Risk Factors Comparison 2025-03-17 to 2024-02-29 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 **Risks Related to the Merger and the Combined Company • The Merger may not be completed and the Merger Agreement may be terminated in accordance with its terms. • The market price for shares of our common stock may be affected by factors different from, or in addition to, those that historically have affected or currently affect the market price of shares of Akoya common stock. • Actions of activist or dissident stockholders could delay or prevent the approval of the Merger and negatively affect our business and operations. • The issuance of shares of our common stock to Akoya stockholders in connection with the Merger may cause the market price of our common stock to decline. • The Merger, and uncertainty regarding the Merger, may cause our customers, service providers, partners, vendors, suppliers and other business relationships to delay or defer decisions concerning us and adversely affect our ability to effectively manage our business, which could adversely affect our operating results and financial position and, following the completion of the Merger, the business, operating results and financial position of us and Akoya as a combined company (the " Combined Company "). • Whether or not the Merger is completed, the announcement and pendency of the Merger could cause disruptions in our business, which could have an adverse effect on our business and financial results. • The Merger Agreement contains provisions that could discourage a potential acquirer from acquiring or merging with us. • We expect to incur substantial costs related to the Merger and integration. • Combining our business and the business of Akoya may be more difficult, costly or time- consuming than expected and the Combined Company may fail to realize the anticipated benefits of the Merger, which may adversely affect the Combined Company' s business results and negatively affect the value of our common stock following completion of the Merger. Risks Related to** Our ~~business~~ **Business** ~~is~~ **• Failure to remediate material weaknesses in, or inherent limitations associated with, our internal control over financial reporting have resulted in, and in the future could result in, material misstatements in our financial statements. • The restatement of our financial statements as of December 31, 2023 and 2022 and for each of the three years in the period ended December, 31 2023 and for the quarterly and year- to- date (as applicable) periods ended March 31, 2022, June 30, 2022, September 30, 2022, March 31, 2023, June 30, 2023, September 30, 2023, March 31, 2024, and June 30, 2024 (the " Restatement ") may affect stockholder and investor confidence in us or harm our reputation, and may** subject **us** to ~~numerous~~ **additional** risks and uncertainties **, including increased costs and** ~~. The following summary highlights some of~~ the ~~risks to be considered with respect to~~ **increased possibility of legal proceedings and regulatory inquiries, sanctions** ~~our~~ **or investigations** ~~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 to remediate material weaknesses in, or inherent limitations associated with, our internal control over financial reporting could result in material misstatements in our 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 not be successful in penetrating the diagnostics market. • 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. • **We may experience delays in launching our next- generation instrument, Simoa ONE, on our anticipated timeline, which could adversely affect our business, financial condition, and results of operations. •** Defects or other quality issues in our products could lead to 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, harm our reputation, and negatively affect our sales, operating results and financial condition. • ~~• 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 **for** ~~to manufacture and supply~~ our Simoa HD- X instrument and ~~rely~~ on a different single contract manufacturer **for** ~~to manufacture and supply~~ our Simoa SR- X **instrument, and we expect to rely on a different single contract manufacturer for our new Simoa ONE instrument** . If ~~either~~ **any** 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 the life sciences research and diagnostic markets. ~~●~~ **• Changes in U. S. government policies, including increased tariffs and potential reductions in federal research funding, could adversely affect our business. •** 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 comply with medical device law, including in some cases a requirement** 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 **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. Risks Relating to the Merger The Merger is subject to a number of conditions that must be satisfied (or waived, to the extent permitted), including (i) receipt of the approval of the issuance of shares of our common stock in the Merger by our stockholders; (ii) receipt of the approval of the Merger by Akoya stockholders; (iii) the effectiveness of the registration statement on Form S- 4 filed with the SEC in connection with the Merger; (iv) the absence of any order issued or entered, or any law enacted or promulgated having the effect of restraining, enjoining, making illegal or otherwise prohibiting the consummation of the Merger; (v) the submission by us to Nasdaq of a notification of shares of our common stock to be issued in connection with the Merger; (vi) performance by each party of its respective obligations under the Merger Agreement; and (vii) the absence of a material adverse effect with respect to each of Akoya and us. These conditions to the completion of the Merger, some of which are beyond our control, may not be satisfied or waived in a timely manner or at all, and, accordingly, the Merger may be delayed or not completed. Additionally, either we or Akoya may terminate the Merger Agreement under certain circumstances, subject to the payment of a termination fee of $ 9 million by us to Akoya or $ 7 million by Akoya to us in certain cases. These termination fees may have the effect of discouraging alternative transaction proposals. We have incurred and will incur costs in connection with entering into the Merger Agreement and consummating the Merger, many of which will be payable by us whether or not the Merger is completed. Even if the Merger Agreement is terminated under circumstances that would require Akoya to pay us a $ 7 million termination fee, it may not cover all of the expenses and costs we have incurred. Failure to complete the Merger could negatively impact our future business and financial results and the trading price of our common stock. If the Merger is not completed for any reason, our ongoing business may be adversely affected and, without realizing any of the expected benefits of having completed the Merger, we would be subject to a number of risks, including the following: • we may experience negative reactions from the financial markets, including negative impacts on our stock price; • we may experience negative reactions from our customers, service providers, partners, vendors, suppliers and employees; • it could negatively impact our ability to achieve future growth, expand our addressable market and achieve scale and profitability on expected timelines; • we will have incurred substantial costs towards completion of the Merger and will generally be required to pay our costs relating to the Merger, such as financial advisory, legal, strategic advisory, accounting costs and associated fees and expenses, whether or not the Merger is completed; • we may provide up to $ 30 million in bridge financing to Akoya, which would be subordinated to Akoya' s existing credit facility, and if the Merger is not completed for any reason, Akoya may not have the financial resources to repay the bridge financing when due, or at all; and • we will have committed substantial time and resources to matters relating to the Merger (including integration planning) which would otherwise have been devoted to day- to- day operations and other opportunities that may have been beneficial to us as an independent company. Recently one of our stockholders has indicated that it intends to oppose the Merger. In addition, on March 3, 2025, the same stockholder announced that it is nominating three directors for election to the Board at our 2025 annual meeting of stockholders. As a result of these actions, we will incur significant expenses even if we are successful in completing the Merger or are successful in a potential proxy contest. In addition, perceived uncertainties as to our future direction, strategy, or leadership, and the diversion of management' s and our board of director' s attention and resources from our business, created by such activism may result in the loss of business opportunities and make it more difficult to complete strategic transactions or attract and retain investors, customers, employees, and other business partners. Such stockholder activism may also cause significant fluctuation in our stock price based on temporary or speculative market perceptions or other factors that** do not ~~comply~~ **necessarily reflect the underlying fundamentals and prospects of our business. We cannot predict the outcome or timing of any matters relating to stockholder activism or potential proxy contests or the ultimate impact that such matters may have on our business, liquidity, financial condition, or results of operations. Upon completion of the Merger, Akoya stockholders will receive 0. 318 (the " Exchange Ratio ") shares of our common stock for each share of Akoya common stock they hold. Based on 49, 588, 743 shares of Akoya common stock issued and outstanding as of February 1, 2025 and the Exchange Ratio, it is expected that we will issue approximately 15, 769, 220 shares of our common stock to Akoya stockholders in connection** with ~~governmental~~ **the Merger. In addition, Akoya restricted stock units (" RSUs ") and options to purchase Akoya common stock will be converted into RSUs for our common stock and options to purchase our common stock based on the Exchange Ratio upon completion of the Merger. Former Akoya stockholders may decide not to hold the shares of our common stock that they will receive in the Merger, and our stockholders may decide to reduce their investment in Quanterix as a result of the changes to our investment profile as a result of the Merger. Both the issuance of this amount of new shares in the Merger and any subsequent sales of these shares may cause the market price of our common stock to decline. After the Merger, our stockholders will have a reduced ownership and voting interest in the Combined Company and may not realize a benefit from the Merger commensurate with their ownership dilution. The Merger will**

dilute the ownership position of our stockholders and result in Akoya stockholders having an ownership stake in the Combined Company. Based on the number of shares of our common stock and Akoya common stock outstanding as of February 1, 2025, upon completion of the Merger, our current stockholders are expected to own approximately 71 % of our outstanding common stock and former Akoya stockholders are expected to own approximately 29 % of our outstanding common stock. If the Combined Company is unable to fully and timely realize the strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the Combined Company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger. Until the completion of the Merger or the termination of the Merger Agreement pursuant to our terms, we are prohibited from entering into certain transactions and taking certain actions that might otherwise be beneficial to us and our stockholders. From and after the date of the Merger Agreement and prior to the completion of the Merger or the termination of the Merger Agreement pursuant to our terms, the Merger Agreement restricts us from taking specified actions without the consent of Akoya and requires that our business be conducted in the ordinary course, subject to certain exceptions. These restrictions may prevent us from taking actions during the pendency of the Merger that would have been beneficial. Adverse effects arising from these restrictions during the pendency of the Merger could be exacerbated by any delays in the completion of the Merger or termination of the Merger Agreement. Obtaining required approvals and satisfying closing conditions may prevent or delay completion of the Merger, and ~~regulations~~ regulatory approvals may not be received, may take longer than expected or may impose conditions that are not presently anticipated or cannot be met. The Merger is subject to a number of conditions to closing. No assurance can be given that the required stockholder approvals can be obtained or that the required conditions to closing will be satisfied, and, if all required approvals are obtained and the required conditions are satisfied, no assurance can be given as to the terms, conditions and timing of such approvals. Any delay in completing the Merger could cause the Combined Company not to realize, or to be delayed in realizing, some or all of the benefits that we expect to achieve if the Merger is successfully completed within our expected time frame. Additionally, any delays in receipt of required regulatory approvals or satisfaction of the closing conditions will increase the length of time that we are subject to certain restrictive covenants under the Merger Agreement during the pendency of the Merger and increases the risk of disruptions to our operations and business relationships and the impediments to our ability to pursue certain business opportunities or strategic initiatives, which may in turn cause the Combined Company to not realize some or all of the expected benefits of the Merger or adversely impact our future financial and strategic conditions on a standalone basis if the required approvals and conditions to closing are not obtained or satisfied. Failure to attract, motivate and retain executives and other key employees could diminish the anticipated benefits of the Merger. The success of the Merger will depend in part on the Combined Company' s ability to retain the talent and dedication of key employees of each company. It is possible that these employees may decide not to remain with us or Akoya, as applicable **~~to~~, while the Merger is pending, ~~our~~ or ~~CLIA- certified laboratory~~ with the Combined Company following consummation of the Merger. If key employees of either company terminate their employment, or if an insufficient number of employees or sales representatives are retained to maintain effective operations, the Combined Company' s business activities may be adversely affected and management' s attention may be diverted from successfully integrating Quanterix and Akoya to hiring suitable replacements, all of which may cause the Combined Company' s business to suffer. In addition** , we **and Akoya** may not be able to ~~continue our operations~~ **locate suitable replacements ~~or~~ for ~~continue offering~~ any key employees that leave either company ~~our~~ or ~~LDTs~~ offer employment to potential replacements on reasonable terms** . **Moreover ~~● Cybersecurity breaches~~, ~~loss of data~~ there could be disruptions to or distractions for the workforce and management, including disruptions associated with integrating employees into the Combined Company. No assurance can be given that the Combined Company will be able to attract or retain key employees to the same extent that those companies have been able to attract or retain their own employees in the past. The Merger, and uncertainty regarding the Merger, may cause our customers, service providers, partners, vendors, suppliers** and other ~~disruptions could compromise sensitive information related to our~~ business **relationships to delay or defer decisions and adversely affect ~~or~~ our ~~prevent us from accessing critical information and expose us to liability~~ ability to effectively manage our business** , which could adversely affect our business **, operating results** and **financial position and, following the completion of the Merger, the Combined Company' s business, operating results and financial position. The Merger will happen only if certain stated conditions are met. Accordingly, there may be uncertainty regarding the completion of the Merger. This uncertainty may cause existing ~~our~~ or ~~reputation~~ prospective customers, service providers, partners, vendors, suppliers and other business relationships to delay or defer other decisions, including entering into contracts or making other decisions, or seek to change or cancel existing business relationships** . **~~● If~~ Additionally,** we are ~~unable~~ **subject** to ~~protect~~ **certain restrictive covenants under the Merger Agreement during the pendency of the Merger that may (i) cause us to delay ~~our~~ or ~~intellectual property~~ defer other decisions including entering into contracts or arrangements with existing or prospective customers** , **service providers, partners, vendors, suppliers and other business relationships or (ii) inhibit** our ability to ~~maintain~~ **take advantage of certain business opportunities or strategic initiatives. Any such disruptions such as delays or deferrals of those decisions or changes in existing agreements could adversely affect our business, operating results and financial position, whether the Merger is ultimately completed, and following the completion of the Merger, the Combined Company, including an adverse effect on the Combined Company' s ability to realize the anticipated synergies and other benefits of the Merger. The risk, and adverse effect, of** any ~~technological~~ **such disruptions could be exacerbated by a delay in completion of the Merger or termination of the Merger Agreement. Whether or not the Merger is completed, the announcement and pendency of the Merger could cause disruptions in ~~or~~ our ~~competitive advantage~~ business, including by diverting the**

attention of our management and employee team, such as those involved in day- to- day operations, toward the completion of the Merger. In addition, we have diverted significant management resources in an effort to complete the Merger and are each subject to restrictions contained in the Merger Agreement on the conduct of our business. If the Merger is not completed, we will have incurred significant costs, including the diversion of management resources, for which we will have received little or no benefit. The Merger Agreement contains provisions that could discourage a potential competing acquirer that might be willing to pay more to acquire or merge with us. The Merger Agreement contains provisions that make it more difficult for us to be acquired by, or enter into certain combination transactions with, a third party. The Merger Agreement contains certain provisions that restrict our ability to, among other things, solicit, initiate or knowingly encourage, or take any other action to knowingly facilitate any alternative transaction, participate in any discussions or negotiations, or cooperate in any way with any person, with respect to any alternative transaction or amend or grant any waiver of any standstill or similar agreement. In addition, following receipt by either us or Akoya of any alternative transaction proposal that constitutes a " superior proposal, " each of us or Akoya, respectively, will have an opportunity to offer to modify the terms of the Merger Agreement before our board or the Akoya board, respectively, may withdraw or qualify our recommendation to stockholders, with respect to the approval of the Merger, in favor of such superior proposal. If the Merger Agreement is terminated under specified circumstances, we may be required to pay a termination fee of $ 9 million to Akoya. These provisions could discourage a potential third- party acquirer, strategic transaction partner or business combination partner that might have an interest in acquiring or combining with all us or pursuing an alternative transaction from considering or proposing such a transaction. If the Merger Agreement is terminated we determine to seek another business combination transaction, we may not be able to successfully negotiate a transaction with another party on terms comparable to, or better than, the terms of the Merger. We have incurred and expect to incur substantial non- recurring costs associated with combining the operations of the two companies, as well as transaction fees and other costs related to the Merger. Such costs include, among others, filing and registration fees with the SEC, and legal, accounting, investment banking, consulting, public relations and proxy solicitation fees. Most of these costs are payable by us regardless of whether the Merger is completed. The Combined Company will also incur restructuring and integration costs in connection with the Merger. There are processes, policies, procedures, operations, technologies and systems that must be integrated in connection with the Merger and the integration of Akoya' s business into the Combined Company. Although we expect that the elimination of duplicative costs, strategic benefits and additional income, as well as the realization of other efficiencies related to the integration of the businesses, may offset incremental transaction expenses, Merger- related and restructuring costs over ~~our competitors and potential competitors~~ **time, any net benefit** may **not** be ~~reduced and~~ **achieved in the near term** ~~our~~ **or at all** ~~business may be harmed~~. **While** ~~● If~~ we **have assumed that certain expenses** ~~or any of our partners are sued for infringing intellectual property rights of third parties, the resulting litigation~~ would be ~~costly~~ **incurred in connection with the Merger and the other transactions contemplated by the Merger Agreement, there are many factors beyond our control that could affect the total amount or the timing of the integration and implementation expenses. Lawsuits or other legal proceedings may be filed against us, Akoya, the Combined Company and members of their respective boards of directors, in connection with the Merger, and** ~~and~~ **an adverse ruling in any such lawsuit may prevent the Merger from becoming effective or from becoming effective within the expected** time **frame** ~~, consuming~~, ~~and~~ **or have** an ~~unfavorable~~ **adverse impact on the Combined Company' s business and operations. Transactions such as the Merger are frequently subject to litigation or other legal proceedings, including actions alleging that our board or Akoya' s board breached their respective fiduciary duties to their stockholders by entering into the Merger Agreement, by failing to obtain a greater value in the transaction for their stockholders or otherwise. Neither we nor Akoya can provide assurance that such litigation or other legal proceedings will not be brought. If litigation or other legal proceedings are in fact brought against us or Akoya, or against our board or Akoya' s board, they will defend against it, but might not be successful in doing so. An adverse** outcome in ~~that litigation~~ **such matters, as well as the costs and efforts of a defense even if successful,** could have a material adverse effect on ~~our~~ **the** business **, results of operation or financial position of Quanterix, Akoya or the Combined Company, including through the possible diversion of either company' s resources or distraction of key personnel** . ~~● Our~~ **Furthermore, one of the conditions to the completion of the Merger is the absence of an order (whether temporary or permanent) issued or entered after the date of the Merger Agreement by any governmental body enjoining or otherwise prohibiting the consummation of the Merger. As such, if any plaintiffs are successful in obtaining an injunction preventing the consummation of the Merger, that injunction may prevent the Merger from becoming effective or from becoming effective within the expected time frame. If the Merger is completed, the Combined Company may be exposed to increased litigation or other legal proceedings from stockholders, customers, partners, suppliers, contractors and other third parties due to the merger of our and Akoya' s businesses following the Merger. Even if such lawsuits or other legal proceedings are without merit, defending against these claims can result in substantial costs and divert management time and attention. Such litigation or an adverse judgment resulting in monetary damages may have an adverse impact on the Combined Company' s business and results of operations or may cause disruptions to the Combined Company' s operations. Risks Relating to the Combined Company Combining the businesses of Quanterix and Akoya may be more difficult, costly or time- consuming than expected and the Combined Company may fail to realize the anticipated benefits of the Merger, which may adversely affect the Combined Company' s business results and negatively affect the value of our common** stock ~~price~~ **following the Merger. The success of the Merger will depend on, among other things, our ability to realize the anticipated benefits, synergies and efficiencies from combining the businesses of Quanterix and Akoya. This success will depend on, among other factors, our ability to integrate our business with the business of Akoya. If we are not able to successfully integrate Akoya' s business into the Combined**

Company within the anticipated time frame, or at all, the anticipated synergies, efficiencies and other benefits of the Merger may ~~fluctuate significantly~~ **not be realized fully, or at all, or may take longer to realize than expected. We and Akoya have operated and, until the completion of the Merger, will continue to operate independently. There can be no assurances that these businesses can be integrated successfully. It is possible that the integration process could result in the loss of key employees, a reduction in the ability to attract talent, the inability to maintain relationships with our and Akoya' s customers, service providers, partners, vendors, suppliers and other business relationships, the disruption of either company' s or both companies' ongoing businesses, inconsistencies in standards, controls, procedures and policies, unexpected integration issues, higher than expected integration costs and an overall post- completion integration process that takes longer than originally anticipated. The challenges involved in this integration, which will be complex and time- consuming, include the following: combining the businesses of Quanterix and Akoya, including respective operations and corporate functions, and meeting the capital requirements of the Combined Company in a manner that permits the Combined Company to achieve any revenue synergies or efficiencies anticipated to result from the Merger, the failure of which would result in the anticipated benefits of the Merger not being realized in the time frame currently anticipated or at all; • integrating, retaining and, where applicable, cross- training personnel from the two companies; • integrating the offerings and services available to customers; • integrating each company' s technologies and technologies licensed by them from third parties; • identifying and eliminating redundant and underperforming functions and assets; • harmonizing each company' s operating practices, employee development and compensation programs, internal controls and other policies, procedures and processes; • maintaining existing relationships with each company' s customers, service providers, partners, vendors and suppliers, and leveraging relationships with such third parties for the benefit of the Combined Company; • addressing possible differences in business backgrounds, corporate cultures and management philosophies; • consolidating each company' s administrative and information technology infrastructure; • coordinating geographically dispersed organizations; and • effecting actions that may be required in connection with obtaining regulatory or other governmental approvals. In addition, at times the attention of certain members of either company' s or both companies' management and resources may be focused on completion of the Merger and the integration of the businesses of the two companies and diverted from day- to- day business operations or other opportunities that may have been beneficial to such company, which may disrupt each company' s ongoing business and the business of the Combined Company. An inability to realize the full extent of the anticipated benefits of the Merger, as well as any delays or higher than expected integration costs encountered in the integration process, could have an adverse effect upon the revenues, level of expenses and operating results of the Combined Company, which may adversely affect the value of our common stock following the Merger. Certain customers may seek to modify contractual relationships with the Combined Company, which could have an adverse effect on the Combined Company' s business and operations. As a result of the Merger, the Combined Company may experience impacts on relationships with our customers that may harm the Combined Company' s business and results of operations. Certain counterparties may seek to terminate or modify contractual obligations following the Merger whether or not contractual rights are triggered as a result of the Merger. There can be no guarantee that our or Akoya' s contractual counterparties will continue to have a relationship with the Combined Company or do so on the same or similar contractual terms following the Merger. If any contractual counterparties (such as customers, service providers, partners, vendors or suppliers) seek to terminate or modify contractual obligations or discontinue the relationship with the Combined Company, then the Combined Company' s business and results of operations may be harmed. Completion of the Merger may trigger change in control, assignment or other provisions in certain agreements to which Akoya is a party, which may have an adverse impact on the Combined Company' s business and results of operations. The completion of the Merger may trigger change in control, assignment and other provisions in certain agreements to which Akoya is a party. If Akoya is unable to negotiate waivers of or consents under those provisions, the counterparties may exercise their rights and remedies under the agreements, potentially terminating the agreements or seeking monetary damages or other remedies. Even if Akoya is able to negotiate waivers, the counterparties may require a fee for such waivers or seek to renegotiate the agreements on terms less favorable to the Combined Company. Any of the foregoing or similar developments may have an adverse impact on the business, financial condition and results of operations of the Combined Company, or the ability of us to successfully integrate Akoya' s business** . Risks Related to ~~Our~~ **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~~ **Financial** planning and forecasting difficult. In addition..... with, internal control over financial reporting **Reporting Matters** ~~could result in material misstatements in our financial statements.~~ In our Annual Report on Form 10- K for the year ended December 31, 2022, **filed with the SEC on March 6, 2023,** we identified four material weaknesses in our internal control over financial reporting ~~,~~ relating to the operating effectiveness of our internal controls **, including a material weakness** associated with ~~:~~ (i) the accounting for inventory, including excess and obsolescence reserves (the " Inventory MW "), (ii) the accounting for 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 (the " Property and Equipment MW "). ~~20During~~ **In our Annual Report on Form 10- K for the year ended December 31,** 2023 **(the " 2023 Original Report "), filed with the SEC on February 29, 2024** , we **indicated that** ~~took a number of actions designed to improve our internal control over financial reporting to remediate these material weaknesses. Based on these efforts, and after demonstrating the operating effectiveness of the related internal controls for a sufficient period of time,~~ our management ~~has~~

concluded that the Financial Statement Close Process MW and Compensation MW were remediated ~~as of December 31, 2023~~. However, ~~management~~ **we** also concluded that control deficiencies ~~did exist~~ **existed** as of December 31, 2023, and that these control deficiencies constituted material weaknesses in our 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~~ **Subsequent to the filing** of **the 2023 Original Report, in Amendment No. 1 to our Annual Report on Form 10- K / A for the year ended December 31, 2023, filed with the SEC on December 26, 2024 (the " Amended Annual Report on Form 10- K / A "), we indicated that our management concluded that the Restatement in the Amended Annual Report on Form 10- K / A was a result of a newly identified design deficiency associated with** the Inventory Valuation MW ~~is our reliance~~ **, related to the Company' s internal controls over the capitalization of labor and overhead costs. Based** on ~~manual processes to verify the completeness and accuracy of information used in~~ our **efforts** ~~inventory valuation outputs,~~ and **after demonstrating** ~~the adequacy and documentation of reviews over these~~ -- **the operating effectiveness of** ~~outputs. For the Property and Equipment MW, while~~ the related internal controls ~~were implemented~~ **for a sufficient period of time, management has concluded that the Property** and ~~effective~~ **Equipment MW was remediated** as of December 31, ~~2023~~ **2024 . However** , **as of December 31, 2024,** ~~they~~ - **the** ~~were~~ **Inventory Valuation MW, including the additional control design deficiency, was** not **remediated and we have identified an additional material weakness** in ~~all cases in place~~ **the operating effectiveness of our internal controls associated with the accounting for Accelerator Laboratory revenue, a component of our service and other revenue. We are working to remediate these two outstanding material weaknesses, but will not be able to consider any material weakness remediated until the applicable remedial controls operate** for a sufficient period of time ~~to demonstrate~~ **and our management has concluded, through testing, that our controls are** operating ~~effectiveness~~ **effectively** ~~as of December 31, 2023. For a discussion of these material weaknesses and our efforts to remediate them, please see " Item 9A. Controls and Procedures "~~. Our efforts to remediate ~~the~~ outstanding material weaknesses, and to maintain effective internal 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. 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 **outstanding** ~~the remaining~~ material weaknesses 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. **We have** ~~During the year ended December 31, 2023, we~~ incurred significant expense and dedicated significant internal resources to address the material weaknesses described above, and we expect that the continued execution of the plan to remediate the remaining material weaknesses will **continue to** be costly and will distract management from other activities. There can be no assurance that we will conclude in the future that we have effectively remediated **outstanding** ~~the remaining~~ material weaknesses or that we will not identify any **additional** 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. ~~not,could adversely affect our business,financial condition,and results of operations.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,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,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 $ ~~38~~ **32** . ~~5~~ **3** million,$ ~~28~~ **96** . ~~4~~ **7** million ~~,~~and $ ~~99~~ **57** . ~~6~~ **7** million for the years ended December 31, ~~2024,~~2023, ~~and~~ 2022 **,and 2021** ,respectively.As of December 31, ~~2024~~ **2023** ,we had an accumulated deficit of $ ~~470~~ **434** . ~~1~~ **5** million.We cannot predict if or when we will achieve profitability or if or when we will be able to sustain profitability once achieved.We expect that our losses will continue at least through the next 24 months as we 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 to remediate material weaknesses in,or inherent limitations associated with,internal control over financial reporting** Our ability to use net operating losses to offset future income may be subject to certain limitations. As of December 31, ~~2023~~ **2024** , we had federal net operating loss (" NOLs ") carryforwards to offset future taxable income of approximately $ ~~313~~ **320** . ~~4~~ **0** million, **of** which **approximately $ 108. 5 million** 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~~ **our** ability to utilize ~~its~~ **our** NOLs to offset future taxable income. We **may** 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~~ **our** ~~BusinessIf~~ -- **Business** ~~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 ~~21technology~~ -- **technology** platform and products and other platforms and products we may develop in the future **, such as Simoa ONE,** will depend on many factors, including our ability to convince potential customers that our technology is an attractive alternative to other available technologies. If we are unable to continue to motivate customers to use Simoa technology or other technologies we may develop, adoption of our technology may be slowed and our ability to retain and grow our customer base and increase our revenue would 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~~. 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 not be successful in penetrating the diagnostics market. We~~ believe our Simoa technology has the capability to enable the development of a new category of less- invasive diagnostic tests that could replace current invasive, 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 processes, marketing and sales activities, regulatory compliance, reimbursement and billing activities and infrastructure to 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, or 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 these risks effectively, our efforts to penetrate the diagnostics market may be unsuccessful, and our business, operating results and financial condition could suffer. 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 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. ~~22Because~~ **Purchase of our Simoa instruments requires** a significant ~~portion~~ **capital investment which can impact sales in times** of **constrained spending. The purchase of** our ~~revenue comes from~~ **Simoa instruments requires** a ~~few large~~ **significant investment by our** customers, ~~any significant decrease~~ **and a reduction** in **capital spending by potential customers can result in lower instrument** sales ~~to these~~ **. During periods of constrained capital spending, potential instrument** customers ~~, due~~ **may instead choose** to **engage** ~~industry consolidation or our Accelerator lab otherwise, could harm our~~ **or an outside lab,** ~~operating results. One customer accounted for~~ **or** ~~greater~~ **may use another instrument platform that they already have or that is less expensive** than ~~10 % of our total revenue for~~ **the Simoa instruments. We believe that a constrained capital funding environment resulted in softness in instrument sales throughout 2024 and that this constrained spending environment will continue into 2025. For** the year ended December 31, ~~2023~~ **2024** , ~~and several other~~ **our top five** customers accounted for ~~a significant portion~~ **approximately 21 %** 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 **and timely** . 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, introduction of new products could result in a decrease in revenues from 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. 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. ~~Defects~~ **We currently expect to launch** ~~or~~ **our next- generation instrument, Simoa ONE, by the end of 2025. However,** ~~other --~~ **there are various risks that** ~~quality issues in our products~~ could ~~lead~~ **delay or prevent the successful launch and commercialization of the instrument. These risks include, but are not limited** to **,** unforeseen ~~costs~~ **technical challenges** , ~~product recalls~~ **supply chain disruptions** , ~~adverse regulatory actions, negative publicity,~~ and ~~litigation~~ **delays in manufacturing. Many of these risks are beyond our control. If we experience significant delays in launching Simoa ONE** , **our** ~~including product liability --~~ **ability** ~~claims, any of which~~ **to generate revenue and achieve market adoption may be adversely impacted. Delays or setbacks** could ~~cause customers~~ **also allow competitors** to ~~decide not to purchase~~ **introduce alternative solutions, erode our market position,** ~~our --~~ **or** ~~products, harm our reputation, and~~ negatively affect **customer confidence in our product pipeline. Additionally, if development costs exceed our expectations,** ~~our --~~ **or** ~~sales~~ **if we are unable to successfully commercialize the platform** , **our** ~~operating results and~~ financial condition **and results of operations could suffer** . 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. We have in the past devoted, and will continue to devote, funding and resources to technology development, quality assurance and manufacturing initiatives designed to ensure or improve quality, such as the assay redevelopment program **which was** initiated in 2022 **and substantially completed in the fourth quarter of 2023** . 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, errors or quality issues in our products may discourage customers from purchasing our products and could harm our reputation. We may also be subject to warranty claims and litigation involving claims for damages 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. 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. ~~23Our --~~ **Our** reliance on distributors for sales of our products outside of the United States could impact our revenue. We have established distribution agreements for our Simoa instruments and related consumable products 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, **2024,** 2023, **and** 2022, ~~and 2021,~~ approximately ~~37~~ **36** %, 38 % **,** and ~~36~~ **38** %, 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; ~~•~~ a shortage of high- quality salespeople and distributors; ~~•~~ pricing pressure that we may experience internationally; ~~•~~ 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 **E. U. General Data Protection Regulation (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~~ **If** we are unable to manage these risks effectively, our business, operating results and financial condition will suffer. We **currently** 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 **Biomedical AG (“ 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 **Corporation (“ Paramit ”)** , a contract manufacturer located in California, to manufacture and supply all of our SR- X instruments. ~~Since~~ **We also expect to rely on a single contract manufacturer to supply** our **new Simoa ONE instrument. 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 **Accordingly** , we may not be able to obtain adequate supplies in a timely manner or on commercially reasonable terms. If either of these manufacturers ~~were~~ **are** not able to supply instruments, our business would be harmed. In the event it becomes necessary to utilize a different contract manufacturer for **an** ~~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~~ **relies** 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 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~~ **We** could be adversely affected by violations of the U. S. Foreign Corrupt Practices Act and other worldwide anti- bribery laws by us or 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 or 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~~ **requires** 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 internationally demands a high degree of vigilance in maintaining our policy against participation in corrupt activity, because there are circumstances under which we 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 of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction, involve significant costs and expenses, including legal fees, and could result in a material adverse effect on our business, prospects, financial condition, or results of operations. We could also 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 **have acquired, and** may **in the future** acquire other businesses, products or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. 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 in connection with the integration of any acquired business, product or technology; • 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. 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. Risks Related to Government Regulation and Diagnostic Product Reimbursement **Recent policy actions, including the imposition of new tariffs on imported materials and goods from certain foreign countries, may have an adverse impact on our business. Increased tariffs on materials, goods and components used by us or our suppliers could raise our production costs, disrupt our supply chain and reduce our competitiveness in the marketplace. Additionally, reduction in or suspension of certain federal research grants (or certain components of grants), including funding from the National Institutes of Health (NIH), may negatively impact spending within our industry and cause uncertainty. Certain of our customers, including academic institutions and research organizations, may depend in whole or in part on federal grants to advance their medical research activities. Any prolonged suspensions or reductions in such funding could slow innovation, delay collaborations, and limit the adoption of new technologies that contribute to our business growth.** If ~~the~~ **these** ~~FDA determines that~~ **or similar policy changes continue or expand, we may face increased costs and demand for** our products **could** ~~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 **impacted** ~~required to obtain regulatory clearance (s) or approval (s)~~. ~~Any such regulatory process~~ **We cannot predict the full extent of these impacts, but any prolonged disruption** ~~would~~ **could** ~~be expensive~~ **adversely affect our business** , ~~time- consuming~~ **financial condition,** and **results of operations** ~~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 " **(" RUO ")** . 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 **in vitro diagnostic (“** IVD **”)** devices, either alone or in collaboration with third parties. IVD products are 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 **Premarket Approval (“** 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 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 classification of the device through the de novo classification process. 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~~ **our** intended use. If any of our products are subject to medical device regulation, we would be subject to a substantial number of additional requirements for medical devices, including establishment registration, device listing, ~~QSRs~~ **quality system regulations** — 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, ~~27post --~~ **post** - market surveillance, post- approval studies, adverse event reporting, and correction and removal (recall) regulations. One or more of the products we 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 expensive. We may be required to expend significant resources to ensure ongoing compliance with the FDA regulations. Failure

to comply with these requirements may subject us 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 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 **Clinical Laboratory Improvement Amendments of 1988 (“** 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 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 **neurofilament light chain (“** 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~~ **In October 2023,** FDA **issued** ~~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 LDTs could affect our business. Most recently, in September 2023, FDA announced~~ a proposed rule regarding LDTs that would make explicit that in vitro diagnostic products are devices under the **FDCA** ~~Federal Food, Drug, and Cosmetic Act~~, including when the manufacturer is a laboratory. ~~The proposed~~ **FDA finalized this** rule ~~also describes a policy~~ **in April 2024.** ~~under~~ **Under** ~~which~~ **the Final Rule,** FDA ~~would provide greater oversight~~ **will increase our regulation** of LDTs by phasing out ~~its~~ **our** general enforcement discretion approach, and phase in medical device regulation, for **most** LDTs over a period of four years. **However,** FDA ~~requested comment on several~~ **intends to exercise continued enforcement discretion from certain** aspects of **medical device regulation for** ~~its proposal and approach, including whether~~ certain types of LDTs ~~should remain under enforcement~~ **. For example, FDA intends to exercise regulatory** discretion ~~.~~ **to not require premarket review or most quality system requirements for “** ~~Currently~~ **currently marketed ” LDTs, which include LDTs that were offered as of May 6, 2024, which is the date the** FDA’ s ~~target date for final action on this~~ rule **was finalized. Because our LDTs were offered as of May 6, 2024, they may qualify as “ currently marketed ” LDTs, which means they would not be subject to premarket review or certain quality system requirements, although compliance with other aspects of medical device regulation would apply. Certain groups have challenged the legality of FDA’ s Final Rule regarding LDTs, asserting (among other things) that the rule exceeds FDA’ s statutory authority to regulate medical devices. That lawsuit** is **pending** ~~April 2024~~ , **with a decision** ~~but we cannot predict the ultimate timing or form~~ **from** ~~of FDA guidance or regulation, legislative action or their~~ -- **the** ~~potential impact~~ **District Court expected sometime in 2025** . ~~Any new regulatory approach~~ **It is also possible that the federal government will modify, delay,** ~~for~~ **or revoke** ~~LDTs by~~ the **Final Rule. If** ~~FDA, including as described in~~ the ~~September 2023 proposed~~ **Final Rule is not modified, delayed, revoked, or invalidated when the requirements of the** rule **go into effect** , ~~would likely lead to~~ **the rule will result in** 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 or approval from FDA~~ . 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 LDTs, thereby reducing the financial incentive for laboratories to develop new LDTs or invest in instruments, which could reduce demand for our instruments and our other products. 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~~ **U** . 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. 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 **new IVD regulation (the "** IVD Regulation **")** is significantly different from **European directive for IVD medical devices (** 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 **UmanDiagnostics AB' s ("** Uman' s **")** NfL **enzyme- linked immunosorbent assay ("** 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, 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 NfL ELISA ~~assay~~ kit for **cerebrospinal fluid ("** 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. 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. 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. CLIA is a federal law that regulates clinical laboratories that perform examination of human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the 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~~ **has applied for a license in the State of New York. We** may **seek to** 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 ~~29inspections~~ -- **inspections** 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~~ **we** 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, **CROs** ~~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~~ **LDTs that we have** launched ~~LDTs~~ **or may launch in the future** , 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 **the Center for Medicare & Medicaid Services ("** 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~~ **However, a significant** 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. Risks Related to ~~Our~~ **our** ~~Operations~~We -- **Operations We** 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~~ -- **preventive** 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 ~~30or~~ **or** 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~~ **us** 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 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 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. 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 third parties may be able to circumvent 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. ~~31Any --~~ **Any** 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 state or federal 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. 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. 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 collect, store, transfer, use or process sensitive data, including personally identifiable information of employees **and others** , and intellectual property and proprietary business information owned or controlled by ~~ourselves~~ **itself** 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 disclosures to California consumers 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. More recently, other states, including Connecticut, Colorado, Utah and Virginia have 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 **, including under Washington' s consumer health data privacy law** . 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. ~~32Furthermore~~ -- **Furthermore** , regulations promulgated pursuant to **the Health Insurance Portability and Accountability Act of 1996 (" 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 **information constitutes** 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 **, if applicable,** the HIPAA, **the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH ")** , and regulatory penalties. **Where such laws are applicable,** ~~Notice~~ **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 of the 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 Protection Law ~~(" PIPL ")~~ . The GDPR, which governs the collection and use of personal data in the E. U. and 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. Risks Related to Intellectual ~~PropertyIf~~ -- **Property 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. 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 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. ~~33In~~ **In** 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~~ **has** 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 **University (" 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. 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. 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~~ **us** 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. 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. 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. We believe any such claims made to date are without merit. However, 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~~ **itself** 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 exceptional cases, treble damages and attorneys' fees; • 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. ~~35We~~ **We** 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. Patent litigation can be very costly and time- consuming, and the outcome is uncertain. In addition, 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, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. The outcome following legal assertions of invalidity and unenforceability is unpredictable. 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 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. 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~~ **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. Risks Related to ~~Our~~ **our** Common Stock and Being a Public ~~CompanyOur~~ --- **Company The market price of our common** 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 **(such as the Merger)** , commercial relationships or capital commitments **, including the Merger** ; ~~●~~ • 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; ~~●~~ • 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 **the** 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 **our** 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~~ **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 stockholders in the foreseeable future. Consequently, in the foreseeable future, stockholders will likely only experience a gain from an investment in our common stock if the price of our common stock increases. Anti- takeover provisions contained in our restated certificate of incorporation and restated by- laws, as well as provisions of Delaware law, could impair a takeover attempt. Our restated certificate of incorporation, restated by- laws and Delaware law contain provisions which could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by the our board. Our corporate governance documents include provisions: • authorizing our board to issue up to 5, 000, 000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our board may determine; • specifying that special meetings of our stockholders can be called only by our board and that our stockholders may not act by written consent; • establishing an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board; • providing that directors may be removed only for cause; • providing that our board may create new directorships and that vacancies on the board may be filled only by a majority of directors then in office, even though less than a quorum; • establishing that our board is divided into three classes with each class serving staggered three- year terms; • providing that our board may amend the our bylaws without approval of our stockholders; and • requiring a super- majority of votes to amend certain of the above- mentioned provisions. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents some stockholders holding more than 15 % of outstanding our common stock from engaging in certain business combinations**

without approval of the holders of substantially all of the outstanding our common stock. Any provision of our certificate of incorporation, our bylaws or the DGCL that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.