our stock; ● positive or adverse regulatory announcements; ● disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; ~~62~~ ● commencement of, or our involvement in, litigation; ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● conditions in our markets; ● manufacturing disputes or delays **, product defects or material product quality control issues** ; ● any future sales of our common stock or other securities; ● any change to the composition of our board of directors or key personnel; ● general economic conditions and slow or negative growth of our markets **; ● a material cybersecurity incident** ; ● share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ● announcement or expectation of additional debt or equity financing efforts; and ● other factors described in this Risk Factors section of this Annual Report on Form 10- K. 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 common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general, and life science companies in particular, have experienced extreme 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 on occasion instituted securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit against us, the defense

and disposition of the lawsuit could be costly and divert the time and attention of our management and harm our operating results. **37** ~~If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts who cover us issues an adverse opinion about our company, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to regularly publish reports on us, we could lose visibility in the public markets, which could cause our stock price or trading volume to decline. We have never paid dividends on our capital stock, and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases. We have not paid dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the shareholders in the foreseeable future. Consequently, in the foreseeable future, shareholders will likely only experience a gain from an investment in our common stock if the price of our common stock increases. 63~~